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Federal Register

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NATIONAL SCIENCE FOUNDATION

2 CFR Part 2500

RIN 3145-AA57

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

AGENCY: National Science Foundation.

ACTION: Final rule.

SUMMARY: NSF has adopted as final its interim final rule outlining uniform administrative requirements, cost principles, and audit requirements for Federal awards, pursuant to the approval NSF received from OMB to implement requirements via use of a policy, rather than a regulation. In order to establish a single location for each of the Departments' and Agencies' implementation of the Uniform Guidance, NSF has provided a link to its policy implementation of OMB's Uniform Guidance for inclusion in this issuance.

DATES: This rule is effective on November 27, 2015.

ADDRESSES: The Foundation's implementation document, the NSF Proposal and Award Policies and Procedures Guide, may be found at: <http://www.nsf.gov/pubs/policydocs/pappguide/nsf16001/?org=NSF>.

FOR FURTHER INFORMATION CONTACT: Erin Dawson, Assistant General Counsel, Office of the General Counsel, National Science Foundation, 4201 Wilson Boulevard, Room 1265, Arlington, VA 22230; (703) 292-8060, edawson@nsf.gov (please include RIN 3145-AA57 in the subject line of the message).

SUPPLEMENTARY INFORMATION: On December 19, 2014, the Office of Management and Budget (OMB) published an Interim Final Rule that implemented for all Federal award-making agencies, including NSF, OMB's final guidance on Uniform

Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 FR 75871. OMB published the uniform rules as 2 CFR part 200. As part of that rulemaking, NSF adopted part 200 through an agency-specific addendum at 2 CFR part 2500. The Foundation's implementation document, the NSF Proposal and Award Policies and Procedures Guide, may be found at: <http://www.nsf.gov/pubs/policydocs/pappguide/nsf16001/?org=NSF>.

NSF received no comments in response to its adoption of the Interim Final Rule. Therefore, 2 CFR part 2500 as described in the Interim Final Rule, is adopted with no changes.

Regulatory Findings

For the regulatory findings regarding this rulemaking, please refer to the analysis prepared by OMB in the Interim Final Rule, which is incorporated herein. 79 FR at 75876.

Accordingly, the Interim Final Rule adding 2 CFR part 2500, which was published at 79 FR 75871 on December 19, 2014, is adopted as a Final Rule without change.

Dated: November 20, 2015.

Lawrence Rudolph,

General Counsel, National Science Foundation.

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket No. OCC-2015-0021]

RIN 1557-AD99

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Docket No. R-1443]

RIN 7100-AD 90

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

RIN 3170-AA11

Appraisals for Higher-Priced Mortgage Loans Exemption Threshold

AGENCY: Board of Governors of the Federal Reserve System (Board); Bureau of Consumer Financial Protection (Bureau); and Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Final rule; official interpretations; technical amendment.

SUMMARY: The OCC, the Board and the Bureau are publishing final rules amending the official interpretations for their regulations that implement section 129H of the Truth in Lending Act (TILA). Section 129H of TILA establishes special appraisal requirements for "higher-risk mortgages," termed "higher-priced mortgage loans" or "HPMLs" in the agencies' regulations. The OCC, the Board, the Bureau, the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA) and the Federal Housing Finance Agency (FHFA) (collectively, the Agencies) issued joint final rules implementing these requirements, effective January 18, 2014. The Agencies' rules exempted, among other loan types, transactions of \$25,000 or less, and required that this loan amount be adjusted annually based on any annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W). If there is no annual percentage increase in the CPI-W, the OCC, the Board and the Bureau will not adjust this

exemption threshold from the prior year. Based on the annual percentage decrease in the CPI-W as of June 1, 2015, the exemption threshold will remain at \$25,500 through December 31, 2016.

DATES: This final rule is effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

OCC: Beth Knickerbocker, Counsel, Legislative & Regulatory Activities Division, at (202) 649-5490; for persons who are deaf and hard of hearing, TTY, (202) 649-5597.

Board: Lorna M. Neill, Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452-3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263-4869.

Bureau: James Wylie, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435-7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) amended the Truth in Lending Act (TILA) to add special appraisal requirements for “higher-risk mortgages.”¹ In January 2013, the Agencies issued a joint final rule implementing these requirements and adopted the term “higher-priced mortgage loan” (HPML) instead of “higher-risk mortgage” (the January 2013 Final Rule).² In July 2013, the Agencies proposed additional exemptions from the January 2013 Final Rule (the 2013 Supplemental Proposed Rule).³ In December 2013, the Agencies issued a supplemental final rule with additional exemptions from the January 2013 Final Rule (the December 2013 Supplemental Final Rule).⁴ Among other exemptions, the Agencies adopted an exemption from the new HPML appraisal rules for transactions of \$25,000 or less, to be adjusted annually for inflation.

The Bureau’s, the OCC’s, and the Board’s versions of the January 2013 Final Rule and December 2013 Supplemental Final Rule and corresponding official interpretations are substantively identical. The FDIC, NCUA, and FHFA adopted the Bureau’s version of the regulations under the

January 2013 Final Rule and December 2013 Supplemental Final Rule.⁵

Section 34.203(b)(2) of Subpart G of part 34 of the OCC’s regulations, § 226.43(b)(2) of the Board’s Regulation Z, and § 1026.35(c)(2)(ii) of the Bureau’s Regulation Z, and their accompanying interpretations, provide that the exemption threshold for smaller loans will be adjusted effective January 1 of each year based on any annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W) that was in effect on the preceding June 1. Any increase in the threshold amount will be rounded to the nearest \$100 increment. For example, if the annual percentage increase in the CPI-W would result in a \$950 increase in the threshold amount, the threshold amount will be increased by \$1,000. However, if the annual percentage increase in the CPI-W would result in a \$949 increase in the threshold amount, the threshold amount will be increased by \$900.⁶ If there is no annual percentage increase in the CPI-W, the Agencies will not adjust the threshold amounts from the prior year.⁷

II. Adjustment and Commentary Revision

Effective January 1, 2016, the exemption threshold amount remains at \$25,500. This threshold amount is based on the CPI-W in effect on June 1, 2015, which was reported on May 22, 2015. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a Consumer Price Index change on June 1; adjustments are reported in the middle of the month. The CPI-W is a subset of the Consumer Price Index for All Urban Consumers (CPI-U) and represents approximately 28 percent of the U.S. population. Because there was a 0.8 percent decrease in the CPI-W from April 2014 to April 2015, the OCC, the Board, and the Bureau are not adjusting the exemption threshold amount. The OCC, the Board, and the Bureau are revising the interpretations to their respective regulations to add new comments as follows:

⁵ See NCUA: 12 CFR 722.3; FHFA: 12 CFR part 1222. Although the FDIC adopted the Bureau’s version of the regulation, the FDIC did not issue its own regulation containing a cross-reference to the Bureau’s version. See 78 FR 10368, 10370 (Feb. 13, 2013).

⁶ See 12 CFR part 34, Appendix C to Subpart G, comment 203(b)(2)-1 (OCC); 12 CFR part 226, Supplement I, comment 43(b)(2)-1 (Board); and 12 CFR part 1026, Supplement I, comment 35(c)(2)(ii)-1 (Bureau).

⁷ See 78 FR 48547, 48565 (Aug. 8, 2013) (“Thus, under the proposal, if the CPI-W decreases in an annual period, the percentage increase would be zero, and the dollar amount threshold for the exemption would not change.”).

- Comment 203(b)(2)-1.iii to 12 CFR part 34, Appendix C to Subpart G (OCC);
- Comment 43(b)(2)-1.iii to Supplement I of 12 CFR part 226 (Board); and
- Comment 35(c)(2)(ii)-1.iii in Supplement I of 12 CFR part 1026 (Bureau).

These new comments state that, from January 1, 2016, through December 31, 2016, the threshold amount is \$25,500. These revisions are effective January 1, 2016.

III. Administrative Law Matters

Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if an agency finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest.⁸ The amendment in this notice is technical and applies the method previously set forth in the 2013 Supplemental Proposed Rule.⁹ For these reasons, the OCC, the Board, and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.¹⁰ As noted previously, the Agencies have determined that it is unnecessary to publish a general notice of proposed rulemaking for this joint final rule. Accordingly, the RFA’s requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,¹¹ the Agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

Unfunded Mandates Reform Act

The OCC analyzes proposed rules for the factors listed in Section 202 of the Unfunded Mandates Reform Act of 1995, before promulgating a final rule

⁸ 5 U.S.C. 553(b)(B).

⁹ See 78 FR 48547, 48565 (Aug. 8, 2013) (“Thus, under the proposal, if the CPI-W decreases in an annual period, the percentage increase would be zero, and the dollar amount threshold for the exemption would not change.”).

¹⁰ 5 U.S.C. 603 and 604.

¹¹ 44 U.S.C. 3506; 5 CFR part 1320.

¹ Public Law 111-203 section 1471, 124 Stat. 1376 (2010), codified at TILA section 129H, 15 U.S.C. 1639h.

² 78 FR 10368 (Feb. 13, 2013).

³ 78 FR 48547 (Aug. 8, 2013).

⁴ 78 FR 78520 (Dec. 26, 2013).

for which a general notice of proposed rulemaking was published.¹² As discussed above, the OCC has determined that the publication of a general notice of proposed rulemaking is unnecessary.

List of Subjects

12 CFR Part 34

Appraisal, Appraiser, Banks, Banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 226

Advertising, Appraisal, Appraiser, Consumer protection, Credit, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Authority and Issuance

For the reasons set forth in the preamble, the OCC amends 12 CFR part 34 as set forth below:

PART 34—REAL ESTATE LENDING AND APPRAISALS

■ 1. The authority citation for part 34 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 25b, 29, 93a, 371, 1463, 1464, 1465, 1701j-3, 1828(o), 3331 *et seq.*, 5101 *et seq.*, 5412(b)(2)(B) and 15 U.S.C. 1639h.

Subpart G—Appraisals for Higher-Priced Mortgage Loans

■ 2. In Appendix C to Subpart G, under *Section 34.203—Appraisals for Higher-Priced Mortgage Loans*, paragraph 34.203(b)(2)–1.iii is added to read as follows:

Appendix C to Subpart G—OCC Interpretations

* * * * *

Section 34.203—Appraisals for Higher-Priced Mortgage Loans

* * * * *

34.203(b) Exemptions

* * * * *

Paragraph 34.203(b)(2)

1. *Threshold Amount.* * * *

iii. From January 1, 2016, through December 31, 2016, the threshold amount is \$25,500.

* * * * *

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation Z, 12 CFR part 226, as set forth below:

PART 226—TRUTH IN LENDING (REGULATION Z)

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), 1639(l), and 1639h; Pub. L. 111–24, section 2, 123 Stat. 1734; Pub. L. 111–203, 124 Stat. 1376.

■ 4. In Supplement I to part 226, under *Section 226.43—Appraisals for Higher-Risk Mortgage Loans*, under paragraph 43(b)(2), paragraph 43(b)(2)–1.iii is added to read as follows:

Supplement I to Part 226—Official Staff Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 226.43—Appraisals for Higher-Risk Mortgage Loans

* * * * *

43(b) Exemptions

* * * * *

Paragraph 43(b)(2)

1. * * *

iii. From January 1, 2016, through December 31, 2016, the threshold amount is \$25,500.

* * * * *

BUREAU OF CONSUMER FINANCIAL PROTECTION

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 5. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 6. In Supplement I to part 1026, under *Section 1026.35—Requirements for Higher-Priced Mortgage Loans*, under paragraph 35(c)(2)(ii), paragraph 35(c)(2)(ii)–1.iii is added to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

35(c) Appraisals

* * * * *

35(c)(2) Exemptions

* * * * *

Paragraph 35(c)(2)(ii)

1. * * *

iii. From January 1, 2016, through December 31, 2016, the threshold amount is \$25,500.

* * * * *

Dated: November 19, 2015.

Amy Friend,

Senior Deputy Comptroller and Chief Counsel.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, November 18, 2015.

Robert deV. Frierson,

Secretary of the Board.

Dated: October 8, 2015.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2015–30097 Filed 11–25–15; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 4810–AM–P

FEDERAL RESERVE SYSTEM

12 CFR Part 213

[Docket No. R–1519]

RIN 7100 AE–35

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1013

RIN 3170–AA06

Consumer Leasing (Regulation M)

AGENCIES: Board of Governors of the Federal Reserve System (Board); and Bureau of Consumer Financial Protection (Bureau).

¹² 12 U.S.C. 1532.

ACTION: Final rules, official interpretations and commentary.

SUMMARY: The Board and the Bureau are publishing final rules amending the official interpretations and commentary for the agencies' regulations that implement the Consumer Leasing Act (CLA). The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended the CLA by requiring that the dollar threshold for exempt consumer leases be adjusted annually by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W). If there is no annual percentage increase in the CPI-W, the Board and Bureau will not adjust this exemption threshold from the prior year. Based on the annual percentage decrease in the CPI-W as of June 1, 2015, the exemption threshold will remain at \$54,600 through December 31, 2016.

Because the Dodd-Frank Act also requires similar adjustments in the Truth in Lending Act's threshold for exempt consumer credit transactions, the Board and the Bureau are making similar amendments to each of their respective regulations implementing the Truth in Lending Act elsewhere in this issue of the **Federal Register**.

DATES: This final rule is effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Board: Vivian W. Wong, Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452-3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263-4869.

Bureau: James Wylie, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435-7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) increased the threshold in the Consumer Leasing Act (CLA) for exempt consumer leases from \$25,000 to \$50,000, effective July 21, 2011.¹ In addition, the Dodd-Frank Act requires that this threshold be adjusted annually for inflation by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W), as published by the Bureau of Labor Statistics. In April 2011, the Board issued a final rule amending Regulation M (which implements the CLA) consistent with

these provisions of the Dodd-Frank Act along with a similar final rule amending Regulation Z (which implements the Truth in Lending Act) (collectively, the Board Final Threshold Rules).²

Title X of the Dodd-Frank Act transferred rulemaking authority for a number of consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In connection with this transfer of rulemaking authority, the Bureau issued its own Regulation M implementing the CLA in an interim final rule, 12 CFR part 1013 (Bureau Interim Final Rule).³ The Bureau Interim Final Rule substantially duplicated the Board's Regulation M, including the revisions to the threshold for exempt transactions made by the Board in April 2011. Although the Bureau has the authority to issue rules to implement the CLA for most entities, the Board retains authority to issue rules under the CLA for certain motor vehicle dealers covered by section 1029(a) of the Dodd-Frank Act, and the Board's Regulation M continues to apply to those entities.⁴

Section 213.2(e)(1) of the Board's Regulation M and § 1013.2(e)(1) of the Bureau's Regulation M, and their accompanying commentaries, provide that the exemption threshold will be adjusted annually effective January 1 of each year based on any annual percentage increase in the CPI-W that was in effect on the preceding June 1. Any increase in the threshold amount will be rounded to the nearest \$100 increment. For example, if the annual percentage increase in the CPI-W would result in a \$950 increase in the threshold amount, the threshold amount

² 76 FR 18349 (Apr. 4, 2011); 76 FR 18354 (Apr. 4, 2011).

³ 76 FR 78500 (Dec. 19, 2011).

⁴ Section 1029(a) of the Dodd-Frank Act states: "Except as permitted in subsection (b), the Bureau may not exercise any rulemaking, supervisory, enforcement, or any other authority . . . over a motor vehicle dealer that is predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both." 12 U.S.C. 5519(a). Section 1029(b) of the Dodd-Frank Act states: "Subsection (a) shall not apply to any person, to the extent that such person (1) provides consumers with any services related to residential or commercial mortgages or self-financing transactions involving real property; (2) operates a line of business (A) that involves the extension of retail credit or retail leases involving motor vehicles; and (B) in which (i) the extension of retail credit or retail leases are provided directly to consumers; and (ii) the contract governing such extension of retail credit or retail leases is not routinely assigned to an unaffiliated third party finance or leasing source; or (3) offers or provides a consumer financial product or service not involving or related to the sale, financing, leasing, rental, repair, refurbishment, maintenance, or other servicing of motor vehicles, motor vehicle parts, or any related or ancillary product or service." 12 U.S.C. 5519(b).

will be increased by \$1,000. However, if the annual percentage increase in the CPI-W would result in a \$949 increase in the threshold amount, the threshold amount will be increased by \$900.⁵ As stated in the Board Final Threshold Rules, if there is no annual percentage increase in the CPI-W, the Board and Bureau will not adjust the exemption threshold from the prior year.⁶

II. Adjustment and Commentary Revision

Effective January 1, 2016, the exemption threshold amount remains at \$54,600. This is based on the CPI-W in effect on June 1, 2015, which was reported on May 22, 2015. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a CPI change on June 1; adjustments are reported in the middle of the month. The CPI-W is a subset of the CPI-U index (based on all urban consumers) and represents approximately 28 percent of the U.S. population. Because the CPI-W reported on May 22, 2015 reflects a 0.8 percent decrease in the CPI-W from April 2014 to April 2015, the Board and the Bureau are not adjusting the exemption threshold amount. The Board and the Bureau are revising the commentaries to their respective regulations to add new comment 2(e)-9.vii to state that, from January 1, 2016 through December 31, 2016, the threshold amount is \$54,600. These revisions are effective January 1, 2016.

III. Administrative Law Matters

Administrative Procedure Act

Under the Administrative Procedure Act, notice and opportunity for public comment are not required if the Board and the Bureau find that notice and public comment are impracticable, unnecessary, or contrary to the public interest.⁷ The amendment in this notice is technical and applies the method previously set forth in the Board Final Threshold Rules.⁸ For these reasons, the Board and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a

⁵ See comments 2(e)-9 in Supplements I of 12 CFR part 213 and 12 CFR part 1013.

⁶ 76 FR 18354, 18355 n.1 (Apr. 4, 2011) ("[A]n annual period of deflation or no inflation would not require a change in the threshold amount.")

⁷ See 5 U.S.C. 553(b)(B).

⁸ See *supra* note 6.

¹ Public Law 111-203 section 1100E, 124 Stat. 1376 (2010).

general notice of proposed rulemaking is not required.⁹ As noted previously, the agencies have determined that it is unnecessary to publish a general notice of proposed rulemaking for this joint final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,¹⁰ the agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

List of Subjects

12 CFR Part 213

Advertising, Consumer leasing, Consumer protection, Federal Reserve System, Reporting and recordkeeping requirements.

12 CFR Part 1013

Advertising, Consumer leasing, Reporting and recordkeeping requirements.

Board of Governors of the Federal Reserve System

Text of Final Revisions

For the reasons set forth in the preamble, the Board amends Regulation M, 12 CFR part 213, as set forth below:

PART 213—CONSUMER LEASING (REGULATION M)

■ 1. The authority citation for part 213 continues to read as follows:

Authority: 15 U.S.C. 1604 and 1667f; Pub. L. 111–203 section 1100E, 124 Stat. 1376.

■ 2. In Supplement I to Part 213, under *Section 213.2—Definitions*, under 2(e) *Consumer Lease*, paragraph 9.vii is added to read as follows:

Supplement I to Part 213—Official Staff Commentary to Regulation M

* * * * *

Section 213.2—Definitions

* * * * *

2(e) *Consumer Lease*.

9. * * *

vii. From January 1, 2016 through December 31, 2016, the threshold amount is \$54,600.

* * * * *

Bureau of Consumer Financial Protection

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation M, 12 CFR part 1013, as set forth below:

PART 1013—CONSUMER LEASING (REGULATION M)

■ 3. The authority citation for part 1013 continues to read as follows:

Authority: 15 U.S.C. 1604 and 1667f; Pub. L. 111–203 section 1100E, 124 Stat. 1376.

■ 4. In Supplement I to part 1013, under *Section 1013.2—Definitions*, under 2(e) *Consumer Lease*, paragraph 9.vii is added to read as follows:

Supplement I to Part 1013—Official Interpretations

* * * * *

Section 1013.2—Definitions

* * * * *

2(e) *Consumer Lease*. * * * .

9. * * *

vii. From January 1, 2016 through December 31, 2016, the threshold amount is \$54,600.

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 18, 2015.

Robert deV. Frierson,

Secretary of the Board.

Dated: September 22, 2015.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2015–30071 Filed 11–25–15; 8:45 am]

BILLING CODE 4810-AM-P; 6210-01-P

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Docket No. R–1520]

RIN 7100 AE–36

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

Truth in Lending (Regulation Z)

AGENCIES: Board of Governors of the Federal Reserve System (Board); and Bureau of Consumer Financial Protection (Bureau).

ACTION: Final rules, official interpretations and commentary.

SUMMARY: The Board and the Bureau are publishing final rules amending the official interpretations and commentary

for the agencies' regulations that implement the Truth in Lending Act (TILA). The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended TILA by requiring that the dollar threshold for exempt consumer credit transactions be adjusted annually by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W). If there is no annual percentage increase in the CPI-W, the Board and Bureau will not adjust this exemption threshold from the prior year. Based on the annual percentage decrease in the CPI-W as of June 1, 2015, the exemption threshold will remain at \$54,600 through December 31, 2016.

Because the Dodd-Frank Act also requires similar adjustments in the Consumer Leasing Act's threshold for exempt consumer leases, the Board and the Bureau are making similar amendments to each of their respective regulations implementing the Consumer Leasing Act elsewhere in this issue of the **Federal Register**.

DATES: This final rule is effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Board: Vivian W. Wong, Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

Bureau: James Wylie, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) increased the threshold in the Truth in Lending Act (TILA) for exempt consumer credit transactions¹ from \$25,000 to \$50,000, effective July 21, 2011.² In addition, the Dodd-Frank Act requires that this threshold be adjusted annually for inflation by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W), as published by the Bureau of Labor Statistics. In April 2011, the Board issued a final rule amending Regulation Z (which implements TILA) consistent

¹ Although consumer credit transactions above the threshold are generally exempt, loans secured by real property or by personal property used or expected to be used as the principal dwelling of a consumer and private education loans are covered by TILA regardless of the loan amount. See 12 CFR 226.3(b)(1)(i) and 12 CFR 1026.3(b)(1)(i).

² Public Law 111–203 section 1100E, 124 Stat. 1376 (2010).

⁹ See 5 U.S.C. 603 and 604.

¹⁰ 44 U.S.C. 3506; 5 CFR part 1320.

with these provisions of the Dodd-Frank Act along with a similar final rule amending Regulation M (which implements the Consumer Leasing Act) (collectively, the Board Final Threshold Rules).³

Title X of the Dodd-Frank Act transferred rulemaking authority for a number of consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In connection with this transfer of rulemaking authority, the Bureau issued its own Regulation Z implementing TILA in an interim final rule, 12 CFR part 1026 (Bureau Interim Final Rule).⁴ The Bureau Interim Final Rule substantially duplicated the Board's Regulation Z, including the revisions to the threshold for exempt transactions made by the Board in April 2011. Although the Bureau has the authority to issue rules to implement TILA for most entities, the Board retains authority to issue rules under TILA for certain motor vehicle dealers covered by section 1029(a) of the Dodd-Frank Act, and the Board's Regulation Z continues to apply to those entities.⁵

Section 226.3(b)(1)(ii) of the Board's Regulation Z and § 1026.3(b)(1)(ii) of the Bureau's Regulation Z, and their accompanying commentaries, provide that the exemption threshold will be adjusted annually effective January 1 of each year based on any annual percentage increase in the CPI-W that was in effect on the preceding June 1. Any increase in the threshold amount will be rounded to the nearest \$100 increment. For example, if the annual percentage increase in the CPI-W would result in a \$950 increase in the

threshold amount, the threshold amount will be increased by \$1,000. However, if the annual percentage increase in the CPI-W would result in a \$949 increase in the threshold amount, the threshold amount will be increased by \$900.⁶ As stated in the Board Final Threshold Rules, if there is no annual percentage increase in the CPI-W, the Board and Bureau will not adjust the exemption threshold from the prior year.⁷

II. Adjustment and Commentary Revision

Effective January 1, 2016, the exemption threshold amount remains at \$54,600. This is based on the CPI-W in effect on June 1, 2015, which was reported on May 22, 2015. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a CPI change on June 1; adjustments are reported in the middle of the month. The CPI-W is a subset of the CPI-U index (based on all urban consumers) and represents approximately 28 percent of the U.S. population. Because the CPI-W reported on May 22, 2015 reflects a 0.8 percent decrease in the CPI-W from April 2014 to April 2015, the Board and the Bureau are not adjusting the exemption threshold amount. The Board and the Bureau are revising the commentaries to their respective regulations to add new comment 3(b)-1.vii to state that, from January 1, 2016 through December 31, 2016, the threshold amount is \$54,600. These revisions are effective January 1, 2016.

III. Administrative Law Matters

Administrative Procedure Act

Under the Administrative Procedure Act, notice and opportunity for public comment are not required if the Board and the Bureau find that notice and public comment are impracticable, unnecessary, or contrary to the public interest.⁸ The amendment in this notice is technical and applies the method previously set forth in the Board Final Threshold Rules.⁹ For these reasons, the Board and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

⁶ See comments 3(b)-1 in Supplements I of 12 CFR part 226 and 12 CFR part 1026.

⁷ 76 FR 18354, 18355 n.1 (Apr. 4, 2011) (“[A]n annual period of deflation or no inflation would not require a change in the threshold amount.”).

⁸ 5 U.S.C. 553(b)(B).

⁹ See *supra* note 7.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.¹⁰ As noted previously, the agencies have determined that it is unnecessary to publish a general notice of proposed rulemaking for this joint final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,¹¹ the agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

List of Subjects

12 CFR Part 226

Advertising, Consumer protection, Federal Reserve System, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 1026

Advertising, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Text of Final Revisions

For the reasons set forth in the preamble, the Board amends Regulation Z, 12 CFR part 226, as set forth below:

PART 226—TRUTH IN LENDING (REGULATION Z)

- 1. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), and 1639(l); Pub. L. 111-24, section 2, 123 Stat. 1734; Pub. L. 111-203, 124 Stat. 1376.

- 2. In Supplement I to part 226, under *Section 226.3—Exempt Transactions*, under *3(b) Credit over applicable threshold amount*, paragraph 1.vii is added to read as follows:

Supplement I to Part 226—Official Staff Interpretations

* * * * *

Subpart A—General

* * * * *

¹⁰ 5 U.S.C. 603 and 604.

¹¹ 44 U.S.C. 3506; 5 CFR part 1320.

Section 226.3—Exempt Transactions

* * * * *

3(b) Credit over applicable threshold amount.

1. * * *

vii. From January 1, 2016 through December 31, 2016, the threshold amount is \$54,600.

* * * * *

BUREAU OF CONSUMER FINANCIAL PROTECTION**Authority and Issuance**

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 3. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 4. In Supplement I to part 1026, under Section 1026.3—Exempt Transactions, under 3(b) Credit Over Applicable Threshold Amount, paragraph 1.vii is added to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart A—General

* * * * *

Section 1026.3—Exempt Transactions

* * * * *

3(b) Credit Over Applicable Threshold Amount

1. * * *

vii. From January 1, 2016 through December 31, 2016, the threshold amount is \$54,600.

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 18, 2015.

Robert deV. Frierson,
Secretary of the Board.

Dated: September 22, 2015.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2015–30091 Filed 11–25–15; 8:45 am]

BILLING CODE: 6210–01–P; 4810–AM–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2014–0346; Directorate Identifier 2014–NM–010–AD; Amendment 39–18324; AD 2015–23–08]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–100,–200,–200C,–300,–400, and –500 series airplanes. This AD was prompted by reports of cracks in fuselage frames, and a report of a missing strap that was not installed on a fuselage frame during production. This AD requires an inspection to determine if the strap adjacent to a certain stringer is installed, and repair if it is missing; repetitive inspections of the frame for cracking or a severed frame web; and related investigative and corrective actions if necessary. This AD also provides optional actions to terminate certain repetitive inspections. We are issuing this AD to detect and correct missing fuselage frame straps and frame cracking that can result in severed frames which, with multiple adjacent severed frames, or the combination of a severed frame and fuselage skin chemical mill cracks, can result in uncontrolled decompression of the airplane.

DATES: This AD is effective January 4, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 4, 2016.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0346.”

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0346; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: galib.abumeri@faa.gov.

SUPPLEMENTARY INFORMATION:**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–100,–200,–200C–300,–400, and–500 series airplanes. The NPRM published in the **Federal Register** on June 30, 2014 (79 FR 36672). The NPRM was prompted by reports of cracks in fuselage frames, and a report of a missing strap that was not installed on a fuselage frame during production. The NPRM proposed to require an inspection to determine if the strap adjacent to a certain stringer is installed, and repair if it is missing; repetitive inspections of the frame for cracking or a severed frame web; and related investigative and corrective actions if necessary. The NPRM also provided optional actions to terminate certain repetitive inspections. We are issuing this AD to detect and correct missing fuselage frame straps and frame cracking that can result in severed frames. Continued operation of the airplane with multiple adjacent severed frames, or the combination of a severed frame and fuselage skin chemical mill cracks, can result in uncontrolled decompression of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 36672,

June 30, 2014) and the FAA's response to each comment.

Effect of Winglets on AD

Aviation Partners Boeing stated that installation of winglets per Supplemental Type Certificate (STC) ST01219SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/\\$FILE/ST01219SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf)) does not affect the actions specified in the NPRM (79 FR 36672, June 30, 2014).

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD (79 FR 36672, June 30, 2014) as paragraph (c)(1) of this AD, and have added a new paragraph (c)(2) to this AD to state that installation of STC ST01219SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/\\$FILE/ST01219SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf)) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Revise Preamble Wording

Boeing noted that the SUMMARY of the NPRM (79 FR 36672, June 30, 2014) explained that some optional actions would terminate "certain" repetitive inspections. Boeing requested that we use this same wording in the Proposed AD Requirements section of the NPRM (which omitted the word "certain").

Although we agree with the commenter's statement, the Proposed AD Requirements section is not repeated in a final rule. Since the referenced omission does not affect the required actions or the unsafe condition, no changes to this final rule are needed.

Request To Specify Inspection Method

Boeing requested that we add an inspection in paragraph (g) of the proposed AD (79 FR 36672, June 30, 2014). Boeing stated that this is consistent with the compliance information described in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013.

We agree with the commenter's request. We inadvertently omitted the inspection requirement in paragraph (g) of the proposed AD (79 FR 36672, June 30, 2014), which is described in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. We have revised paragraph (g) of this AD to require that the inspection and

applicable repair be done by using a method approved in accordance with the procedures specified in paragraph (q) of this AD. Paragraph (g) of this AD applies only to airplanes identified as Group 1 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. Currently, there are no Group 1 airplanes in service in the United States, so notice of this new requirement is not necessary.

Request To Revise Terminating Action Wording

Boeing requested that we revise the wording in paragraphs (i) and (j) of the proposed AD (79 FR 36672, June 30, 2014) to state the following actions.

- Doing the repair or preventive modification of the frame at station 328 terminates the applicable repetitive inspection requirements.
- Doing the preventive modification of the frame at station 360 terminates the applicable station 360 inspection requirements.
- Doing the repair or preventive modification of the frame at station 328, and doing the preventive modification of the frame at station 360 terminates the applicable repetitive inspection requirements of the frame at station 344, and the Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, skin inspections.

Boeing stated that the proposed wording in paragraphs (i) and (j) of the proposed AD (79 FR 36672, June 30, 2014) is not clear. Boeing stated that inspections of the frame at station 328 or at station 360 can be terminated by a single action (applicable repair or modification). Boeing explained that accomplishing both specified actions at station 328 and station 360 terminates the station 344 frame inspections and the option 2 skin inspections.

We agree to clarify the acceptable terminating actions. We have added new paragraph (m) of this AD, which provides the following terminating actions. We have redesignated subsequent paragraphs accordingly.

- Accomplishing the repair or preventive modification of the frame at station 328 terminates the inspections of that frame required by paragraphs (i), (j), and (k) of this AD.
- Accomplishing the repair or preventive modification of the frame at station 328 and the preventive modification of the frame at station 360, terminates the inspections of the frame at station 344 and the fuselage skin inspections required by paragraphs (i) and (j) of this AD.
- Accomplishing the repair or preventive modification of the frame at station 360 terminates the inspections of

that frame required by paragraphs (i) and (j) of this AD.

- Accomplishing the repair or preventive modification of the frame at station 328 terminates the fuselage skin inspections and the station 328 frame inspections required by paragraphs (i) and (j) of this AD.

Recommendation To Specify Optional Preventive Modification

Boeing recommended that we specify in paragraphs (i) and (j) of the proposed AD (79 FR 36672, June 30, 2014) that the station 328 repair described in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, can be used as an optional preventive modification.

We partially agree with the commenter's request. The commenter's request is already addressed in the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. However, additional text might help clarify this provision. We have added additional text to paragraphs (i), (j), and (k) of this AD that operators may do the repair of the frame at station 328, as specified in paragraph (m) of this AD, as an optional preventive modification for that frame.

Requests To Revise Paragraph Format and Inspection Method

Boeing requested that we revise paragraphs (i) and (j) of the proposed AD (79 FR 36672, June 30, 2014) by moving the requirements for Group 6 airplanes to a new paragraph. Boeing stated that the service information for Group 6 airplanes provides directed inspection instructions for the station 328 frame only, as provided in table 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. Boeing added that for Group 6 airplanes, there are no directed inspections for station 344 or station 360, but there are related investigative and corrective actions for detailed inspections of the frame at station 312 and station 344.

Southwest Airlines (SWA) requested that we specify that the frame at station 344 requires detailed inspections, not detailed and eddy current inspections. SWA stated that Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, describes only detailed inspections at station 344.

We partially agree with both commenters. We disagree with making the changes requested by the commenters. However, we agree that certain actions are only done at certain locations and for certain airplanes. The inspections at station 344 are detailed inspections only. Application of the

appropriate inspection method to a given frame is addressed by the phrase “as applicable,” *i.e.*, actions are applicable to the frames identified in the service information for each group of airplane. We have revised paragraphs (i)(1), (i)(2)(i), (i)(2)(ii), (j)(1), and (j)(2) of this AD by adding “as applicable” after the station locations. This revision clarifies that those actions are done only as specified in the service information.

Request To Add Sub-Paragraph Headers

Boeing requested that we add the subtitles “Initial Inspections” and “Follow-on Inspections” to paragraphs (i)(1) and (i)(2), respectively, of the proposed AD (79 FR 36672, June 30, 2014). Boeing also requested that we change the wording in paragraph (i)(2) of the proposed AD to “Accomplishing the follow-on inspections required by paragraph (i)(2) of this AD,” instead of “Accomplishing the initial inspections” Boeing stated that paragraph (i) of the proposed AD would mandate the inspections for airplanes with fewer than 28,300 total flight cycles, where compliance (tables 4, 7, and 8 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013) consists of initial inspections and then follow-on inspections that contain options. Boeing explained that paragraph (i)(1) of the proposed AD would mandate the initial inspections, and paragraph (i)(2) of the proposed AD would mandate the follow-on inspections. Boeing also explained that paragraph (i)(2) of the proposed AD phrase “accomplishing the initial inspections” is understood to refer to the first follow-on inspection directed by the compliance time (threshold).

We do not agree with the commenter’s request. Paragraph (i)(2) of this AD follows the format of Boeing’s service bulletin compliance tables, which has a different repeat interval from the inspections specified in paragraph (i)(1) of this AD. Paragraphs (i)(1) and (i)(2) of this AD contain both initial and repetitive inspections as well as related investigative actions. We have not changed this AD in this regard.

Request To Revise Repetitive Inspection Wording

Boeing requested that we revise the last sentence of paragraph (i)(2)(ii) of the proposed AD (79 FR 36672, June 30, 2014) to state, “Repeat the inspections specified in this paragraph thereafter” Boeing stated that this wording would then match the wording for the repetitive inspections specified in paragraph (i)(2)(i) of the proposed AD.

We agree with the commenter’s request. In this case, similar wording will provide consistent paragraph wording without changing the intent of the NPRM (79 FR 36672, June 30, 2014). We have revised the wording in paragraph (i)(2)(ii) of this AD to “Repeat the inspections specified in this paragraph thereafter at the applicable time and intervals specified in”

Request To Clarify a Certain Compliance Time

Europe Airpost requested that, in order to avoid any confusion, we clearly state a compliance time for paragraph (j) of the proposed AD (79 FR 36672, June 30, 2014) for airplanes that have 28,300 total flight cycles or more. The commenter asked whether those airplanes would fall under the condition 28,300 total flight cycles but less than 32,800 total flight cycles, or 32,800 total flight cycles or more.

We agree that clarification is necessary. In this case, paragraph (j) of this AD states to use the applicable times specified in tables 4, 5, 7, and 8, of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013. Individual airplanes within an operator’s fleet could fall into different categories and thus have different compliance times. Operators are to use the appropriate compliance times and repetitive intervals based upon the applicable number of total flight cycles that have been accumulated on each airplane as of the effective date of this AD. We have added new paragraph (n)(3) of the AD to inform operators that the “Condition” columns of the compliance tables also contain compliance information that corresponds to the effective date of the AD. We have also revised paragraphs (i)(1) and (j)(1) of this AD to refer to paragraph (n)(3) of this AD.

Request To Clarify Terminating Action Wording

SWA requested that we revise the terminating action portion of paragraph (j) of the proposed AD (79 FR 36672, June 30, 2014) to clarify the specified actions. SWA stated that, as written, the terminating action statement seems to imply that the operator is required to accomplish both the preventive modification of the frame at station 360 and the repair of the frame at station 328 to terminate the repetitive inspection requirements for any of the station 328, 344, and 360 frames. SWA also stated that the terminating action in paragraph (j) of the proposed AD does not specify actions or terminating actions if a repair is installed at the station 344 frame.

SWA explained that Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, contains terminating action in the footnotes of the compliance tables in paragraph 1.E., “Compliance,” which the commenter thinks should be restated in the AD.

We agree with the commenter’s request. For clarity, we have moved the terminating action provisions that were specified in paragraphs (i)(1), (i)(2), (j), and (k) of the proposed AD (79 FR 36672, June 30, 2014) to new paragraphs (m)(1) through (m)(4) of this AD. We have redesignated subsequent paragraphs accordingly.

Requests To Specify Eddy Current Inspection

Europe Airpost requested that we clarify whether we meant to exclude the eddy current inspection at station 328 described in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, in paragraph (k) of the proposed AD (79 FR 36672, June 30, 2014). Boeing requested that we add the eddy current inspection at station 328 described in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, in paragraph (k) of the proposed AD.

We agree with Boeing’s request to specify the eddy current inspection and Europe Airpost’s request to clarify the eddy current inspection requirement. We inadvertently omitted the eddy current inspection from paragraph (k) of the proposed AD (79 FR 36672, June 30, 2014) which applies to Group 7 airplanes. Our intention was to match the actions described in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013. In the NPRM (79 FR 36672, June 30, 2014), we did not identify any differences with Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, in regards to the required inspections, which includes repetitive eddy current inspections at station 328. For Groups 2 through 7 airplanes, paragraphs (i) and (j) of the proposed AD do specify detailed and HFEC inspections for Groups 2 through 6 airplanes. Therefore, we have revised paragraph (k) of this AD to specify doing eddy current inspections, in addition to the detailed inspections, of the frame at station 328 for Group 7 airplanes.

Request To Specify Terminating Actions for Station 380

SWA requested that we specify procedures or terminating actions for repairs installed at the station 380 frame, since paragraph (l) of the proposed AD (79 FR 36672, June 30, 2014) does not specify such actions.

We do not agree with the commenter's request. Boeing has not provided such repairs for our approval in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. Therefore, we have no specific engineering data to review and approve. We have not changed this AD in this regard.

Request for Credit for Certain Repairs

SWA requested that we revise paragraphs (i) through (l) of the proposed AD (79 FR 36672, June 30, 2014) to include provisions for existing repairs that were done using the service repair manual (SRM) or the original equipment manufacturer (OEM) instructions. SWA requested that the NPRM be revised to either terminate the inspections or include alternative actions if existing repairs inhibit the ability to perform the inspections.

We partially agree with the commenter's request. We agree that repairs approved by Boeing via FAA Form 8100-9 (Statement of Compliance with Airworthiness Standards) would have also included the appropriate inspections. We disagree that SRM repairs would necessarily provide the same level of safety. The commenter did

not specify for which SRM repairs it was requesting approval. Such repairs might or might not have included consideration of the safety issues addressed by Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, and this AD (e.g., skin cracking combined with frame cracking). We have added a new paragraph (p) to this AD to provide credit for repairs of the station 328, 344, 360, and 380 frames in the areas addressed by this AD that have been approved by the Boeing ODA via FAA Form 8100-9 prior to the effective date of this AD for the repairs specified in paragraphs (i), (j), (k), and (l) of this AD. We have redesignated subsequent paragraphs accordingly.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 36672, June 30, 2014) for correcting the unsafe condition; and

- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 36672, June 30, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. The service information describes procedures for inspection for cracking and missing straps, modification, and repair of certain fuselage frames. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this AD.

Costs of Compliance

We estimate that this AD affects 417 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	21 work-hours × \$85 per hour = \$1,785 per inspection cycle.	\$0	\$1,785 per inspection cycle.	\$744,345 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for certain on-condition

actions specified in this AD. However, we estimate the following costs to do any necessary repairs of the station 328

frame and the station 360 frame. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Frame 328 repair	25 work-hours × \$85 per hour = \$2,125	Negligible ...	\$2,125
Frame 360 repair	5 work-hours × \$85 per hour = \$425	Negligible ...	425

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations

for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015–23–08 The Boeing Company:

Amendment 39–18324; Docket No. FAA–2014–0436; Directorate Identifier 2014–NM–010–AD.

(a) Effective Date

This AD is effective January 4, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/\\$FILE/ST01219SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf)) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01920SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracks in fuselage frames, and a report of a missing strap that was not installed on a fuselage frame during production. We are issuing this AD to detect and correct missing fuselage frame straps and frame cracking that can result in severed frames. Continued operation of the airplane with multiple adjacent severed frames, or the combination of a severed frame and fuselage skin chemical mill cracks, can result in uncontrolled decompression of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Actions for Group 1 Airplanes

For airplanes identified as Group 1 in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013: At the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as provided by paragraph (n)(1) of this AD, do the inspection for cracking of the frames and applicable repairs using a method approved in accordance with the procedures specified in paragraph (q) of this AD.

(h) Groups 2 Through 7 Airplanes: Inspection for Strap Installation at Station 312

For airplanes identified as Groups 2 through 7 in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013: At the applicable time specified in tables 2 and 3 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as provided by paragraph (n)(1) of this AD, do a general visual inspection of the frame at station 312 to determine if the strap adjacent to stringer S–22 right is installed, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013. If the strap is not installed, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (q) of this AD.

(i) Groups 2 Through 6 Airplanes With Less Than 28,300 Total Flight Cycles: Repetitive Inspections, Related Investigative Actions, and Corrective Actions at Stations 328, 344, and 360

For airplanes identified as Groups 2 through 6 in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, that have accumulated less than 28,300 total flight cycles as of the effective date of this AD: Do the actions required by paragraphs (i)(1) and (i)(2) of this AD. Operators may do the repair of the frame at station 328 as specified in paragraph (m) of this AD as an optional preventive modification for that frame.

(1) At the applicable times specified in tables 4, 5, 7, and 8 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as provided by paragraphs (n)(1) and (n)(3) of this AD: Do detailed and eddy current inspections of the frame at stations 328, 344, and 360, as applicable, for cracking or a severed frame web; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the applicable inspections thereafter at the applicable time and intervals specified in paragraph 1.E., “Compliance,” of Boeing

Alert Service Bulletin 737–53A1323, dated December 6, 2013, until the inspection required by paragraph (i)(2) of this AD is done.

(2) At the applicable time specified in tables 4, 5, 7, and 8 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, do the actions specified in paragraph (i)(2)(i) or (i)(2)(ii) of this AD. Accomplishing the initial inspections required by paragraph (i)(2) of this AD terminates the inspections required by paragraph (i)(1) of this AD.

(i) Do detailed and eddy current inspections of the frame at stations 328, 344, and 360, as applicable, for cracking or a severed frame web; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspections specified in this paragraph thereafter at the applicable time and intervals specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013.

(ii) Do detailed and eddy current inspections of the frame at stations 328, 344, and 360, as applicable, for cracking or a severed frame web; and external detailed and eddy current inspections of the fuselage skin for cracking; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspections specified in this paragraph thereafter at the applicable time and intervals specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013.

(j) Groups 2 Through 6 Airplanes With 28,300 Total Flight Cycles or More: Repetitive Inspections, Related Investigative Actions, and Corrective Actions at Stations 328, 344, and 360

For airplanes identified as Groups 2 through 6 in Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, that have accumulated 28,300 total flight cycles or more as of the effective date of this AD: At the applicable times specified in tables 4, 5, 7, and 8 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as provided by paragraphs (n)(1) and (n)(3) of this AD, do the inspections specified in paragraph (j)(1) or (j)(2) of this AD; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the applicable inspections specified in paragraph (j)(1) or

(j)(2) of this AD thereafter at the applicable time and intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. Operators may do the repair of the frame at station 328, as specified in paragraph (m) of this AD, as an optional preventive modification for that frame.

(1) Do detailed and eddy current inspections of the frame at stations 328, 344, and 360, as applicable, for cracking or a severed frame web.

(2) Do detailed and eddy current inspections of the frame at stations 328, 344, and 360, as applicable, for cracking or a severed frame web; and external detailed and eddy current inspections of the fuselage skin for cracking.

(k) Group 7 Airplanes: Repetitive Inspections, Related Investigative Actions, and Corrective Actions at Station 328

For airplanes identified as Group 7 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: At the applicable time specified in table 6 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as provided by paragraph (n)(1) of this AD, do a detailed inspection and eddy current inspection of the frame at station 328 for cracking or a severed frame web; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspections specified in this paragraph thereafter at the applicable time and intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013. Operators may do the repair of the frame at station 328, as specified in paragraph (m) of this AD, as an optional preventive modification for that frame.

(l) Groups 2 Through 5 Airplanes: Repetitive Inspections, Related Investigative Actions, and Corrective Actions at Station 380

For airplanes identified as Groups 2 through 5 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: At the applicable time specified in tables 9 and 10 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as provided by paragraph (n)(1) of this AD, do detailed and eddy current inspections of the frame at station 380 for cracking or a severed frame web; and do all applicable corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as specified in paragraph (n)(2) of this AD. Do all applicable corrective actions before further flight. Repeat the inspections specified in this paragraph thereafter at the applicable time and intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013.

(m) Terminating Actions for Airplanes Identified as Groups 2, 3, 4, 5, 6, and 7

(1) For airplanes identified as Groups 2, 3, 4, 5, and 7 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: Accomplishing the repair or preventive modification of the frame at station 328, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as required by paragraph (n)(2) of this AD, terminates the inspections of that frame required by paragraphs (i), (j), and (k) of this AD.

(2) For airplanes identified as Groups 2, 3, 4, and 5 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: Accomplishing the repair or preventive modification of the frame at station 328 and the preventive modification of the frame at station 360, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as required by paragraph (n)(2) of this AD, terminates the inspections of the frame at station 344 and the fuselage skin inspections required by paragraphs (i) and (j) of this AD.

(3) For airplanes identified as Groups 2, 3, 4, and 5 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: Accomplishing the repair or preventive modification of the frame at station 360, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as required by paragraph (n)(2) of this AD, terminates the inspections of that frame required by paragraphs (i) and (j) of this AD.

(4) For airplanes identified as Group 6 in Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013: Accomplishing the repair or preventive modification of the frame at station 328, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, except as required by paragraph (n)(2) of this AD, terminates the fuselage skin inspections and the station 328 frame inspections required by paragraphs (i) and (j) of this AD.

(n) Exceptions to Service Information

(1) Where Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, specifies a compliance time after the "original issue date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, specifies to contact Boeing for appropriate action: Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (q) of this AD.

(3) The Condition column of Tables 4, 5, 7, and 8 in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, refers to total flight cycles "at the original issue date of this service bulletin." This AD, however, applies to the airplanes with the specified total flight cycles as of the effective date of this AD.

(o) Post-Repair Inspections and Post-Modification Inspections

(1) The post-repair and post-modification inspections specified in tables 13 through 15 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, are not required by this AD.

(2) The post-repair and post-modification inspections specified in Tables 13 through 15 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, may be used in support of compliance with section 121.1109(c)(2) or 129.109(b)(2) of the Federal Aviation Regulations (14 CFR 121.1109(c)(2) or 14 CFR 129.109(b)(2)). The corresponding actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013, are not required by this AD.

(p) Credit for Previous Actions

This paragraph provides credit for repairs of the station 328, 344, 360, and 380 frames in the areas addressed by this AD that have been approved by the Boeing Organization Designation Authorization (ODA) via FAA Form 8100-9 (Statement of Compliance with Airworthiness Standards) prior to the effective date of this AD for the repairs specified in paragraphs (i), (j), (k), and (l) of this AD.

(q) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (r) of this AD. Information may be emailed to: 9-ANM-LAACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(r) Related Information

For more information about this AD, contact Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5324; fax: 562-627-5210; email: galib.abumeri@faa.gov.

(s) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference

(IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737-53A1323, dated December 6, 2013.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on October 30, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-28824 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-3642; Directorate Identifier 2015-CE-028-AD; Amendment 39-18335; AD 2015-24-03]

RIN 2120-AA64

Airworthiness Directives; SOCATA Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for SOCATA Model TB 9, TB 10, TB 20, TB 21, and TB 200 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrosion of the horizontal stabilizer. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective January 4, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of January 4, 2016.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3642; or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact SOCATA NORTH AMERICA, North Perry Airport, 601 NE 10 Street, Pompano Beach, Florida 33060; phone: (954) 366-3331; Internet: <http://www.socatanorthamerica.com/default.htm>. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the Internet at <http://www.regulations.gov> by searching for Docket No. FAA-2015-3642.

FOR FURTHER INFORMATION CONTACT:

Albert J. Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4119; fax: (816) 329-4090; email: albert.mercado@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to SOCATA Models TB 9, TB 10, TB 20, TB 21, and TB 200 airplanes. The NPRM was published in the **Federal Register** on August 28, 2015 (80 FR 52215). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

During accomplishment of SOCATA Service Bulletin (SB) SB10-152-55 at original issue, some operators reported finding heavy corrosion of the horizontal stabilizer (HS) spar.

The results of the technical investigation have identified that the corrosion was caused by humidity ingress in the HS on aeroplanes subject to severe environmental conditions.

This condition, if not detected and corrected, could result in buckling and permanent HS distortion, possibly resulting in reduced control of the aeroplane.

To address this unsafe condition, SOCATA issued SB 10-152-55 Revision 1 to provide

instructions for inspection and corrective action.

For the reasons described above, this AD requires repetitive inspections of the affected area of the HS and, depending on findings, accomplishment of applicable corrective action(s).

The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/#!documentDetail;D=FAA-2015-3642-0001>.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the proposal and the FAA's response to the comment.

Request

Anthony Pynes commented that that he does not believe the methodology used and the foundational data available supports the need for this AD, and thus he believes that this AD is not necessary.

We do not agree. The FAA, in working with the State of Design airworthiness authority (EASA), determined that the actions of this AD on the horizontal stabilizer of the affected airplanes are necessary to correct an unsafe condition. Included in this is the risk in establishing such actions at the required compliance times. No changes to the AD have been made based on this comment.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting the AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 52215, August 28, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 52215, August 28, 2015).

Related Service Information Under 14 CFR Part 51

We reviewed DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015. The service information describes procedures for inspection for corrosion on the horizontal stabilizer spar and repair, if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of the AD.

Costs of Compliance

We estimate that this AD will affect 195 products of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$33,150, or \$170 per product.

In addition, we estimate that any necessary follow-on actions would take about 15 to 38 work-hours and require parts costing \$250 to \$400 depending on the type of repair, for a cost of \$2,325 to \$4,280 per product. The cost may vary depending on the extent of damage found. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative,

on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3642; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new AD:

2015-24-03 SOCATA: Amendment 39-18335; Docket No. FAA-2015-3642; Directorate Identifier 2015-CE-028-AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 4, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to SOCATA Models TB 9, TB 10, TB 20, TB 21, and TB 200 airplanes, all manufacturer serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 55: Stabilizers.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrosion of the horizontal stabilizer. We are issuing this AD to detect and correct corrosion of the

horizontal stabilizer (HS) spar, which could result in buckling and permanent HS distortion, possibly resulting in reduced control.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(5) of this AD:

(1) Within 13 months after January 4, 2016 (the effective date of this AD) and repetitively thereafter at intervals not to exceed 72 months, do a special detailed inspection of the HS spar following the instructions of DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015.

(2) If no discrepancy is detected during any inspections required by paragraph (f)(1) of this AD, protect the HS spar following the instructions of DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015.

(3) If any discrepancy is detected during any inspection required by paragraph (f)(1) of this AD, before further flight, do the applicable corrective action(s) following the instructions of DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015.

(4) Accomplishment of protection or corrective actions on an airplane as required by paragraph (f)(2) or (f)(3) of this AD, as applicable, does not constitute terminating action for the repetitive inspections as required by paragraph (f)(1) of this AD for that airplane.

(5) Inspections and corrective actions on an airplane done before January 4, 2016 (the effective date of this AD) following the instructions of DAHER-SOCATA TB Aircraft Recommended Service Bulletin SB 10-152, dated May 2013, are acceptable to comply with the requirements of this AD for that airplane. After January 4, 2016 (the effective date of this AD), repetitive inspections and applicable corrective actions, as required by this AD, must be done as required by paragraph (f)(1) of this AD following the instructions of DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4119; fax: (816) 329-4090; email: albert.mercado@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority

(or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2015-0130, dated July 7, 2015; and DAHER-SOCATA TB Aircraft Recommended Service Bulletin SB 10-152, dated May 2013, for related information. The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/>#!/documentDetail;D=FAA-2015-3642-0001.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) DAHER-SOCATA TB Aircraft Mandatory Service Bulletin SB 10-152, Amendment 1, dated April 2015.

(ii) Reserved.

(3) For SOCATA service information identified in this AD, contact SOCATA NORTH AMERICA, North Perry Airport, 601 NE 10 Street, Pompano Beach, Florida 33060; phone: (954) 366-3331; Internet: <http://www.socatanorthamerica.com/default.htm>.

(4) You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3642.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on November 17, 2015.

Melvin Johnson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-29876 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-3073; Directorate Identifier 2015-CE-017-AD; Amendment 39-18334; AD 2015-24-02]

RIN 2120-AA64

Airworthiness Directives; Viking Air Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Viking Air Limited Model DHC-3 Airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrugation cracking found at various wing stations and on the main spar lower cap. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective January 4, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of January 4, 2016.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3073; or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; Fax: 250-656-0673; telephone: (North America) 1-800-663-8444; email: technical.support@vikingair.com; Internet: <http://www.vikingair.com/support/service-bulletins>. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the Internet at <http://www.regulations.gov> by searching for Docket No. FAA-2015-3073.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Safety Engineer, FAA, New York Aircraft Certification Office (ACO), 1600 Steward Avenue, suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: aziz.ahmed@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to add an AD that would apply to Viking Air Limited Model DHC-3 airplane. The NPRM was published in the **Federal Register** on July 28, 2015 (80 FR 44892). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

An operator found cracks on the upper inner wing skin corrugations emanating from the rib attachment points. As a result, Viking Air Limited released Service Bulletin (SB) V3/0002, Revision NC to inspect for possible corrugation cracking between wing stations 34 and 110. Subsequently, operators discovered additional corrugation cracking at multiple wing stations and on the main spar lower cap.

These cracks, if not detected and rectified, may compromise the structural integrity of the wing. In order to address this potentially unsafe condition, Viking Air Limited has issued SB V3/0002, Revision C, specifying repetitive internal borescope and visual inspections. This AD is issued to mandate compliance with that SB.

The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/>#!/documentDetail;D=FAA-2015-3073-0002.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the proposal and the FAA's response to the comment.

Request From Viking

Viking has reviewed the FAA NPRM (80 FR 44892, July 28, 2015) and found that paragraph (f)(4) is not applicable or relevant to Viking SB V3/0002 Revision C. All cycle information is with respect to the wing. Viking noted that it is important to make the distinction between the airplane and the wings. The possibility has come to Viking's attention that some operators may rotate wings within their airplane fleet. Additionally, the Model DHC-3 airplane nominal cycles to hours ratio used by Viking is 1.33 cycles per hour. In most cases, Viking would consider an

average flight length to be 45 minutes. Therefore, Viking recommends that the calculation of the proposed AD paragraph (f)(4) not be part of the mandated actions.

We agree and will remove paragraph (f)(4) of the proposed AD and state in paragraph (f)(1) of this AD that the operator may contact Viking to help determine wing flight cycles. We will also change all reference of “flight cycles” to “wing flight cycles.” We redesignated paragraph (f)(5) of the proposed AD as paragraph (f)(4) of this AD.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting the AD with the change described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 44892, July 28, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 44892, July 28, 2015).

Related Service Information Under 14 CFR Part 51

We reviewed Viking DHC-3 Otter Service Bulletin No. V3/0002, Revision “C”, dated April 30, 2014; and Viking DHC-3 Otter Service Bulletin 3-STC (03-50)-001, Revision “NC”, dated July 3, 2013. The service information describes procedures for installing additional wing inspection access panels and inspecting the wings using borescope and visual methods. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD will affect 38 products of U.S. registry. We also estimate that it would take about 36 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$5,000 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be \$306,280, or \$8,060 per product.

The scope of damage found in the required inspection could vary significantly from airplane to airplane. We have no way of determining how much damage may be found on each

airplane or the cost to repair damaged parts on each airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3073; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section.

Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new AD:

2015-24-02 Viking Air Limited:

Amendment 39-18334; Docket No. FAA-2015-3073; Directorate Identifier 2015-CE-017-AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective January 4, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Viking Air Limited DHC-3 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 57: Wings.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrugation cracking found at various wing stations and on the main spar lower cap. We are issuing this proposed AD to detect cracking and correct as necessary to address the unsafe condition on these products.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) through (f)(4) of this AD:

(1) Within 30 days after January 4, 2016 (the effective date of this AD), determine the accumulated wing flight cycles or wing flight hours for each wing by contacting Technical Support at Viking Air Limited. You can find contact information for Viking Air Limited in paragraph (i) of this AD.

(2) Within 30 days after January 4, 2016 (the effective date of this AD), determine all installed supplemental type certificates (STC) or modifications affecting the wings. Based on the accumulated air time determined from

paragraph (f)(1) of this AD and before the initial inspection required in paragraph (f)(3) of this AD, install access panels as follows:

(i) If the airplane is free of STCs or any other modifications affecting the wings, install additional inspection access panels following the Accomplishment Instructions Part A of Viking DHC-3 Otter Service Bulletin No. V3/0002, Revision "C", dated April 30, 2014.

(ii) If the airplane is fitted with STC SA2009NY (which can be found on the internet at: http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/F7309B7D9B008C588625734F00730144?OpenDocument&Highlight=sa02009ny), incorporate additional inspection access panels following the Accomplishment Instructions of Viking Air Limited SB 3-STC (03-50)-001, Revision "NC", dated July 3, 2013.

Note 1 to paragraph (f)(2)(ii) of this AD: STC SA03-50 would be the Canadian equivalent of the United States (FAA) STC SA2009NY.

(iii) If there are other STCs or modifications affecting the wings the operator must contact the FAA to request an FAA-approved alternative method of compliance using the procedures in

paragraph (g)(1) of this AD and 14 CFR 39.19. To develop these procedures, we recommend you contact the STC holder for guidance in developing substantiating data.

(3) Based on the accumulated air time on the wings determined in paragraph (f)(1) of this AD, perform initial and repetitive borescope and visual inspections of both the left-hand and right-hand wing box following Part B of the Accomplishment Instructions of Viking DHC-3 Otter Service Bulletin V3/0002, Revision "C", dated April 30, 2014, using the inspection schedules specified in Table 1 of paragraph (f)(3) of this AD:

TABLE 1 OF PARAGRAPH (f)(3) OF THIS AD—INSPECTION SCHEDULE

Effectivity	Initial inspection	Repetitive inspection
If Viking Air Limited SB V3/0002, Revision "A", dated February 22, 2013; or Viking Air Limited SB V3/0002, Revision "B", dated July 3, 2013; were complied with prior to January 4, 2016 (the effective date of this AD).	The initial inspection is not required since the inspection was accomplished while complying with Revision "A" or "B" of Viking Air Limited SB V3/0002.	Repetitively inspect not to exceed every 1,600 wing flight hours accumulated after the last inspection or 2,100 wing flight cycles after the last inspection, whichever occurs first.
If, as of January 4, 2016 (the effective date of this AD), the airplane has less than 31,200 wing flight hours.	Inspect within 800 wing flight hours after January 4, 2016 (the effective date of this AD), or within 6 months January 4, 2016 (the effective date of this AD), whichever occurs first.	Repetitively inspect not to exceed every 1,600 wing flight hours accumulated after the last inspection or 2,100 wing flight cycles after the last inspection, whichever occurs first.
If, as of January 4, 2016 (the effective date of this AD), the airplane has 31,200 wing flight hours or more but less than 31,600 wing flight hours.	Inspect upon or before accumulating 32,000 wing flight hours or within 6 months after January 4, 2016 (the effective date of this AD), whichever occurs first.	Repetitively inspect not to exceed every 1,600 wing flight hours accumulated after the last inspection or 2,100 wing flight cycles after the last inspection, whichever occurs first.
If, as of January 4, 2016 (the effective date of this AD), the airplane has 31,600 wing flight hours or more.	Inspect within 400 wing flight hours accumulated after January 4, 2016 (the effective date of this AD) or 3 months after January 4, 2016 (the effective date of this AD), whichever occurs first.	Repetitively inspect not to exceed every 1,600 wing flight hours accumulated after the last inspection or 2,100 wing flight cycles after the last inspection, whichever occurs first.

(4) If any cracks are found, contact Technical Support at Viking Air Limited for an FAA-approved repair and incorporate the repair before further flight. You can find contact information for Viking Air Limited in paragraph (i) of this AD. The FAA-approved repair must specifically reference this AD.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Safety Engineering, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7329; fax: (516) 794-5531; email: aziz.ahmed@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required

to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(h) Related Information

Refer to MCAI Transport Canada AD No. CF-2015-05, dated March 18, 2015, for related information. The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/#/documentDetail;D=FAA-2015-3073-0002>.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Viking DHC-3 Otter Service Bulletin No. V3/0002, Revision "C", dated April 30, 2014.

(ii) Viking DHC-3 Otter Service Bulletin 3-STC (03-50)-001, Revision "NC", dated July 3, 2013.

(3) For Viking Air Limited service information identified in this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; Fax: 250-656-0673; telephone: (North America) 1-800-663-8444; email: technical.support@vikingair.com; Internet: <http://www.vikingair.com/support/service-bulletins>.

(4) You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on November 16, 2015.

Melvin Johnson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-29855 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2014-0928; Directorate Identifier 2014-NM-040-AD; Amendment 39-18333; AD 2015-24-01]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A330-200 Freighter, A330-200, A330-300, A340-200, A340-300, A340-500, and A340-600 series airplanes. This AD was prompted by a report of skin disbonding on a composite side panel of a rudder installed on an A310 airplane. This AD requires a review of the maintenance records of the rudder to determine if any composite side shell panel repair has been done; a thermography inspection limited to the repair areas or complete side shells, as applicable, to identify possible in-service rudder repairs, damages, or fluid ingress; and applicable related investigative and corrective actions. We are issuing this AD to detect and correct the rudder skin disbonding, which could affect the structural integrity of the rudder, and could result in reduced controllability of the airplane.

DATES: This AD becomes effective January 4, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 4, 2016.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov>/#!docketDetail;D=FAA-2014-0928 or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-

30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email airworthiness.A330-A340@airbus.com; Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0928.

FOR FURTHER INFORMATION CONTACT:

Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1138; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Model A330-200 Freighter, A330-200, A330-300, A340-200, A340-300, A340-500, and A340-600 series airplanes. The NPRM published in the **Federal Register** on December 29, 2014 (79 FR 77972).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014-0033, dated February 4, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Airbus Model A330-200 Freighter, A330-200, A330-300, A340-200, A340-300, A340-500, and A340-600 series airplanes. The MCAI states:

A case of skin disbonding was reported on a composite side panel of a rudder installed on an A310 aeroplane.

The investigation results revealed that this disbonding started from a skin panel area previously repaired in-service in accordance with the Structural Repair Manual (SRM).

The initial damage has been identified as a disbonding between the core and skin of the repaired area. This damage may not be visually detectable and likely propagates during normal operation due to the variation of pressure during ground-air-ground cycles.

Composite rudder side shell panels are also installed on A330 and A340 aeroplanes, which may have been repaired in-service using a similar method.

This condition, if not detected and corrected, could affect the structural integrity of the rudder, possibly resulting in reduced control of the aeroplane.

For the reasons described above, this [EASA] AD requires a one-time thermography inspection of a repaired rudder or a rudder whose maintenance records are incomplete and, depending on findings, accomplishment of applicable corrective and follow-up actions [including repetitive inspections].

The related investigative actions in this AD include, as applicable, an ultrasonic inspection, an elasticity laminate checker inspection, a tap test inspection, detailed inspections, and thermography inspections, and ventilation of the core. The repetitive inspections include detailed inspections and thermography inspections. The corrective actions in this AD include repairs.

The compliance time for the related investigative actions is before further flight after accomplishing the applicable inspection required by paragraph (g)(1) or (g)(2)(ii) of this AD.

The intervals for the repetitive inspections are either 900 flight hours or 1,000 flight cycles, depending on the applicable conditions identified in the service information.

The compliance times for the corrective actions range, depending on the applicable conditions identified in the service information, from before further flight to within 4,500 flight cycles but not to exceed 24 months after accomplishing the applicable inspection required by paragraph (g)(1) or (g)(2)(ii) of this AD.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov>/#!documentDetail;D=FAA-2014-0928-0002.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 77972, December 29, 2014) and the FAA’s response to each comment.

Request To Use the Latest Service Information

American Airlines (AAL) and Delta Airlines (DAL) requested that we revise the NPRM (79 FR 77972, December 29, 2014) to cite the latest service information.

We agree with the commenters’ request. Airbus has issued Airbus Service Bulletin A330-55-3043, Revision 1, dated August 20, 2014, Airbus Service Bulletin A340-55-4039, Revision 1, dated August 20, 2014, and Airbus Service Bulletin A340-55-5007,

Revision 1, dated August 20, 2014. The new service information requires no additional work, and there are no new actions required by this AD. We have updated the AD with the latest service information, and we have also added a credit paragraph for previous actions done before the effective date of this AD using the service information cited in the NPRM (79 FR 77972, December 29, 2014).

Request To Clarify the Structural Repair Manual Repairs That Are Affected

AAL requested that the NPRM (79 FR 77972, December 29, 2014) clarify the specific structural repair manual (SRM) repairs that are affected. AAL stated that paragraph (j) of the proposed AD states specific serial number ranges that are not affected by the AD provided that it is determined that no repair has been accomplished on the composite side shell panel of that rudder since first installation on the airplane. AAL believes this last sentence is too broad and not in line with the intent of the service information requirements. AAL commented that stating no repair has been accomplished limits acceptable repairs covered by an Airbus repair design approval sheet, designated engineering representative repairs, and other SRM repairs not affected by the improper practices that are the subject of the NPRM. AAL stated that paragraphs (g)(1) and paragraph (l) of the proposed AD list the affected SRM repairs in the service information figures.

We agree with the commenter's request. We have revised paragraph (j) of this AD to clarify the specific repairs accomplished as described in the SRM procedures identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of the service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, as applicable.

Request To Add the Manufacturer Part Number

DAL requested that the NPRM (79 FR 77972, December 29, 2014) include the manufacturer part numbers of the rudder serial numbers specified in paragraph (j), which provides only a list of rudder serial numbers not affected by the requirements of paragraphs (g) and (h) of the proposed AD. DAL commented that in the event of future aircraft acquisitions or rudder (component only) purchases, operators will need the manufacturer part numbers associated with the listed serial numbers to determine AD applicability.

We disagree with the commenter's request to add part numbers to paragraph (j) of this AD. The rudder serial number, regardless of the part number, is the key to identifying whether the rudder is not affected. Only rudders that have certain serial numbers that meet the conditions specified in paragraph (j) of this AD are exempt from the actions required by paragraphs (g) and (h) of this AD. Airbus has informed us that rudders with the same manufacturer part number might or might not be affected; it is the serial number that determines whether it is an affected rudder. We have not changed the AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 77972, December 29, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 77972, December 29, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information:

- Airbus Service Bulletin A330–55–3043, Revision 1, dated August 20, 2014.
- Airbus Service Bulletin A340–55–4039, Revision 1, dated August 20, 2014.
- Airbus Service Bulletin A340–55–5007, Revision 1, dated August 20, 2014.

The service information describes procedures for a review of the maintenance records of the rudder to determine if any composite side shell panel repair has been done; a thermography inspection limited to the repair areas or complete side shells, as applicable, to identify possible in-service rudder repairs, damages, or fluid ingress; and applicable related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD affects 55 airplanes of U.S. registry.

We also estimate that it would take about 45 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$0 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$210,375, or \$3,825 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov/#!docketDetail;D=FAA-2014-0928>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015-24-01 Airbus: Amendment 39-18333. Docket No. FAA-2014-0928; Directorate Identifier 2014-NM-040-AD.

(a) Effective Date

This AD becomes effective January 4, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Airbus Model A330-201, -202, -203, -223, -223F, -243, -243F, -301, -302, -303, -321, -322, -323, -341, -342, and -343 airplanes, all manufacturer serial numbers.

(2) Airbus Model A340-211, -212, -213, -311, -312, -313, -541, and -642 airplanes, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Reason

This AD was prompted by a report of skin disbonding on a composite side panel of a rudder installed on an A310 airplane. We are issuing this AD to detect and correct the rudder skin disbonding, which could affect the structural integrity of the rudder, and could result in reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Review the Maintenance Records

Within 24 months after the effective date of this AD: Review the maintenance records of the rudder to determine if any composite side shell panel repair has been accomplished on the rudder since first installation on an airplane.

(1) If, based on the maintenance record review, any repair identified in Figure A-GBBAA (Sheet 01 and 02) or Figure A-GBCAA (Sheet 02) of the service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD is found: Within 24 months after the effective date of this AD, do a thermography inspection for repair, damages, and fluid ingress, limited to the repaired areas, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD:

(i) Airbus Service Bulletin A330-55-3043, Revision 1, dated August 20, 2014 (for Model A330-201, -202, -203, -223, -223F, -243, -243F, -301, -302, -303, -321, -322, -323, -341, -342, and -343 airplanes).

(ii) Airbus Service Bulletin A340-55-4039, Revision 1, dated August 20, 2014 (for Model A340-211, -212, -213, -311, -312, and -313 airplanes).

(iii) Airbus Service Bulletin A340-55-5007, Revision 1, dated August 20, 2014 (for Model A340-541 and -642 airplanes).

(2) For a rudder for which maintenance records are unavailable or incomplete, do the actions specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD:

(i) No later than 3 months before accomplishment of the thermography inspection, as required by paragraph (g)(2)(ii) of this AD, contact Airbus to request related rudder manufacturing data by submitting the serial number of the rudder to Airbus.

(ii) Within 24 months after the effective date of this AD: Do a thermography inspection for any repair on complete side shells to identify and mark any repair, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD.

(h) Related Investigative Actions, Corrective Actions, and Repetitive Inspections

After the inspection as required by paragraph (g)(1) or (g)(2) of this AD: At the applicable compliance times specified in paragraph 1.E., “Compliance,” of Tables 3, 4A, 4B, 4C, 4D, and 5 of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, accomplish all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD; except as provided by paragraphs (i)(1) and (i)(2) of this AD. Options provided in the service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD for accomplishing the actions are acceptable for the corresponding requirements of this paragraph provided that the related investigative and corrective actions are done at the applicable times specified in paragraph 1.E., “Compliance,” of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, including applicable repetitive inspection intervals, except as required by paragraphs (i)(1) and (i)(2) of this AD. Thereafter repeat the inspections of the restored and repaired areas at the applicable compliance time specified in paragraph 1.E., “Compliance,” of Tables 3, 4A, 4B, 4C, 4D, and 5 of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD.

(i) Exceptions to the Service Information

(1) Where the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD specifies a compliance time relative to the date of the service information, this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If the service information in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD specifies to contact Airbus: At the applicable compliance times specified in paragraph 1.E., “Compliance,” of the applicable service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, repair using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus’s EASA Design Organization Approval (DOA).

(j) Provisions for Certain Airplanes

Airplanes fitted with a rudder having a serial number (S/N) that is not in the range of S/N TS-1001 through S/N TS-1043 inclusive, S/N TS-2001 through S/N TS-2074 inclusive, S/N TS-3000 through S/N TS-3525 inclusive, S/N TS-4001 through S/N TS-4170 inclusive, S/N TS-6001 through S/N TS-6246 inclusive, or S/N TS-5001 through S/N TS-5138 inclusive, are not

affected by the requirements of paragraphs (g) and (h) of this AD provided that it is determined that no repair has been accomplished as described in the procedures identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of the service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, as applicable, on the composite side shell panel of that rudder since first installation on an airplane.

(k) Parts Installation Limitations

As of the effective date of this AD, no person may install, on any airplane, a rudder, unless the record review and thermography inspection specified in paragraph (g) of this AD has been done on that rudder and thereafter all applicable related investigative actions, repetitive inspections, and corrective actions are done as required by paragraph (h) of this AD, except as provided in paragraph (j) of this AD.

(l) Repair Prohibition

As of the effective date of this AD, no person may accomplish a side shell repair on any rudder using a structure repair manual procedure identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of the service information specified in paragraphs (g)(1)(i) through (g)(1)(iii) of this AD, as applicable, on any airplane.

(m) Credit for Previous Actions

This paragraph provides credit for the actions specified in this AD, if those actions were performed before the effective date of this AD using the service information in paragraphs (m)(1), (m)(2), and (m)(3) of this AD.

(1) Airbus Service Bulletin A330–55–3043, dated February 7, 2013.

(2) Airbus Service Bulletin A340–55–4039, dated February 7, 2013.

(3) Airbus Service Bulletin A340–55–5007, dated February 7, 2013.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective

actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0033, dated February 4, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0928.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(3) and (p)(4) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Service Bulletin A330–55–3043, Revision 1, dated August 20, 2014.

(ii) Airbus Service Bulletin A340–55–4039, Revision 1, dated August 20, 2014.

(iii) Airbus Service Bulletin A340–55–5007, Revision 1, dated August 20, 2014.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email airworthiness.A330-A340@airbus.com; Internet <http://www.airbus.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on November 9, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–29851 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–1048; Directorate Identifier 2014–NM–055–AD; Amendment 39–18332; AD 2015–23–14]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. This AD was prompted by reports that cracks can occur in a frame of the tail section on certain airplanes. This AD requires a one-time detailed inspection of the oblique frame 67–2 for any cracking, and repair if necessary. We are issuing this AD to detect and correct such cracking, which could lead to failure of the oblique frame 67–2, and consequent loss of the structural integrity of the tail section.

DATES: This AD becomes effective January 4, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 4, 2016.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov/#/docketDetail;D=FAA-2014-1048> or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–1048.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington WA 98057-3356; telephone (425) 227-1137; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. The NPRM published in the **Federal Register** on January 23, 2015 (80 FR 3500). We are issuing this AD to detect and correct cracking of the oblique frame 67-2, which could lead to failure of the oblique frame 67-2, and consequent loss of the structural integrity of the tail section.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014-0039, dated February 20, 2014, dated (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. The MCAI states:

Service experience has shown that cracks can occur in oblique frame 67-2 in the tail section on aeroplanes with more than 29 000 flight cycles (FC).

This condition, if not detected and corrected, can result in an exponential crack growth rate, possibly leading to failure of the oblique frame 67-2 over a certain length and consequent loss of the structural integrity of the tail section of the aeroplane.

For the reasons described above, this [EASA] AD requires a one-time [detailed] inspection of the oblique frame 67-2 for cracks and, depending on findings, accomplishment of a repair.

Repetitive inspections are planned to be incorporated into a revision of Fokker Services Report SE-623, which is part of the Airworthiness Limitations Section of the Instructions for Continued Airworthiness, for which a separate [EASA] AD is expected to be published.

Fokker Services All Operators Message AOF100.187#02 provides additional information concerning the subject addressed by this [EASA] AD.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov/#!documentDetail;D=FAA-2014-1048-0002>.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80

FR 3500, January 23, 2015) or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 3500, January 23, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 3500, January 23, 2015).

Related Service Information Under 1 CFR Part 51

Fokker Services B.V. has issued Service Bulletin SBF100-53-124, dated January 23, 2014; and Service Bulletin SBF100-53-125, Revision 1, dated February 13, 2014. The service information describes procedures for a one-time detailed inspection of the oblique frame 67-2 for any cracking, and repair if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD affects 8 airplanes of U.S. registry.

We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$680, or \$85 per product.

In addition, we estimate that any necessary follow-on actions will take about 12 work-hours and require parts costing \$0, for a cost of \$1,020 per product. We have no way of determining the number of aircraft that might need this action.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in

air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov/#!docketDetail;D=FAA-2014-1048>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015-23-14 Fokker Services B.V.:

Amendment 39-18332. Docket No. FAA-2014-1048; Directorate Identifier 2014-NM-055-AD.

(a) Effective Date

This AD becomes effective January 4, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by reports that cracks can occur in the oblique frame 67-2 in the tail section on certain airplanes. We are issuing this AD to detect and correct such cracking, which could lead to failure of the oblique frame 67-2, and consequent loss of the structural integrity of the tail section.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection and Repair

For airplanes that have accumulated more than 29,000 total flight cycles since the airplane's first flight as of the effective date of this AD: Within 500 flight cycles or 12 months after the effective date of this AD, whichever occurs first, do a one-time detailed inspection of the oblique frame 67-2 for any cracking, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100-53-124, dated January 23, 2014. For the purposes of this AD, a detailed inspection is an intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.

(h) Corrective Action

If any cracking is found during the inspection required by paragraph (g) of this AD, before further flight, repair the oblique frame 67-2, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100-53-125, Revision 1, dated February 13, 2014.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International

Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington WA 98057-3356; telephone (425) 227-1137; fax (425) 227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Fokker B.V. Service's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0039, dated February 20, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov/#/documentDetail;D=FAA-2014-1048-0002>.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Fokker Service Bulletin SBF100-53-124, dated January 23, 2014.

(ii) Fokker Service Bulletin SBF100-53-125, Revision 1, dated February 13, 2014.

(3) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88-6280-350; fax +31 (0)88-6280-111; email technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call

202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on November 11, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-29852 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****18 CFR Part 35**

[Docket No. RM15-2-000; Order No. 819]

Third-Party Provision of Primary Frequency Response Service

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is revising its regulations to foster competition in the sale of primary frequency response service. Specifically, the Commission amends its regulations governing market-based rates for public utilities pursuant to the Federal Power Act (FPA) to permit the sale of primary frequency response service at market-based rates by sellers with market-based rate authority for sales of energy and capacity.

DATES: This Final Rule will become effective February 25, 2016.

FOR FURTHER INFORMATION CONTACT: Rahim Amerkhalil (General Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502-8266.

Gregory Basheda (Market Power Screening Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502-6479.

Lina Naik (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502-8882.

SUPPLEMENTARY INFORMATION:**Order No. 819****Final Rule**

(Issued November 20, 2015)

1. The Federal Energy Regulatory Commission (Commission) is revising

its regulations to foster competition in the sale of primary frequency response service.¹ Specifically, the Commission amends its regulations to revise Subpart H to Part 35 of Title 18 of the Code of Federal Regulations governing market-based rates for public utilities pursuant to sections 205 and 206 of the Federal Power Act (FPA)² to permit the sale of primary frequency response service at market-based rates by sellers with market-based rate authority for sales of energy and capacity.

2. This proceeding derives from Order No. 784,³ in which the Commission revised Part 35 of its regulations to reflect reforms to its *Avista* policy⁴ governing the sale of certain ancillary services at market-based rates to public utility transmission providers. Specifically, Order No. 784 found that when appropriate intra-hour transmission scheduling practices are in place, the *Avista* restrictions need not apply to the sale of Energy Imbalance, Generator Imbalance, Operating Reserve-Spinning and Operating Reserve-Supplemental services, because with those scheduling practices in place the existing market power screens for sales of energy and capacity can also be applied to sales of those ancillary services.⁵

3. However, because of the unique technical and geographic requirements associated with Reactive Supply and Voltage Control (under OATT Schedule 2) and Regulation and Frequency Response (under OATT Schedule 3),⁶

the Commission only allowed market-based rate sales of Schedule 2 and Schedule 3 services to a public utility that is purchasing ancillary services to satisfy its OATT requirements if either: (a) The sale is made pursuant to a competitive solicitation that meets certain specified requirements; or (b) the sale is made at or below the buying public utility transmission provider's own Schedule 2 or 3 rate, as applicable. The Commission further stated its intention to gather more information regarding the technical, economic and market issues concerning the provision of these services in a separate proceeding.

4. Commission staff held a workshop on April 22, 2014 in this proceeding and then issued a notice of proposed rulemaking that distinguished between regulation service and primary frequency response service, and proposed to allow sales of primary frequency response service at market-based rates by entities granted market-based rate authority for sales of energy and capacity.⁷ In response to the NOPR, 19 sets of comments were submitted.

I. Background

5. The Commission in Order No. 888⁸ delineated two categories of ancillary services: Those that the transmission provider is required to provide to all of its basic transmission customers⁹ and those that the transmission provider is only required to *offer* to provide to transmission customers serving load in the transmission provider's control area.¹⁰ With respect to the second

provide autonomous, pre-programmed changes in output to rapidly arrest large changes in frequency until dispatched resources can take over while regulation service is centrally dispatched through automatic generation control (AGC) and is not focused exclusively on frequency control.

⁷ *Third-Party Provision of Primary Frequency Response Service*, Notice of Proposed Rulemaking (NOPR), 80 FR 10,426 (Feb. 26, 2015), FERC Stats. & Regs. ¶ 32,705 (2015).

⁸ See *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities*, Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g*, Order No. 888-A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g*, Order No. 888-B, 81 FERC ¶ 61,248 (1997), *order on reh'g*, Order No. 888-C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group v. FERC*, 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York v. FERC*, 535 U.S. 1 (2002).

⁹ The first category consists of Scheduling, System Control and Dispatch service and Reactive Supply and Voltage Control from Generation Sources service.

¹⁰ The second category consists of Regulation and Frequency Response service, Energy Imbalance service, Operating Reserve-Spinning service, and Operating Reserve-Supplemental service. Order No. 890 later added an additional ancillary service to this category: Generator Imbalance service. See *Preventing Undue Discrimination and Preference in*

category, the Commission reasoned that the transmission provider is not always uniquely qualified to provide the services, and customers may be able to more cost-effectively self-supply them or procure them from other entities. The Commission contemplated that third parties (*i.e.*, parties other than a transmission provider supplying ancillary services pursuant to its OATT obligation) could provide these ancillary services on other than a cost-of-service basis if such pricing was supported, on a case-by-case basis, by analyses that demonstrated that the seller lacks market power in the relevant product market.¹¹

6. Subsequently, in *Avista*,¹² the Commission adopted a policy allowing third-party ancillary service providers that could not perform a market power study to sell certain ancillary services at market-based rates with certain restrictions.¹³

7. As noted earlier, the instant proceeding derives from Order No. 784 in which the Commission found that when appropriate intra-hour transmission scheduling practices are in place, the *Avista* restrictions need not apply to the sale of Energy Imbalance, Generator Imbalance, Operating Reserve-Spinning and Operating Reserve-Supplemental services, because with those practices in place, the results of the existing market power screens for sales of energy and capacity can also be applied to sales of these ancillary services.¹⁴

Transmission Service, Order No. 890, FERC Stats. & Regs. ¶ 31,241, at P 85, *order on reh'g*, Order No. 890-A, FERC Stats. & Regs. ¶ 31,261 (2007), *order on reh'g*, Order No. 890-B, 123 FERC ¶ 61,299 (2008), *order on reh'g*, Order No. 890-C, 126 FERC ¶ 61,228 (2009), *order on clarification*, Order No. 890-D, 129 FERC ¶ 61,126 (2009).

¹¹ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,720–21.

¹² See *supra* n.4.

¹³ These ancillary services included: Regulation and Frequency Response, Energy Imbalance, Operating Reserve-Spinning, and Operating Reserve-Supplemental. The Commission did not extend this *Avista* policy to Reactive Supply and Voltage Control from Generation Sources service, which means that third parties wishing to sell this ancillary service at market-based rates would be required to present specific evidence of a lack of market power in the provision of this specific product before the Commission would authorize sales of this service at market-based rates. The Commission also did not extend the *Avista* policy to Scheduling, System Control and Dispatch service. Because only balancing area operators can provide this ancillary service, it does not lend itself to competitive supply. Order No. 784, FERC Stats. & Regs. ¶ 31,349 at n.17.

¹⁴ Because energy and generator imbalance services merely require the ability to respond to dispatch within the hour, the Commission found that any sub-hourly transmission scheduling interval would be sufficient. Order No. 784-A, 146 FERC ¶ 61,114 at P 12 (2012). As the operating reserve services require more rapid response within

¹ As described in more detail below, this Final Rule defines primary frequency response service as a resource standing by to provide autonomous, pre-programmed changes in output to rapidly arrest large changes in frequency until dispatched resources can take over.

² 16 U.S.C. 824d, 824e (2012).

³ *Third-Party Provision of Ancillary Services; Accounting and Financial Reporting for New Electric Storage Technologies*, Order No. 784, 78 FR 46,178 (July 30, 2013), FERC Stats. & Regs. ¶ 31,349 (2013).

⁴ *Avista Corp.*, 87 FERC ¶ 61,223, *order on reh'g*, 89 FERC ¶ 61,136 (1999) (*Avista*). Outside the markets operated by regional transmission organizations and independent system operators, *Avista* authorizes suppliers who cannot show a lack of market power with respect to certain ancillary services to nevertheless sell such services, subject to certain restrictions. As relevant to this Final Rule, these restrictions prohibit sales to a public utility that is purchasing ancillary services to satisfy its own Open Access Transmission Tariff (OATT) requirements to offer ancillary services to its own customers, or sales to a traditional, franchised public utility affiliated with the third-party seller, or where the underlying transmission service is on the transmission system of the affiliated public utility.

⁵ Order No. 784, FERC Stats. & Regs. ¶ 31,349 at P 4, PP 57–58.

⁶ *Id.* PP 59–61. Although the title of Schedule 3 addresses both frequency response and regulation, the two services are distinct from each other. Frequency response is a resource standing by to

8. However, the Commission also found in Order No. 784 that the record developed to that point did not support expanding these market-based rate authorizations to include sales of Reactive Supply and Voltage Control (under OATT Schedule 2) (Schedule 2 service) and Regulation and Frequency Response (under OATT Schedule 3) services (Schedule 3 service).¹⁵ Instead, the Commission allowed market-based rate sales of Schedule 2 and Schedule 3 services to a public utility that is purchasing ancillary services to satisfy its OATT requirements, provided the sale is made pursuant to a competitive solicitation that meets certain specified requirements¹⁶ or the sale is made at or below the buying public utility transmission provider's own Schedule 2 or 3 rate, as applicable.¹⁷ The Commission further stated its intention to gather more information regarding the technical, economic and market issues concerning the provision of these services in a separate proceeding that considers, among other things, the ease and cost-effectiveness of relevant equipment upgrades, the need for and availability of appropriate special arrangements such as dynamic scheduling or pseudo-tie arrangements, and other technical requirements related to the provision of Schedule 2 and Schedule 3 services.¹⁸

9. Pursuant to that directive, Commission staff held a workshop on April 22, 2014 to obtain input from interested persons regarding the technical, economic and market issues concerning the provision of Schedule 2 and Schedule 3 services.¹⁹ Among other things, the workshop explored issues surrounding the sale of these services at market-based rates. Comments submitted in response to the workshop that discussed the characteristics associated with a primary frequency response product indicated that market-

the hour (spinning reserves must be available immediately and supplemental reserves must be available within a short period of time), the Commission required potential sellers of operating reserve services to satisfactorily explain, in their market-based rate applications, how the particular intra-hour transmission scheduling practices or other protocols in their regions permit resources in one balancing authority area to respond to contingencies in a neighboring balancing authority area within these tight time frames. Order No. 784-A, 146 FERC ¶ 61,114 at PP 13-15.

¹⁵ Order No. 784, FERC Stats. & Regs. ¶ 31,349 at PP 59-61.

¹⁶ *Id.* PP 99-101.

¹⁷ *Id.* PP 82-85.

¹⁸ *Id.* P 61.

¹⁹ See *Third-Party Provision of Reactive Supply and Voltage Control and Regulation and Frequency Response Services*, Final Agenda, Docket No. AD14-7-000 (Apr. 22, 2014).

based rate sales of such a product are feasible.²⁰

10. Separately, the Commission on January 16, 2014 issued a Final Rule approving reliability standard BAL-003-1²¹ under which a balancing authority²² must maintain a minimum frequency response obligation.²³ While most balancing authorities should be able to meet the new reliability standard using their own resources,²⁴ some may nevertheless be interested in purchasing primary frequency response service from others if doing so would be economically beneficial.

11. Based upon information received at the workshop and in the subsequently-filed 11 written comments, the Commission issued a NOPR that differentiated between regulation service and primary frequency response service, analyzed the technical characteristics of primary frequency response service to show why the existing market power screens for sales of energy and capacity could be used to show lack of market power for sales of primary frequency response as well, and therefore proposed to allow sales of primary frequency response service at market-based rates by entities granted market-based rate authority for sales of energy and capacity.²⁵ The NOPR sought comment on all aspects of this proposal.²⁶

12. Most of the 19 sets of comments submitted in response to the NOPR are supportive of the proposal, with some commenters seeking clarification of

²⁰ For example, most commenters echo Edison Electric Institute's (EEL) arguments that virtually all generators can provide primary frequency response, and because it is provided at the interconnection level, balancing authority areas have more flexibility on the location of the resource than they would for other products. See, e.g., Edison Electric Institute Post-Workshop Comments, Docket No. AD14-7-000, at 7-8 (filed June 3, 2014).

²¹ Reliability standards proposed by the North American Electric Reliability Corporation (NERC) are subject to the Commission's jurisdiction under section 215 of the Federal Power Act, 16 U.S.C. 824o(d). The Commission has authority to approve or reject such standards, and to enforce those that are approved.

²² The NERC Glossary defines a balancing authority as "(t)he responsible entity that integrates resource plans ahead of time, maintains load-interchange-generation balance within a Balancing Authority Area, and supports Interconnection frequency in real time." See http://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.

²³ See *Frequency Response and Frequency Bias Setting Reliability Standard*, Order No. 794, 146 FERC ¶ 61,024 (2014).

²⁴ *Id.* PP 62-63.

²⁵ NOPR, FERC Stats. & Regs. ¶ 32,705 (2015). With respect to the remainder of the issues discussed in the workshop and associated written comments, the Commission did not see sufficient evidence to pursue generic reforms through this rulemaking proceeding. *Id.* P 10.

²⁶ *Id.* P 30.

various issues. Meanwhile, the limited set of adverse comments fall into two broad categories: (1) Comments seeking to contest the technical arguments regarding market power relied upon by the NOPR; and (2) comments that do not relate to market power screening but rather relate to various aspects of the implementation of actual primary frequency response transactions.

13. For the reasons described more fully below, the Commission finds that it is appropriate to finalize the NOPR proposal to permit voluntary sales of primary frequency response service at market-based rates for entities granted market-based rate authority for sales of energy and capacity. We also address various requests for clarification, as discussed more fully below. We emphasize that this Final Rule does not place any limits on the types of transactions available to procure primary frequency response service; they may be cost-based or market-based, bundled with other services or unbundled as discussed further below, and inside or outside of organized markets. This Final Rule focuses solely on how jurisdictional entities can qualify for market-based rates for primary frequency response service in the context of voluntary bilateral sales.

II. Discussion

14. In the NOPR in this proceeding, the Commission proposed to define primary frequency response service as the "autonomous, automatic, and rapid action of a generator, or other resource, to change its output (within seconds) to rapidly dampen large changes in frequency."²⁷ Elsewhere in the NOPR, the Commission discussed the idea that individual autonomous responses to large changes in frequency will be of short duration, sustained only until dispatched regulation or operating reserve resources begin responding.²⁸ As there are aspects of both statements that are important to properly defining this product, in this Final Rule the Commission will refine and clarify the NOPR's definition to state that primary frequency response service is defined as a resource standing by to provide autonomous, pre-programmed changes in output to rapidly arrest large changes in frequency until dispatched resources can take over.

²⁷ *Id.* P 12.

²⁸ *Id.* P 24.

A. Technical Issues Related to the Application of Existing Market Power Screens to Primary Frequency Response Service

1. Geographic Market and the Impact of Resource Distance

15. The Commission analyzes horizontal market power for market-based sales of energy and capacity²⁹ using two indicative screens, the wholesale market share screen and the pivotal supplier screen, to identify sellers that raise no horizontal market power concerns and can otherwise be considered for market-based rate authority.³⁰ The wholesale market share screen measures whether a seller has a dominant position in the relevant geographic market in terms of the number of megawatts of uncommitted capacity owned or controlled by the seller, as compared to the uncommitted capacity of the entire market.³¹ A seller whose share of the relevant market is less than 20 percent during all seasons passes the wholesale market share screen.³² The pivotal supplier screen evaluates the seller's potential to exercise horizontal market power based on the seller's uncommitted capacity at the time of annual peak demand in the relevant market.³³ A seller satisfies the pivotal supplier screen if its uncommitted capacity is less than the net uncommitted supply in the relevant market.³⁴

16. Passing both the wholesale market share screen and the pivotal supplier screen creates a rebuttable presumption that the seller does not possess horizontal market power; failing either screen creates a rebuttable presumption that the seller possesses horizontal market power.³⁵ A seller that fails one of the screens may present evidence, such as a delivered price test, to rebut the presumption of horizontal market

power.³⁶ In the alternative, a seller may accept the presumption of horizontal market power and adopt some form of cost-based mitigation.³⁷

17. Three of the key components of the analysis of horizontal market power are the definition of products, the determination of appropriate geographic scope of the relevant market for each product, and the identification of the uncommitted generation supply within the relevant geographic market. In Order No. 697, the Commission adopted a default relevant geographic market for sales of energy and capacity.³⁸ Specifically, the Commission generally uses a seller's balancing authority area plus directly interconnected (first-tier) balancing authority areas, or uses the Regional Transmission Organization (RTO) or Independent System Operator (ISO) market if applicable, as the default relevant geographic market. However, where the Commission has made a specific finding that there is a submarket within an RTO/ISO, that submarket becomes the default relevant geographic market for sellers located within the submarket for purposes of the market-based rate analysis. The Commission also provided guidance as to the factors the Commission will consider in evaluating whether, in a particular case, to adopt an alternative larger or smaller geographic market instead of relying on the default geographic market.³⁹

18. The Commission stated in the NOPR that, because primary frequency response service can be effectively supplied by any resource throughout an interconnection and have the same

ability to dampen harmful changes in interconnection-wide frequency, the geographic market for market power analysis of a primary frequency response product could be the entire interconnection within which the buyer resides, and in any event would be no smaller than the geographic market represented in the existing market power screens;⁴⁰ *i.e.*, the home balancing authority area of the seller plus first-tier balancing authority areas or the RTO/ISO market if applicable. The Commission therefore proposed to apply the existing market power screens used for energy and capacity sales, without modification as to geographic market, to sales of primary frequency response service.

19. Most commenters either express specific support for this finding,⁴¹ or are silent on the issue.⁴² However, American Public Power Association, the National Rural Electric Cooperative Association, and the Transmission Access Policy Study Group (together, TAPS), PJM Interconnection, L.L.C. (PJM), and Midcontinent Independent System Operator, Inc. (MISO) raise limited, technical concerns regarding this finding.

20. TAPS argues that while remote generators may be capable of responding, there is reason to be concerned that frequency response from a distant generator would be less effective than frequency response from a nearby generator, and that this alleged impact of distance would upset the Commission's proposal to rely on the existing market-based rate screens used for energy and capacity sales to ensure that sellers of primary frequency response service lack market power when making sales to public utility transmission providers.⁴³

21. PJM similarly asserts, without elaboration, that questions remain as to whether there is sufficient substitutability of units across the Eastern Interconnection so as to support the conclusion that market power issues are of limited concern in the provision of primary frequency response. PJM also asserts that the kind of communications infrastructure, protocols, and compensation policies necessary to permit PJM to obtain primary frequency

²⁹ See 18 CFR 35.37(b) (2015).

³⁰ See *Market-Based Rates for Wholesale Sales of Electric Energy, Capacity and Ancillary Services by Public Utilities*, Order No. 697, FERC Stats. & Regs. ¶ 31,252 at PP 13, 62, *clarified*, 121 FERC ¶ 61,260 (2007), *order on reh'g*, Order No. 697-A, FERC Stats. & Regs. ¶ 31,268, *clarified*, 124 FERC ¶ 61,055, *order on reh'g*, Order No. 697-B, FERC Stats. & Regs. ¶ 31,285 (2008), *order on reh'g*, Order No. 697-C, FERC Stats. & Regs. ¶ 31,291 (2009), *order on reh'g*, Order No. 697-D, FERC Stats. & Regs. ¶ 31,305 (2010), *aff'd sub nom. Mont. Consumer Counsel v. FERC*, 659 F.3d 910 (9th Cir. 2011), *cert. denied*, 133 S. Ct. 26 (2012). See also 18 CFR 35.37(b), (c)(1) (2015).

³¹ Order No. 697, FERC Stats. & Regs. ¶ 31,252 at P 43.

³² *Id.* PP 43-44, 80, 89.

³³ 18 CFR 35.37(c)(1) (2015).

³⁴ Order No. 697, FERC Stats. & Regs. ¶ 31,252 at P 42.

³⁵ 18 CFR 35.37(c)(1) (2015).

³⁶ 18 CFR 35.37(c)(2) (2015). For purposes of rebutting the presumption of horizontal market power, sellers may use the results of the delivered price test to perform pivotal supplier and market share analyses and market concentration analyses using the Herfindahl-Hirschman Index (HHI). The HHI is a widely accepted measure of market concentration, calculated by squaring the market share of each firm competing in the market and summing the results. The Commission has stated that a showing of an HHI less than 2,500 in the relevant market for all season/load periods for sellers that have also shown that they are not pivotal and do not possess a market share of 20 percent or greater in any of the season/load periods would constitute a showing of a lack of horizontal market power, absent compelling contrary evidence from intervenors. Order No. 697, FERC Stats. & Regs. ¶ 31,252 at P 111.

³⁷ 18 CFR 35.37(c)(3) (2015).

³⁸ Order No. 697, FERC Stats. & Regs. ¶ 31,252 at P 15.

³⁹ A necessary condition that must be satisfied to justify an alternative market is a demonstration regarding whether there are frequently binding transmission constraints during historical peak seasons examined in the screens and at other competitively significant times that prevent competing supply from reaching customers within the proposed alternative geographic market. *Id.* P 268.

⁴⁰ NOPR, FERC Stats. & Regs. ¶ 32,705 at P 23.

⁴¹ See, e.g., American Wind Energy Association (AWEA) at 6; Calpine Corporation (Calpine) at 5; EEI at 2; Electricity Consumers Resources Council (ELCON) at 3.

⁴² See Dominion Resources Services, Inc. (Dominion) at 2; Duke Energy Corporation (Duke) at 3; Electric Power Supply Association (EPSA) at 3; Energy Storage Association (ESA) at 1; Idaho Power Company (Idaho Power) at 2; Public Interest Organizations at 2.

⁴³ TAPS at 5-6.

response from resources outside of its market do not yet exist.⁴⁴

22. MISO argues that, while the NOPR is correct that any resource anywhere in an interconnection can help stabilize the frequency of that interconnection following a load or resource loss, there may be negative reliability impacts caused by flows to very remote locations, particularly if there are weak or transmission-limited interfaces.⁴⁵

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23. We adopt the NOPR proposal to apply the existing market power screens used for energy and capacity sales, without modification as to geographic market, to sales of primary frequency response service. With respect to TAPS's arguments, the Commission finds that the delay in sensing a change in frequency associated with resource distance does not undermine the NOPR's proposal to rely upon the default geographic market reflected in the existing market power screens for sales of energy and capacity; *i.e.*, the home balancing authority area of the seller plus first-tier balancing authority areas or the RTO/ISO market if applicable. While TAPS is correct that a resource located far across an interconnection from the site of a contingency event should sense the resulting change in frequency later than would a closer resource, studies of this issue⁴⁶ indicate that this delay would be within the NOPR's product definition that requires primary frequency response resources to change their output within seconds in response to a large change in frequency.⁴⁷

24. With respect to PJM's assertion that questions remain as to the substitutability of units across the Eastern Interconnection, PJM has not explained what those questions may be, and in any event the NOPR does not propose to test market power based on an interconnection-wide geographic market.

25. With respect to PJM's argument that the kind of communications infrastructure, protocols, and compensation policies necessary to permit PJM to obtain primary frequency response from resources outside of its market do not yet exist, the Commission partially agrees and partially disagrees

as described below, but even where we partially agree, this would not impact the NOPR proposal regarding market power screening.

26. With respect to communications protocols, the Commission agrees that in order to effectuate actual voluntary primary frequency response transactions, it may be necessary to further develop or refine existing communications protocols, as more detailed data may be needed for purposes of verifying primary frequency response activity than for other activities. However, this refinement should not pose such a fundamental barrier to sales of primary frequency response service from one balancing authority area to another that it calls into question the default geographic market of the existing market power screens. This is because, as will be discussed further below, there are existing information sharing systems and protocols that should be able to accommodate the more detailed information associated with primary frequency response transactions without requiring an unreasonable amount of effort from affected parties. Hence, for market power screening purposes, resources in first-tier balancing authority areas should remain viable competitors to supply primary frequency response to the home balancing authority area.

27. With respect to compensation policies, the Commission disagrees with PJM that compensation policies necessary to support this Final Rule do not yet exist. As will be further discussed below, this Final Rule does not require development of organized markets for primary frequency response service, but rather is focused on voluntary bilateral sales of primary frequency response at market-based rates. In bilateral markets, compensation would be negotiated between the buyer and the seller pursuant to the seller's market-based rate authority. As such, bilateral transactions will be strictly voluntary and the buyer will presumably only agree to them if it sees an economic reason to do so. Therefore, no further compensation policies are necessary in connection with this Final Rule.

28. Finally, MISO argues that there may be negative reliability impacts caused by flows to very remote locations, particularly if there are weak or transmission-limited interfaces. The Commission agrees but sees this as a practical consideration relevant to particular bilateral transactions rather than a universal issue that invalidates the use of existing market power screens to show lack of market power for sales

of primary frequency response service. Accordingly, this argument does not invalidate the NOPR proposal regarding market power screening for sellers of primary frequency response service.

2. Need for Transmission Reservation and Scheduling

29. With respect to potential barriers related to transmission scheduling or reservation, the Commission stated in the NOPR that primary frequency response service should not require any transmission reservation or scheduling, because by definition individual frequency responses would not be sustained for long enough periods to trigger a need for transmission service or schedule changes. Rather, such individual primary frequency responses should be rapidly replaced by resources centrally dispatched by the relevant balancing authority.⁴⁸

30. Most commenters either specifically agree that transmission scheduling and reservation should not be necessary in connection with the temporary, autonomous changes in output associated with primary frequency response service,⁴⁹ or remain silent on the issue. However, EEI asserts that transmission reservation or scheduling may be needed in some cases. According to EEI, the duration of primary frequency response products could range from a minute or two to supplement a response for only large events, to an unbounded number of minutes for as long as frequency remains beyond a given frequency deadband. In the case of longer durations, according to EEI, transmission providers may have to assess the potential transmission impact of third-party resources providing primary frequency response through their service territory for extended periods of time.⁵⁰ Duke makes similar arguments.⁵¹

31. Similarly, TAPS argues that the Commission did not adequately examine in the NOPR the implications of remote provision of primary frequency response on transmission availability and co-optimization of energy and ancillary services. TAPS argues the Commission should provide additional analysis of how remote supply of frequency response service will affect transmission reserve margin and available transfer capability, how the associated costs are borne, and whether this will have adverse

⁴⁴ PJM at 4.

⁴⁵ MISO at 5.

⁴⁶ See, e.g., http://fnetpublic.utk.edu/eventsamples/20110823175058_E.jpg. See also, John Undrill, *Power and Frequency Control as it Relates to Wind-Powered Generation* (2010), available at <http://www.ferc.gov/CalendarFiles/20110120114503-Power-and-Frequency-Control.pdf>.

⁴⁷ NOPR, FERC Stats. & Regs. ¶ 32,705 at P 12.

⁴⁸ NOPR, FERC Stats. & Regs. ¶ 32,705 at P 24.

⁴⁹ See, e.g., AWEA at 6; ELCON at 3; MISO at 1.

⁵⁰ EEI at 8.

⁵¹ Duke at 7–8.

consequences for market efficiency, particularly in RTOs.⁵²

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32. The Commission continues to believe that transmission reservation and scheduling will not create a barrier to sales of frequency response within an interconnection. While the Commission concedes that in some cases transmission capacity may need to be reserved to support a sale of primary frequency,⁵³ we continue to believe that in the vast majority of cases the sale of primary frequency response service should not require any transmission reservation or scheduling because, by definition, individual frequency responses would not be sustained for long enough periods to trigger a need for transmission service or schedule changes. With respect to EEI's arguments, the Commission disagrees that primary frequency response, as defined in this Final Rule, could last for an unbounded number of minutes. By the definition of primary frequency response provided in this Final Rule, individual primary frequency responses shall be short, lasting only until dispatched resources can take over. Thus, even if a deviation from target frequency lasts longer than the typical short responses envisioned by our primary frequency response product definition, this does not necessarily mean that a particular resource that continues to respond to that deviation is doing so through extended periods of primary frequency response service as EEI suggests.

33. Rather, after the initial autonomous response, any continuing response would be deemed to occur as a result of dispatch instructions from the relevant balancing authority, which would most likely constitute either use of regulation or operating reserves. Accordingly, while a transmission reservation may sometimes be needed to support a sale of primary frequency response, there should never be a need to actually schedule transmission or change a transmission schedule in connection with primary frequency response service. Hence, transmission scheduling should pose no barrier to sales of primary frequency response service, and in the open access transmission environment created by

Order No. 888, reservation by itself does not present any undue barrier to participation. Indeed, all other ancillary service transactions, at least in bilateral markets, are expected to include needed transmission reservation.

34. With respect to TAPS's argument, the Commission agrees that transmission providers may in some cases need to set aside additional transmission capacity to support particular sales of primary frequency response from remote resources. However, the possibility that particular transactions involving remote resources may require additional transmission capacity to be set aside does not undermine the NOPR proposal to grant market-based rate authority for voluntary sales of primary frequency response to entities that pass the existing market power screens for sales of energy and capacity. These screens already limit consideration of imports from first-tier balancing authority areas based on simultaneous transmission import limits as a way to test market power under realistic conditions based on a reasonable simulation of historical conditions.⁵⁴ No further consideration of transmission impacts is necessary to test for seller market power. Analysis of (1) how remote supply of primary frequency response service in particular transactions might affect transmission reserve margin and available transfer capability; (2) how the associated costs would be borne; or (3) whether this might have adverse consequences for market efficiency are concerns that are not relevant to the Commission's market power assessment. Rather, these are concerns that may impact a balancing authority's decision as to whether to enter into any given primary frequency response transaction, or that may become relevant if any RTO or ISO voluntarily chooses to develop an organized market for primary frequency response—something that is not required by this Final Rule.

35. With respect to TAPS's arguments regarding potential distortion of co-optimized RTO/ISO energy and ancillary service markets, this Final Rule merely clarifies the appropriate method for ex ante market power screening for potential sellers of primary frequency response service. It does not require any entity, including RTOs and ISOs, to purchase primary frequency response. Nor does it require RTOs and ISOs to develop organized markets for primary frequency response. The Commission finds it reasonable to assume that if an RTO or ISO ever

decides to purchase primary frequency response service, it will only do so if the RTO or ISO can address its and its stakeholders' concerns as to the impact on its co-optimized markets.

Furthermore, if such purchases require any tariff modifications, the RTO or ISO would also need to submit a filing to the Commission for its review addressing such issues. Accordingly, in the context of this Final Rule focusing on market power screens, these concerns are premature and beyond the scope.

B. Requests for Clarification

1. Purchases Required or Optional

36. A variety of entities request clarification that this Final Rule does not require purchases of primary frequency response or the development of organized markets for primary frequency response.⁵⁵ At the other end of the spectrum, Calpine argues that RTOs and ISOs should be given a deadline to develop tariff changes that would enable them to implement primary frequency response compensation mechanisms.⁵⁶

37. The Commission grants the requests to clarify that this Final Rule does not require any entity to purchase primary frequency response from third parties or to develop an organized market for primary frequency response. This Final Rule is limited to issues associated with market power screening for voluntary bilateral sellers of primary frequency response service. In light of this clarification, we deny Calpine's request for RTOs and ISOs to be given a deadline to develop tariff changes that would enable them to implement primary frequency response compensation mechanisms.

2. Interaction With Regulation Service

38. EEI and Duke both request that sellers be able to retain the reference to "Regulation and Frequency Response Service" in their current market-based rate tariffs, and that the Final Rule make clear that providing market-based rate authorization for primary frequency response service is not intended to limit the options that buyers have in procuring these ancillary services.⁵⁷

39. The Commission does not intend to limit the options that buyers have in procuring these ancillary services but will nevertheless affirm the NOPR proposal to require a separate listing of regulation service and primary frequency response service in market-

⁵² TAPS at 9–11.

⁵³ The Commission expects that sales of primary frequency response from resources in transmission constrained areas would constitute the most likely scenario where a reservation of transmission capacity might be needed to support the sale. Naturally, the added cost of such transmission purchases would likely be considered by the potential purchaser in deciding whether or not to enter into such purchase.

⁵⁴ Order No. 697, FERC Stats. & Regs. ¶ 31,252 at P 354.

⁵⁵ EEI at 1–2; California Independent System Operator Corporation (CAISO) at 2; MISO at 1; PJM at 2, 5.

⁵⁶ Calpine at 9.

⁵⁷ EEI at 4; Duke at 3–7.

based rate tariffs. However, to address EEI's and Duke's concerns, the Commission clarifies that, even though we require that regulation service and primary frequency response service be separately listed in sellers' market-based rate tariffs, this does not mean that buyers and sellers cannot agree to combined transactions involving both regulation service and primary frequency response service with appropriate restrictions. Those restrictions involve the need for the market-based regulation service component to be limited to the buyer's OATT rate for regulation or the outcome of a competitive solicitation as described in Order No. 784.⁵⁸ No such restrictions would apply to the primary frequency response service component of such combined transactions.

40. Duke also expresses concern as to what impact splitting the services in the "Third Party Provider" section of the market-based rate tariff would have on transmission providers and any transmission customers self-providing service under Schedule 3 of the OATT.⁵⁹

41. The Commission clarifies that OATT Schedule 3 serves a different purpose from the market-based rate tariff (cost-based sales from the OATT provider versus market-based sales from third parties), and so OATT Schedule 3 does not need modification as a result of this Final Rule. However, to the extent that a particular OATT provider purchases primary frequency response from a third party in order to help serve its OATT customers, it may propose in a section 205 filing to include such costs in its OATT Schedule 3 rates.

3. Information Sharing and Measurement and Verification

42. A variety of entities emphasize the importance of adequate information sharing and measurement and verification if primary frequency response service is to be traded.⁶⁰ In this regard, SmartSenseCom, Inc. (SmartSenseCom) also argues that in order to support the broadest base of available resources to provide primary frequency response services, potential providers should have flexibility in their ability to select any monitoring device that meets or exceeds applicable industry standards for accuracy as a means to measure frequency and trigger the primary frequency response at a given set point.⁶¹

43. The Commission agrees that these matters are important, and expects that potential buyers will ensure that the resources from which they purchase are capable of providing the service in a useful manner, consistent with relevant NERC requirements and guidelines as discussed earlier. This would require that, among other things, the parties agree to appropriate information sharing and measurement and verification. At this stage, and given the voluntary nature of any primary frequency response transactions that may result from this Final Rule, the Commission sees no need to be more prescriptive regarding specific methods of information sharing and measurement and verification.

44. In a related matter, TAPS asserts that the NOPR's statement that telemetry sharing should not pose any significant barrier to the use of remote resources for the purposes of market-based rates requires further evaluation. TAPS argues that transmitting the telemetry data from one balancing authority area to just one other balancing authority area effectively doubles (or more) the number of points at which the data can be intercepted or attacked. Thus, TAPS argues that the Commission should provide additional analysis to evaluate whether these potential technical barriers will impede the ability of remote generators to compete to make market-based rate sales of primary frequency response across balancing authorities and to multiple balancing authorities.⁶²

45. As mentioned earlier, the Commission finds that balancing authorities already share with their neighbors the same type of operational information contemplated here, both on a day-to-day basis, and occasionally through special arrangements like pseudo-ties or dynamic schedules, though they may not do so with as much detail as would be required for primary frequency response. In sharing such information, they use secure protocols such as Inter-Control Center Communications Protocol.⁶³ There appears to be nothing unique about information related to primary frequency response transactions, which would largely involve the real-time operational state of the resources in question as a way of verifying both their readiness to respond and actual responses to relevant frequency

deviations, that could not be accommodated by this existing secure protocol widely used by the electric utility industry. As a result, the Commission continues to believe that the information sharing required to facilitate sales of primary frequency response service will not create a barrier to such sales and thus we find in this Final Rule that the market power screens used for energy and capacity are valid for primary frequency response service.

4. Definition of Primary Frequency Response Service

46. Parties request various clarifications regarding the definition of primary frequency response service. Calpine and EPSA assert that the product definition for primary frequency response service should include both inertial response from conventional "spinning mass" generators and primary frequency response from discretionary turbine-governor settings.⁶⁴ Similarly, Union of Concerned Scientists argues for the inclusion of synchronous and/or synthetic inertia as a market product that can be used to provide primary frequency response, and requests that the Commission clarify whether the creation of markets for inertia is within the scope of changes that were envisioned by the Commission when it issued this NOPR.⁶⁵

47. The Commission emphasizes that this Final Rule addresses market-based rate authority for sales of services that fit the definition of primary frequency response services, *i.e.*, resources standing by to provide autonomous, pre-programmed changes in output to rapidly arrest large changes in frequency until dispatched resources can take over. True inertia, while also serving an important function, does not fit this definition because it does not arrest large changes in frequency, but rather acts to oppose all changes in frequency. The term "synthetic inertia" is more complicated to address because it is not clear from the record whether there is actual industry consensus on what the term means. However, if it is assumed to mean a resource standing by to provide autonomous, pre-programmed changes in output to rapidly arrest large changes in frequency until dispatched resources can take over, then the Commission would simply consider it a form of primary frequency response subject to this Final Rule. In contrast, if the "synthetic inertia" response either cannot be sustained until dispatched

⁵⁸ Order No. 784, FERC Stats. & Regs. ¶ 31,349 at PP 82 and 99–101.

⁵⁹ Duke at 6, 8.

⁶⁰ CAISO at 2–3; EEI at 5; MISO at 1–4; Duke at 7–8; Dominion at 3; Idaho Power at 2.

⁶¹ SmartSenseCom at 9–10.

⁶² TAPS at 6–9.

⁶³ See International Electrotechnical Commission, *Telecontrol equipment and systems—Part 6–802: Telecontrol protocols compatible with ISO standards and ITU-T recommendations—TASE.2 Object models* (Sept. 2005), available at <https://webstore.iec.ch/publication/18156>.

⁶⁴ Calpine at 7, n.16; EPSA at 5.

⁶⁵ Union of Concerned Scientists at 8.

resources take over, or is merely aimed at slowing all changes in frequency instead of arresting large changes, then “synthetic inertia” would not be a form of primary frequency response, and sales of it would not be encompassed by this Final Rule.

48. Several commenters assert that the product definition must differentiate based on response time in addition to magnitude of response.⁶⁶ Consistent with this idea, SmartSenseCom asks the Commission to amend section 35.28 of its regulations by adding a new paragraph that states the following:

Primary frequency response in ancillary service markets. Each Commission approved independent system operator or regional transmission organization that has a tariff that provides for the compensation for primary frequency response service must provide such compensation based upon the actual service provided, include a capacity payment that takes into account the speed of primary frequency response-providing resources and a payment for performance that reflects the quantity of primary frequency response provided by a resource in response to a frequency deviation.⁶⁷

49. The Commission finds that the Final Rule’s product definition, summarized at the beginning of the discussion section above, already sufficiently incorporates the importance of speed. The Commission finds that no further differentiation based on response time or magnitude is necessary in connection with this Final Rule, which deals only in the appropriate ex ante market power screening of potential sellers of primary frequency response service. For this reason, and because this Final Rule does not require development of organized markets for primary frequency response, the Commission also denies as unnecessary the requested addition to the Commission’s regulations related to organized RTO and ISO markets for primary frequency response.

50. Grid Storage Consulting, LLC (Grid Storage Consulting) and Public Interest Organizations argue that the product definition for this service should require response that is immediate, bi-directional, proportional to the frequency deviation, continuous in the sense of not being prematurely interrupted by competing controls or physical limitations, and certain.⁶⁸ The Commission clarifies that potential voluntary buyers and sellers of primary frequency response service are free to

negotiate any refinements to the basic product definition in this Final Rule that they see fit, so long as such refinements remain consistent with the basic definition. Obviously, any market-based rate authority granted as a result of this Final Rule would only apply to products that are consistent with the definition of primary frequency response service described at the beginning of the discussion section above.

51. SmartSenseCom urges the Commission to define primary frequency response directly within the Commission’s regulations.⁶⁹ The Commission denies this request as unnecessary. The Commission’s regulations do not include definitions of every particular product subject to its jurisdiction; it is sufficient for such product definitions to be described in relevant Commission orders such as this one.

5. Miscellaneous Requests for Clarification

52. EEI encourages the Commission to make clear in the Final Rule that a potential third-party provider would not be disqualified from competing on the basis that it is interconnected to an affiliated transmission provider. According to EEI, not addressing the affiliate restriction provisions of the *Avista* policy could unnecessarily limit the pool of third-party generators that would be eligible to compete to provide market-based primary frequency response service.⁷⁰

53. EEI’s concern relates to the component of the *Avista* restrictions highlighted below:

(2) to address affiliate abuse concerns, the approach [permitting market-based rate sales of ancillary services without a corresponding market power analysis] will not apply to sales to a traditional, franchised public utility affiliated with the third-party supplier, or to sales where the underlying transmission service is on the system of the public utility affiliated with the third-party supplier.⁷¹

54. As the Commission noted in the *Avista* passage quoted above, this second *Avista* restriction was meant to address affiliate abuse. However, EEI’s concern that potential third-party providers should not be disqualified from competing on the basis that they are interconnected to an affiliated transmission provider appears to be based on an overly broad interpretation of the language highlighted above; *i.e.*, one that would prevent sales that only

tangentially involve the affiliated public utility transmission provider’s system. While the Commission understands this concern, we do not believe it is justified because the highlighted language targets a much narrower set of circumstances.

55. In particular, in *Ameren Marketing*,⁷² the Commission approved a case-by-case request for market-based rates for ancillary services sales by a third-party seller to transmission customers located on the transmission system of the seller’s public utility transmission provider affiliate where the seller offered several safeguards to protect against the potential for affiliate abuse.⁷³ *Ameren Marketing* demonstrates the narrow scope of the Commission’s concern related to this *Avista* restriction; namely, third-party sales to customers located on the transmission systems of affiliates. Only in these situations does the second *Avista* restriction apply, and in these situations, we remain willing to consider requests for market-based rate authority for sales of primary frequency response service on a case-by-case basis. In response to EEI’s concern, the Commission clarifies that where the customer is not located on the transmission system of the third-party seller’s affiliate, this aspect of the *Avista* restrictions does not apply.

56. EEI also recommends that the Commission clarify in the Final Rule that the location of primary frequency response purchases be deemed to be where the customer is located within an interconnection, rather than where the underlying generation resides. According to EEI, this would address a potential ambiguity in how the NOPR proposal is described in paragraph 28 of the NOPR, where the Commission stated that “. . . sellers passing existing market-based rate screens in a given geographic market should be granted a rebuttable presumption that they lack market power for sales of primary frequency response in that market.”⁷⁴ EEI states that if a generator has passed the Commission’s existing market power screens (or if the screens are not required to be submitted based on the location of the generation) for the geographic market in which the buyer is located, then the generator should benefit from the rebuttable presumption

⁶⁶ Calpine at 7; AWEA at 4; Grid Storage Consulting at 2–4; Public Interest Organizations at 4; SmartSenseCom at 8.

⁶⁷ SmartSenseCom at Ex. A.

⁶⁸ Grid Storage Consulting at 4–7; Public Interest Organizations at 4.

⁶⁹ SmartSenseCom at 3.

⁷⁰ EEI at 7.

⁷¹ *Avista Corp.*, 87 FERC ¶ 61,223 at n.12 (1999) (emphasis added).

⁷² *Ameren Energy Marketing Co.*, 95 FERC ¶ 61,448, at 62,626 (2001) (*Ameren Marketing*).

⁷³ With respect to all three *Avista* restrictions, the Commission expressed its willingness to consider requests for market-based rate authority under the conditions associated with the restrictions on a case-by-case basis. *Avista Corp.*, 87 FERC ¶ 61,223 at n.12.

⁷⁴ EEI at 7 (citing NOPR, FERC Stats. & Regs. ¶ 32,705 at P 28).

that it lacks market power with respect to sales of primary frequency response service throughout the entire interconnection.⁷⁵

57. EEI appears to be concerned that the language in paragraph 28 might be interpreted to mean that market-based rate sales of primary frequency response are only authorized in specific geographic markets. As will be explained next, this would be similar to how market-based rate sales of operating reserves are handled pursuant to Order No. 784, but different from how authority for market-based rate sales of energy and capacity is granted. With respect to energy and capacity, the Commission's normal practice is to test for market power in the seller's home balancing authority area, and, if the seller is vertically-integrated, first-tier balancing authority areas, because this is where the seller's market power likely would be greatest. However, the market-based rate authority granted based on passage of these market power screens permits sales anywhere that the seller is capable of transacting. In Order No. 784, the Commission had to depart from this standard practice with respect to market-based rate sales of operating reserves because of the special transmission scheduling practices associated with those services. Order No. 784 required sellers of operating reserves to first demonstrate that the scheduling practices in the regions within which they wish to sell could support sales of operating reserves from one balancing authority area to another, and market-based rate authority for sales of operating reserves would only be granted for regions where such showing was made successfully by the seller.⁷⁶ Because primary frequency response is autonomous and individual responses are of short duration, no special scheduling practices would be required. Hence, the Commission finds that market-based rate authority for sales of primary frequency response should be granted on the same basis as sales of energy and capacity; *i.e.*, while market power is tested at the resource's location, authority is granted for sales anywhere the seller is capable of transacting. The Commission, therefore, clarifies the description in paragraph 28 of the NOPR accordingly.

58. AWEA, ESA, Union of Concerned Scientists, and Grid Storage Consulting argue that there may be some resources that have been authorized to sell ancillary services at market-based rates but not energy and capacity, or that are

otherwise eligible to participate in Commission-authorized and supervised markets. They recommend that any such resources be permitted to sell primary frequency response service at market-based rates as well.⁷⁷ In a similar vein, Public Interest Organizations ask the Commission to consider whether there is any class or potential class of emerging resources that sell only ancillary services and not energy or capacity, and if so, whether such resources should be exempted from existing market power screens in exchange for some more appropriate market power analysis.⁷⁸

59. In response to these comments, the Commission clarifies that for resources capable of injecting electric energy onto the interstate transmission grid,⁷⁹ authority to sell at market-based rates, even exclusively in organized RTO or ISO markets, is only granted to entities that either pass the existing market power screens for sales of energy and capacity or where any market power concerns have been adequately mitigated. Thus, even if such sellers only sell ancillary services today, their authorization to do so was granted based in part upon either passage of the existing market power screens for sales of energy and capacity or where there was a demonstration that any market power concerns have been adequately mitigated.⁸⁰ The only current exception to this rule involves demand response resources. If a third-party seller exclusively uses demand response resources to participate in RTO/ISO markets, it does not need to seek market-based rate authority or place any tariff on file with the Commission, because demand response resources do not inject electric energy onto the interstate transmission grid. However, if

⁷⁷ AWEA at 4; ESA at 4–5; Union of Concerned Scientists at 3; Grid Storage Consulting at 10.

⁷⁸ Public Interest Organizations at 5–6.

⁷⁹ Pursuant to section 201(a) of the FPA, the Commission is charged with regulating the transmission of electric energy in interstate commerce and the sale of electric energy at wholesale in interstate commerce. 16 U.S.C. 824(a) (2012). Section 201(b) provides that the Commission shall have jurisdiction over facilities for wholesale sales of electric energy in interstate commerce or for transmission of electric energy in interstate commerce. *Id.* 824(b). In section 201(e), a public utility is defined as a person who owns or operates facilities subject to the jurisdiction of the Commission. *Id.* 824(e).

⁸⁰ In the event that sellers fail the existing market power screens for the RTO/ISO markets, the Commission allows such sellers to seek to obtain or retain market-based rate authority by relying on Commission-approved RTO/ISO monitoring and mitigation. See *Refinements to Policies and Procedures for Market-Based Rates for Wholesale Sales of Electric Energy, Capacity and Ancillary Services by Public Utilities*, Order No. 816, 80 FR 67056, (Oct. 30, 2015), 153 FERC ¶ 61,065, at P 28 (2015).

it ever markets services from other types of resources that result in it injecting electric energy onto the grid, then it would need market-based rate authority and a tariff on file.⁸¹ Accordingly, all sellers with market-based rate authority using resources that can inject electric energy onto the interstate transmission grid, even if they only sell ancillary services today, are already eligible to make use of the rebuttable presumption related to primary frequency response in this Final Rule. Similarly, sellers exclusively using demand response resources are already exempted from the need to submit market power analyses to gain authorization for their sales, and Public Interest Organizations have provided no reason why any new class of resources should be exempted.

60. Union of Concerned Scientists, ESA, and Public Interest Organizations all ask that the Commission clarify that the current Final Rule applies for all resources that can provide primary frequency response.⁸² Steel Producers Alliance makes similar arguments, emphasizing that resources other than generators are able to provide primary frequency response service and should be permitted to compete to provide the service.⁸³ The Commission clarifies that this Final Rule applies to jurisdictional market-based rate sellers of primary frequency response service, irrespective of what specific equipment they may choose to use to make such sales.

61. MISO asserts that certain technical statements within the NOPR require limited clarification. First, while MISO agrees with the NOPR that 60 Hertz (Hz) is the target frequency in North America, MISO notes that scheduled frequency may be offset at times to correct time error.⁸⁴ Second, in response to the NOPR's description of how each balancing authority's automatic generation control system will issue dispatch instructions to regulation resources to try to return the systems frequency to 60 Hz, MISO argues that typically the contingent balancing authority uses a combination of automatic generation control and contingency reserves for this purpose.⁸⁵ The Commission agrees with these clarifications, but finds that they do not alter any fundamental underpinning of the NOPR proposal.

62. Union of Concerned Scientists seeks clarification that procurement of, and payment for, primary frequency

⁸¹ *EnergyConnect, Inc.*, 130 FERC ¶ 61,031, at PP 26–33 (2010).

⁸² Union of Concerned Scientists at 5; ESA at 2–4; Public Interest Organizations at 2–3.

⁸³ Steel Producers Alliance at 2–3.

⁸⁴ MISO at 5.

⁸⁵ *Id.* at 6.

⁷⁵ *Id.* at 7–8.

⁷⁶ Order No. 784, FERC Stats. & Regs. ¶ 31,349 at P 58.

response service would be allowed if the sale of primary frequency response service under market-based rates were allowed. It suggests that the Commission state that markets for primary frequency response service are allowed, subject to petition by appropriate utilities and approval by the Commission.⁸⁶ Union of Concerned Scientists also asks that market eligibility and participation as a seller should not be constrained by disproportionate administrative burdens.⁸⁷ The Commission agrees that market-based rate sales by entities that have been granted authorization for such sales are allowed; that is, of course, the object of a market-based rate application. With respect to the authority for potential buyers to purchase primary frequency response service, this Final Rule only involves market power screening of potential sellers. As with most products in voluntary bilateral markets, potential buyers do not need the Commission's permission. Similarly, the Commission clarifies that RTOs and ISOs remain free to develop organized markets for primary frequency response if they so choose, though nothing in this Final Rule requires them to do so, and if they choose to do so, only then will the Commission review such issues as eligibility requirements for participation.

6. Requests Outside the Scope of This Proceeding

63. AWEA and Public Interest Organizations both request that the Commission permit sales of regulation service at market-based rates by entities with authority for market-based rate sales of energy and capacity.⁸⁸ AWEA further requests that the Commission: (a) Explore the role that dynamic transfer capability, or lack thereof, plays in protecting against exertion of market power;⁸⁹ (b) consider relaxing interconnection standards for resources that only sell ancillary services;⁹⁰ and (c) consider whether entities in bilateral market areas should be required to develop platforms for the sale of primary frequency response, even if on a limited basis such as through open seasons.⁹¹

64. Monitoring Analytics, LLC (Monitoring Analytics) notes that, while the NOPR is mainly concerned with the market power screens typically used in

connection with authorizations to charge market-based rates, in organized markets like PJM's, such rates are granted in significant part based on the market power mitigation rules of the RTO or ISO. Accordingly, Monitoring Analytics recommends that if PJM develops a market for primary frequency response service, the rules for such market should incorporate the three pivotal supplier test that is already used for market power mitigation in PJM's other markets.⁹²

65. ESA argues that fast responding energy storage resources should be allowed to supply both primary frequency response and regulation services simultaneously. In this regard, ESA asserts that the Commission should not inadvertently create a system where all providers of primary frequency response must provide such service for at least 5–10 minutes until the slowest regulation resources can be brought online.⁹³ ESA requests that the Commission ensure that ancillary service market designs and procurement mechanisms are reasonably consistent across regions and reflect non-market compensated benefits in the determination of operational needs for particular capabilities, such as fast response.⁹⁴

66. Grid Storage Consulting argues that balancing authorities should not be able to mandate that primary frequency response be provided as part of other market products,⁹⁵ and that in some circumstances it may be appropriate to permit the costs of dedicated primary frequency response resources to be recovered in transmission rate base.⁹⁶

67. If an RTO seeks to create an organized market for primary frequency response, then Dominion recommends that the Commission require a market design similar to those used currently to procure other ancillary services such as regulation and operating reserves. Alternatively, Dominion also supports allowing RTOs to procure primary frequency response at cost-based rates, in a manner similar to how reactive power is procured. Dominion also argues that generators should either be exempt from charges such as operating reserve and balancing energy when deviating from their schedules in order to provide primary frequency response service or their compensation should include credits to offset such charges.⁹⁷

68. SmartSenseCom asserts that there is a difference in value between resources capable of delivering a rapid response to changing frequency and slower-responding units. Accordingly, SmartSenseCom asks the Commission to require public utility transmission providers to take into account the speed and accuracy of primary frequency response resources when determining reserve requirements for primary frequency response, as the Commission did for regulation service in Order No. 784. SmartSenseCom claims this "is particularly necessary in this instance in light of the language set forth in Order No. 784 and in the instant NOPR that distinguishes [primary frequency response] from regulation and the different requirements that will now exist for each service."⁹⁸

69. The Commission finds all of these issues to be beyond the scope of this Final Rule. This Final Rule deals only with market-based pricing for voluntary bilateral primary frequency response sellers. While some of the issues raised above might be relevant in other proceedings,⁹⁹ none of the issues raised above is relevant to the topic of market-based rates in voluntary bilateral markets. Accordingly, there is no need to address these issues here.

III. Compliance and Implementation

70. In Order No. 697, the Commission provided standard tariff provisions that sellers must include in their market-based rate tariffs to the extent they are applicable based on the services provided by the seller,¹⁰⁰ including a provision for sales of ancillary services as a third-party provider.¹⁰¹ The Commission hereby revises the "Third Party Provider" ancillary services provision to change the reference to "Regulation and Frequency Response Service" to "Regulation Service" and to add a reference to "Primary Frequency Response Service." The new language is as follows:

Third-party ancillary services: Seller offers [include all of the following that the seller is offering: Regulation Service, Reactive Supply and Voltage Control Service, Energy and Generator Imbalance Service, Operating

⁸⁶ Union of Concerned Scientists at 4.

⁸⁷ *Id.* at 3.

⁸⁸ AWEA at 1, 7–9; Public Interest Organizations at 5.

⁸⁹ AWEA at 3.

⁹⁰ *Id.* at 4.

⁹¹ *Id.* at 5.

⁹² Monitoring Analytics at 7.

⁹³ ESA at 5.

⁹⁴ *Id.* at 6.

⁹⁵ Grid Storage Consulting at 8–9.

⁹⁶ *Id.* at 10–11.

⁹⁷ Dominion at 3.

⁹⁸ SmartSenseCom at 8.
⁹⁹ For example, if an RTO or ISO eventually proposes to develop an organized market for primary frequency response service, or if the Commission at some point in the future decides to require such development, then several of the issues raised above might become relevant at that stage.

¹⁰⁰ Order No. 697, FERC Stats. & Regs. ¶ 31,252 at Appendix C.

¹⁰¹ In Order No. 784, the Commission revised the standard third party provider provision to reflect the changes adopted in Order No. 784. Order No. 784, FERC Stats. & Regs. ¶ 31,349 at P 200.

Reserve-Spinning, Operating Reserve-Supplemental, and Primary Frequency Response Service]. Sales will not include the following: (1) sales to an RTO or an ISO, *i.e.*, where that entity has no ability to self-supply ancillary services but instead depends on third parties; and (2) sales to a traditional, franchised public utility affiliated with the third-party supplier, or sales where the underlying transmission service is on the system of the public utility affiliated with the third-party supplier. Sales of Operating Reserve-Spinning and Operating Reserve-Supplemental will not include sales to a public utility that is purchasing ancillary services to satisfy its own open access transmission tariff requirements to offer ancillary services to its own customers, except where the Commission has granted authorization. Sales of Regulation Service and Reactive Supply and Voltage Control Service will not include sales to a public utility that is purchasing ancillary services to satisfy its own open access transmission tariff requirements to offer ancillary services to its own customers, except at rates not to exceed the buying public utility transmission provider's OATT rate for the same service or where the Commission has granted authorization.

71. The Commission finds that a seller that already has market-based rate authority as of the effective date of this Final Rule is authorized as of that date to make sales of primary frequency response service at market-based rates. Such a seller will be required to revise the third-party provider ancillary services provision of its market-based rate tariff to reflect that it wishes to make sales of primary frequency response service at market-based rates. However, while this authorization is effective for sellers with existing market-based rate authority as of the effective date of this Final Rule, in order

to reduce their administrative burden, the Commission permits such sellers to wait to file this tariff revision until the next time they make a market-based rate filing with the Commission, such as a notice of change in status filing or a triennial update.

72. As noted in the NOPR, consistent with the existing requirements of Order No. 2001, any entity selling primary frequency response service will need to report such sales in the Electric Quarterly Report,¹⁰² and the Commission will update its Electric Quarterly Report system to include a specific product name option for primary frequency response service.¹⁰³

IV. Information Collection Statement

73. The Paperwork Reduction Act (PRA)¹⁰⁴ requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB regulations require approval of certain information collection requirements imposed by agency rules.¹⁰⁵ Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of an agency rule will not be penalized for failing to respond to the collection of information unless the collection of information displays a valid OMB control number.

74. The Commission will submit the revised information collection requirements to OMB for its review and approval. The Commission solicits public comments on its need for this information, whether the information

will have practical utility, the accuracy of burden and cost estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

75. *Burden Estimate and Information Collection Costs:* While, to the Commission's knowledge, no entity currently sells primary frequency response service on an unbundled basis,¹⁰⁶ there is no reason why primary frequency response service could not be sold today under cost-based rates. Such cost-based sales, if they occurred, would face all of the burdens associated with cost-of-service regulation, including a variety of requirements from which market-based rate sellers frequently seek and are granted waiver.¹⁰⁷ Furthermore, just like market-based rate sellers, cost-based rate sellers must report all transactions in the Electric Quarterly Report. Accordingly, the Commission views this Final Rule as providing potential market-based rate sellers of primary frequency response service with the opportunity to avoid cost-of-service regulation for such sales and the associated substantial reporting burdens.

76. Below, we discuss the expected increases in burden as a result of this Final Rule. The Commission expects the additional burden to be greatly outweighed by the reduction in burden from avoiding cost-of-service regulation. The additional estimated annual public reporting burdens and costs for the requirements in this Final Rule are as follows.

CHANGES IN FINAL RULE IN RM15-2¹⁰⁸

Number of respondents (a)	Annual number of responses per respondent (b)	Total number of responses (a)×(b)=(c)	Average burden & cost per response (d)	Total annual burden hours & total annual cost (c)×(d)=(e)	Cost per response (e)/(c)
FERC-516 (Electric Rate Schedules and Tariff Filings) (one time, phased in)					
1,585 ¹⁰⁹	110 ^{0.163}	259	6 hrs.; \$432	1,554 hrs.; \$111,888.	\$432

¹⁰² See *Revised Public Utility Filing Requirements*, Order No. 2001, FERC Stats. & Regs. ¶ 31,127, *reh'g denied*, Order No. 2001-A, 100 FERC ¶ 61,074, *reh'g denied*, Order No. 2001-B, 100 FERC ¶ 61,342, *order directing filing*, Order No. 2001-C, 101 FERC ¶ 61,314 (2002), *order directing filing*, Order No. 2001-D, 102 FERC ¶ 61,334, *order refining filing requirements*, Order No. 2001-E, 105 FERC ¶ 61,352 (2003), *order on clarification*, Order No. 2001-F, 106 FERC ¶ 61,060 (2004), *order revising filing requirements*, Order No. 2001-G, 120 FERC ¶ 61,270, *order on reh'g and clarification*, Order No. 2001-H, 121 FERC ¶ 61,289 (2007), *order*

revising filing requirements, Order No. 2001-I, FERC Stats. & Regs. ¶ 31,282 (2008).
¹⁰³ NOPR, FERC Stats. & Regs. ¶ 32,705 at P 29.
¹⁰⁴ 44 U.S.C. 3501-3520 (2012).
¹⁰⁵ See 5 CFR 1320 (2015).
¹⁰⁶ It is likely that some customers purchase primary frequency response service along with other services on a bundled basis, such as through full requirements contracts, but this Final Rule is focused on unbundled sales of primary frequency response service.
¹⁰⁷ Such burdens would include, for example, the need to maintain Open Access Transmission Tariffs

and Open Access Same-Time Information Systems related to any jurisdictional transmission facilities owned by the entity, the need to adhere to the Commission's standards of conduct, the need to adhere to the detailed cost-of-service related requirements of subparts B and C of Part 35 of the Commission's regulations, the need to adhere to the accounting and reporting requirements of Parts 41, 101, and 141 of the Commission's regulations, and the need to seek separate authorizations for issuances of securities and assumptions of liabilities under FPA section 204 and Part 34 of the Commission's regulations.

CHANGES IN FINAL RULE IN RM15-2 ¹⁰⁸—Continued

Number of respondents (a)	Annual number of responses per respondent (b)	Total number of responses (a)×(b)=(c)	Average burden & cost per response (d)	Total annual burden hours & total annual cost (c)×(d)=(e)	Cost per response (e)/(c)
FERC-920 (Electric Quarterly Report) (one-time, phased in)					
1,585	¹¹¹ 0.163	259	2 hrs.; \$144	518 hrs.; \$37,296.	144

Titles: FERC-516 (Electric Rate Schedules and Tariff Filings) and FERC-920 (Electric Quarterly Report (EQR)).

Action: Revision of Currently Approved Collection of Information. *OMB Control Nos.:* 1902-0096 (FERC-516) and 1902-0255 (FERC-920).

Respondents: Public utilities. *Frequency of responses:* One-time, phased in (for both FERC-516 and FERC-920).

¹⁰⁸ For purposes of burden estimation, the NOPR assumed that industry staff members are similarly situated to FERC, in terms of hourly cost per full time employee, and no commenter disputes this assumption. Therefore, the estimated average hourly cost (salary plus benefits) is \$72.00.

¹⁰⁹ The 1,585 respondent universe includes existing sellers (1,999 total market-based rate sellers—697 Category 1 sellers + 70 Category 1 sellers = 1,372 sellers estimated to sell primary frequency response services) plus 213 new market-based rate applicants (as estimated in Docket No. RM14-14). (We estimate that ten percent (or 70, as indicated above) of the Category 1 sellers may choose to sell primary frequency response services.)

¹¹⁰ We expect respondents to enter the primary frequency response market gradually. For each of the next three years, we expect all 213 new market-based rate applicants per year (or 639 total during Years 1-3), to include the primary frequency response language in their tariffs.

Additionally, during the three-year period, we expect a total of ten percent of the existing 1,372 respondents (or 137 respondents), to decide to sell primary frequency response services and to make the corresponding FERC-516 rate filing. The corresponding annual estimate is 46 of the existing respondents (an average of 3.4% annually). Therefore, the annual estimate, including both new respondents and existing respondents, is an average of 259 (213 + 46) respondents and responses per year.

¹¹¹ As respondents decide to sell primary frequency response services, they would report the new offering in their Electric Quarterly Report (FERC-920), and would continue to report in subsequent EQRs. When a filer adds the new service, we estimate the one-time burden to be two hours. We expect any additional burden associated with reporting the new service in the EQR to be negligible after the first implementation as it would become part of the respondent's normal reporting practice in the EQR and would only involve selecting the 'primary frequency response' option from a list of product names. On average, we expect filers of the new primary frequency response service to phase in:

- Year 1, 259 respondents or 16.3 percent of EQR filers.
- Year 2, 259 respondents or 16.3 percent of EQR filers.
- Year 3, 259 respondents or 16.3 percent of EQR filers.

Necessity of the Information: Regarding FERC-516, section 205(c) of the Federal Power Act requires public utilities to file with the Commission schedules showing all rates and charges for any transmission or sale subject to the Commission's jurisdiction. Accordingly, entities wishing to sell primary frequency response service at market-based rates must amend their market-based rate tariffs to include the language included in this Final Rule. Regarding FERC-920, the Commission is revising the EQR to ensure that public utilities that may sell primary frequency response service at market-based rates report those sales in the EQR, consistent with their filing obligations under section 205(c).

Internal Review: The Commission has reviewed the requirements associated with the proposed revisions to the information collections and determined they are necessary to ensure that rates remain just, reasonable, and not unduly discriminatory.

77. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has assured itself, through internal review, that there is specific, objective support for the burden estimates associated with the information collection requirements.

78. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: DataClearance@ferc.gov, Phone (202) 502-8663, fax: (202) 273-0873. Comments on the collections of information and associated burden estimates in the Final Rule should be sent to the Commission in this docket and may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments to OMB should be

submitted by email to: oir_submission@omb.eop.gov. Please refer to OMB Control No. 1902-0096 (FERC-516) and OMB Control No. 1902-0255 (FERC-920).

V. Environmental Analysis

79. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.¹¹² The Commission concludes that neither an Environmental Assessment nor an Environmental Impact Statement is required for this Final Rule under section 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale subject to the Commission's jurisdiction, plus the classification, practices, contracts, and regulations that affect rates, charges, classifications, and services.¹¹³

VI. Regulatory Flexibility Act

80. The Regulatory Flexibility Act of 1980 (RFA)¹¹⁴ generally requires a description and analysis of proposed and final rules that will have significant economic impact on a substantial number of small entities.

81. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.¹¹⁵ The SBA revised its size standard for electric utilities (effective January 22, 2014) from a standard based on megawatt hours to a standard based on the number of employees, including affiliates.¹¹⁶ Under SBA's current size

¹¹² *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, 52 FR 47,897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986-1990 ¶ 30,783 (1987).

¹¹³ 18 CFR 380.4(a)(15) (2015).

¹¹⁴ 5 U.S.C. 601-612 (2012).

¹¹⁵ 13 CFR 121.101 (2015).

¹¹⁶ SBA Final Rule on "Small Business Size Standards: Utilities," 78 FR 77,343 (Dec. 23, 2013).

standards, the entities with market-based rates which are affected by this Final Rule likely come under the following categories¹¹⁷ with the indicated thresholds (in terms of number of employees¹¹⁸):

- Hydroelectric Power Generation, 500 employees.
- Fossil Fuel Electric Power Generation, 750 employees.
- Nuclear Electric Power Generation, 750 employees.
- Solar Electric Power Generation, 250 employees.
- Wind Electric Power Generation, 250 employees.
- Geothermal Electric Power Generation, 250 employees.
- Biomass Electric Power Generation, 250 employees.
- Other Electric Power Generation, 250 employees.

82. The categories for the applicable entities have a size threshold ranging from 250 employees to 750 employees. For the analysis in this Final Rule, we are using the threshold of 750 employees for all categories. We anticipate that a maximum of 82 percent of the entities potentially affected by this Final Rule are small. In addition, we expect that not all of those entities will be able to or will choose to offer primary frequency response service.

83. Based on the estimates above in the Information Collection section, we expect a one-time cost of \$576 (including the burden cost related to filing both the tariff and the EQR) for each entity that decides to offer primary frequency response service.

84. The Commission does not consider the estimated cost per small entity to impose a significant economic impact on a substantial number of small entities. Accordingly, the Commission certifies that this Final Rule will not have a significant economic impact on a substantial number of small entities.

VII. Document Availability

85. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (<http://www.ferc.gov>) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

86. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

87. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

VIII. Effective Date and Congressional Notification

88. The Final Rule is effective February 25, 2016. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this Final Rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule is being submitted to the Senate, House, Government Accountability Office, and Small Business Administration.

List of Subjects in 18 CFR Part 35

Electric power rates; Electric utilities; Reporting and recordkeeping requirements.

By the Commission.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

In consideration of the foregoing, the Commission amends Part 35, Chapter I, Title 18, *Code of Federal Regulations*, as follows.

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

- 1. The authority citation for Part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

- 2. In § 35.37, revise paragraph (c)(1) to read as follows:

§ 35.37 Market power analysis required.

* * * * *

(c)(1) There will be a rebuttable presumption that a Seller lacks horizontal market power with respect to sales of energy, capacity, energy imbalance service, generation imbalance service, and primary frequency response

service if it passes two indicative market power screens: a pivotal supplier analysis based on annual peak demand of the relevant market, and a market share analysis applied on a seasonal basis. There will be a rebuttable presumption that a Seller lacks horizontal market power with respect to sales of operating reserve-spinning and operating reserve-supplemental services if the Seller passes these two indicative market power screens and demonstrates in its market-based rate application how the scheduling practices in its region support the delivery of operating reserve resources from one balancing authority area to another. There will be a rebuttable presumption that a Seller possesses horizontal market power with respect to sales of energy, capacity, energy imbalance service, generation imbalance service, operating reserve-spinning service, operating reserve-supplemental service, and primary frequency response service if it fails either screen.

* * * * *

[FR Doc. 2015-30140 Filed 11-25-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM15-16-000, Order No. 817]

Transmission Operations Reliability Standards and Interconnection Reliability Operations and Coordination Reliability Standards

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Final rule.

SUMMARY: The Commission approves revisions to the Transmission Operations and Interconnection Reliability Operations and Coordination Reliability Standards, developed by the North American Electric Reliability Corporation, which the Commission has certified as the Electric Reliability Organization responsible for developing and enforcing mandatory Reliability Standards. The Commission also directs NERC to make three modifications to the standards within 18 months of the effective date of the final rule.

DATES: This rule will become effective January 26, 2016.

FOR FURTHER INFORMATION CONTACT: Robert T. Stroh (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC

¹¹⁷ 13 CFR 121.201, Sector 22, Utilities.

¹¹⁸ SBA's regulations at 13 CFR 121.201 state that "[t]he number of employees . . . indicates the maximum allowed for a concern and its affiliates to be considered small."

20426, Telephone: (202) 502-8473, Robert.Stroh@ferc.gov.

Eugene Blick (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (301) 665-1759, Eugene.Blick@ferc.gov.

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SUPPLEMENTARY INFORMATION:

Order No. 817

Final Rule

(Issued November 19, 2015)

1. Pursuant to section 215 of the Federal Power Act (FPA),¹ the Commission approves revisions to the Transmission Operations (TOP) and Interconnection Reliability Operations and Coordination (IRO) Reliability Standards, developed by the North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO). The TOP and IRO Reliability Standards improve on the currently-effective standards by providing a more precise set of Reliability Standards addressing operating responsibilities and improving the delineation of responsibilities between applicable entities. The revised TOP Reliability Standards eliminate gaps and ambiguities in the currently-effective TOP requirements and improve efficiency by incorporating the necessary requirements from the eight currently-effective TOP Reliability Standards into three comprehensive Reliability Standards. Further, the standards clarify and improve upon the currently-effective TOP and IRO Reliability Standards by designating requirements in the proposed standards that apply to transmission operators for the TOP standards and reliability coordinators for the IRO standards. Thus, we conclude that there are benefits to clarifying and bringing efficiencies to the TOP and IRO Reliability Standards, consistent with the Commission's policy promoting increased efficiencies in Reliability Standards and reducing requirements that are either redundant with other

currently-effective requirements or have little reliability benefit.²

2. The Commission also finds that NERC has adequately addressed the concerns raised by the Commission in the Notice of Proposed Rulemaking issued in November 2013 concerning the proposed treatment of system operating limits (SOLs) and interconnection reliability operating limits (IROLs) and concerns about outage coordination.³ Further, the Commission approves the definitions for operational planning analysis and real-time assessment, the implementation plans and the violation severity level and violation risk factor assignments. However, the Commission directs NERC to make three modifications to the standards as discussed below within 18 months of the effective date of this Final Rule.

3. We also address below the four issues for which we sought clarifying comments in the June 18, 2015, Notice of Proposed Rulemaking (NOPR) proposing to approve the TOP and IRO Reliability Standards: (A) Possible inconsistencies in identifying IROLs; (B) monitoring of non-bulk electric system facilities; (C) removal of the load-serving entity as an applicable entity for proposed Reliability Standard TOP-001-3; and (D) data exchange capabilities. In addition we address other issues raised by commenters.

I. Background

A. Regulatory Background

4. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.⁴ Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight, or by the Commission independently.⁵ In 2006, the Commission certified NERC as the ERO pursuant to FPA section 215.⁶

² *Electric Reliability Organization Proposal to Retire Requirements in Reliability Standards*, Order No. 788, 145 FERC ¶ 61,147 (2013).

³ *Monitoring System Conditions—Transmission Operations Reliability Standard, Transmission Operations Reliability Standards, Interconnection Reliability Operations and Coordination Reliability Standards*, Notice of Proposed Rulemaking, 145 FERC ¶ 61,158 (2013) (Remand NOPR). Concurrent with filing the proposed TOP/IRO standards in the immediate proceeding, NERC submitted a motion to withdraw the earlier petition that was the subject of the Remand NOPR. No protests to the motion were filed and the petition was withdrawn pursuant to 18 CFR 385.216(b).

⁴ 16 U.S.C. 824o(c) and (d).

⁵ See *id.* 16 U.S.C. 824o(e).

⁶ *North American Electric Reliability Corp.*, 116 FERC ¶ 61,062, *order on reh'g and compliance*, 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa Inc. v. FERC*, 564 F.3d 1342 (D.C. Cir. 2009).

5. The Commission approved the initial TOP and IRO Reliability Standards in Order No. 693.⁷ On April 16, 2013, in Docket No. RM13-14-000, NERC submitted for Commission approval three revised TOP Reliability Standards to replace the eight currently-effective TOP standards.⁸ Additionally, on April 16, 2013, in Docket No. RM13-15-000, NERC submitted for Commission approval four revised IRO Reliability Standards to replace six currently-effective IRO Reliability Standards. On November 21, 2013, the Commission issued the Remand NOPR in which the Commission expressed concern that NERC had "removed critical reliability aspects that are included in the currently-effective standards without adequately addressing these aspects in the proposed standards."⁹ The Commission identified two main concerns and asked for clarification and comment on a number of other issues. Among other things, the Commission expressed concern that the proposed TOP Reliability Standards did not require transmission operators to plan and operate within all SOLs, which is a requirement in the currently-effective standards. In addition, the Commission expressed concern that the proposed IRO Reliability Standards did not require outage coordination.

B. NERC Petition

6. On March 18, 2015, NERC filed a petition with the Commission for approval of the proposed TOP and IRO Reliability Standards.¹⁰ As explained in the Petition, the proposed Reliability Standards consolidate many of the currently-effective TOP and IRO Reliability Standards and also replace the TOP and IRO Reliability Standards that were the subject of the Remand NOPR. NERC stated that the proposed Reliability Standards include

⁷ See *Mandatory Reliability Standards for the Bulk-Power System*, Order No. 693, FERC Stats. & Regs. ¶ 31,242, at P 508, *order on reh'g*, Order No. 693-A, 120 FERC ¶ 61,053 (2007). In addition, in Order No. 748, the Commission approved revisions to the IRO Reliability Standards. *Mandatory Reliability Standards for Interconnection Reliability Operating Limits*, Order No. 748, 134 FERC ¶ 61,213 (2011).

⁸ On April 5, 2013, in Docket No. RM13-12-000, NERC proposed revisions to Reliability Standard TOP-006-3 to clarify that transmission operators are responsible for monitoring and reporting available transmission resources and that balancing authorities are responsible for monitoring and reporting available generation resources.

⁹ Remand NOPR, 145 FERC ¶ 61,158 at P 4.

¹⁰ The TOP and IRO Reliability Standards are not attached to the Final Rule. The complete text of the Reliability Standards is available on the Commission's eLibrary document retrieval system in Docket No. RM15-16 and is posted on the ERO's Web site, available at: <http://www.nerc.com>.

¹ 16 U.S.C. 824o (2012).

improvements over the currently-effective TOP and IRO Reliability Standards in (1) operating within SOLs and IROs; (2) outage coordination; (3) situational awareness; (4) improved clarity and content in foundational definitions; and (5) requirements for operational reliability data. NERC stated that the proposed TOP and IRO Reliability Standards address outstanding Commission directives relevant to the proposed TOP and IRO Reliability Standards. NERC stated that the proposed Reliability Standards provide a comprehensive framework for reliable operations, with important improvements to ensure the bulk electric system is operated within pre-established limits while enhancing situational awareness and strengthening operations planning. NERC explained that the proposed Reliability Standards establish or revise requirements for operations planning, system monitoring, real-time actions, coordination between applicable entities, and operational reliability data. NERC contended that the proposed Reliability Standards help to ensure that reliability coordinators and transmission operators work together, and with other functional entities, to operate the bulk electric system within SOLs and IROs.¹¹ NERC also provided explanations of how the proposed Reliability Standards address the reliability issues identified in the report on the Arizona-Southern California Outages on September 8, 2011, Causes and Recommendations (“2011 Southwest Outage Blackout Report”).

7. NERC proposed three TOP Reliability Standards to replace the existing suite of TOP standards. The proposed TOP Reliability Standards generally address real-time operations and planning for next-day operations, and apply primarily to the responsibilities and authorities of transmission operators, with certain requirements applying to the roles and responsibilities of the balancing authority. Among other things, NERC stated that the proposed revisions to the TOP Reliability Standards help ensure that transmission operators plan and operate within all SOLs. The proposed IRO Reliability Standards, which complement the proposed TOP

Standards, are designed to ensure that the bulk electric system is planned and operated in a coordinated manner to perform reliably under normal and abnormal conditions. The proposed IRO Reliability Standards set forth the responsibility and authority of reliability coordinators to provide for reliable operations. NERC stated that, in the proposed IRO Reliability Standards, reliability coordinators must continue to monitor SOLs in addition to their obligation in the currently effective Reliability Standards to monitor and analyze IROs. These obligations require reliability coordinators to have the wide-area view necessary for situational awareness and provide them the ability to respond to system conditions that have the potential to negatively affect reliable operations.

8. NERC also proposed revised definitions for “operational planning analysis” and “real-time assessment.” For all standards except proposed Reliability Standards TOP-003-3 and IRO-010-2, NERC proposed the effective date to be the first day of the first calendar quarter twelve months after Commission approval. According to NERC’s implementation plan, for proposed TOP-003-3, all requirements except Requirement R5 will become effective on the first day of the first calendar quarter nine months after the date that the standard is approved. For proposed IRO-010-2, Requirements R1 and R2 would become effective on the first day of the first calendar quarter that is nine months after the date that the standard is approved. Proposed TOP-003-3, Requirement R5 and IRO-010-2, Requirement R3 would become effective on the first day of the first calendar quarter twelve months after the date that the standard is approved. The reason for the difference in effective dates for proposed TOP-003-3 and IRO-010-2 is to allow applicable entities to have time to properly respond to the data specification requests from their reliability coordinators, transmission operators, and/or balancing authorities.

C. Notice of Proposed Rulemaking

9. On June 18, 2015, the Commission issued a Notice of Proposed Rulemaking proposing to approve the TOP and IRO Reliability Standards pursuant to FPA section 215(d)(2), along with the two new definitions referenced in the proposed standards, the assigned violation risk factors and violation severity levels, and the proposed implementation plan for each standard.¹²

¹² *Transmission Operations Reliability Standards and Interconnection Reliability Operations and*

10. In the NOPR, the Commission explained that the proposed TOP and IRO Reliability Standards improve on the currently-effective standards by providing a more precise set of Reliability Standards addressing operating responsibilities and improving the delineation of responsibilities between applicable entities. The Commission also proposed to find that NERC has adequately addressed the concerns raised by the Remand NOPR issued in November 2013.

11. In the NOPR, the Commission also discussed the following specific matters and asked for further comment: (A) Possible inconsistencies in identifying IROs; (B) monitoring of non-bulk electric system facilities; (C) removal of the load-serving entity as an applicable entity for proposed Reliability Standard TOP-001-3; and (D) data exchange capabilities.

12. Timely comments on the NOPR were filed by: NERC; Arizona Public Service Company (APS), Bonneville Power Administration (BPA), Dominion Resources Services, Inc. (Dominion), the Edison Electric Institute (EEI); Electric Reliability Council of Texas, Inc. (ERCOT), Independent Electricity System Operator (IESO), ISO/RTOs,¹³ International Transmission Company (ITC); Midcontinent Independent System Operator, Inc., Northern Indiana Public Service Company (NIPSCO), Occidental Energy Ventures, LLC (Occidental), Peak Reliability (Peak), and Transmission Access Policy Study Group (TAPS).

II. Discussion

13. Pursuant to section 215(d) of the FPA, we adopt our NOPR proposal and approve NERC’s revisions to the TOP and IRO Reliability Standards, including the associated definitions, violation risk factors, violation severity levels, and implementation plans, as just, reasonable, not unduly discriminatory or preferential and in the public interest. We note that all of the commenters that address the matter support, or do not oppose, approval of the revised suite of TOP and IRO Reliability Standards. We determine that NERC’s approach of consolidating requirements and removing redundancies generally has merit and is consistent with Commission policy

Coordination Reliability Standards, 151 FERC ¶ 61,236 (2015) (NOPR).

¹³ ISO/RTOs include Independent Electricity System Operator, ISO New England Inc., Midcontinent Independent System Operator, New York Independent System Operator, Inc., PJM Interconnection LLC, and Southwest Power Pool, Inc.

¹¹ The NERC Glossary of Terms defines IROL as “[a] System Operating Limit that, if violated, could lead to instability, uncontrolled separation, or cascading outages that adversely impact the reliability of the Bulk Electric System.” In turn, NERC defines SOL as “[t]he value (such as MW, MVar, Amperes, Frequency or Volts) that satisfies the most limiting of the prescribed operating criteria for a specified system configuration to ensure operation within acceptable reliability criteria. . . .”

promoting increased efficiencies in Reliability Standards and reducing requirements that are either redundant with other currently-effective requirements or have little reliability benefit.¹⁴

14. We also determine that the proposed TOP and IRO Reliability Standards should improve reliability by defining an appropriate division of responsibilities between reliability coordinators and transmission operators.¹⁵ The proposed TOP Reliability Standards will eliminate multiple TOP standards, resulting in a more concise set of standards, reducing redundancy and more clearly delineating responsibilities between applicable entities. In addition, we find that the proposed Reliability Standards provide a comprehensive framework as well as important improvements to ensure that the bulk electric system is operated within pre-established limits while enhancing situational awareness and strengthening operations planning. The TOP and IRO Reliability Standards address the coordinated efforts to plan and reliably operate the bulk electric system under both normal and abnormal conditions.

15. In the NOPR, the Commission proposed to find that NERC adequately addressed the concerns raised by the Commission in the Remand NOPR with respect to (1) the treatment of SOLs in the proposed TOP Reliability Standards, and (2) the IRO standards regarding planned outage coordination, both of which we address below.

Operational Responsibilities and Actions of SOLs and IROs

16. In the Remand NOPR, the Commission expressed concern that the initially proposed (now withdrawn) TOP standards did not have a requirement for transmission operators to plan and operate within all SOLs. The Commission finds that the TOP Reliability Standards that NERC subsequently proposed address the Commission's Remand NOPR concerns by requiring transmission operators to plan and operate within all SOLs, and to monitor and assess SOL conditions within and outside a transmission operator's area. Further, the TOP/IRO Standards approved herein address the possibility that additional SOLs could develop or occur in the same-day or real-time operational time horizon and, therefore, would pose an operational risk to the interconnected transmission network if not addressed. Likewise, the

Reliability Standards give reliability coordinators the authority to direct actions to prevent or mitigate instances of exceeding IROs because the primary decision-making authority for mitigating IRO exceedances is assigned to reliability coordinators while transmission operators have the primary responsibility for mitigating SOL exceedances.¹⁶

17. Furthermore, the revised definitions of operational planning analysis and real-time assessment are critical components of the proposed TOP and IRO Reliability Standards and, together with the definitions of SOLs, IROs and operating plans, work to ensure that reliability coordinators, transmission operators and balancing authorities plan and operate the bulk electric system within all SOLs and IROs to prevent instability, uncontrolled separation, or cascading. In addition, the revised definitions of operational planning analysis and real-time assessment address other concerns raised in the Remand NOPR as well as multiple recommendations in the 2011 Southwest Outage Blackout Report.¹⁷

Outage Coordination

18. In the NOPR, the Commission explained that NERC had addressed concerns raised in the Remand NOPR with respect to the IRO standards regarding planned outage coordination. In the Remand NOPR, the Commission expressed concern with NERC's proposal because Reliability Standards IRO-008-1, Requirement R3 and IRO-010-1a (subjects of the proposed remand and now withdrawn by NERC) did not require the coordination of outages, noting that outage coordination is a critical reliability function that should be performed by the reliability coordinator.¹⁸

19. In the NOPR, the Commission noted that Reliability Standard IRO-017-1, Requirement R1 requires each reliability coordinator to develop, implement and maintain an outage coordination process for generation and transmission outages within its reliability coordinator area. Additionally, Reliability Standard IRO-014-3, Requirement R1, Part 1.4 requires reliability coordinators to include the exchange of planned and

unplanned outage information to support operational planning analyses and real-time assessments in the operating procedures, processes, and plans for activities that require coordination with adjacent reliability coordinators. We believe that these proposed standards adequately address our concerns with respect to outage coordination as outlined in the Remand NOPR. However, as we discuss below we direct NERC to modify the standards to include transmission operator monitoring of non-BES facilities, and to specify that data exchange capabilities include redundancy and diverse routing; as well as testing of the alternate or less frequently used data exchange capability, within 18 months of the effective date of this Final Rule.

20. Below we discuss the following matters: (A) Possible inconsistencies of identifying IROs; (B) monitoring of non-bulk electric system facilities; (C) removal of the load-serving entity function from proposed Reliability Standard TOP-001-3; (D) data exchange capabilities, and (E) other issues raised by commenters.

A. Possible Inconsistencies in IROs Across Regions

NOPR

21. In the NOPR, the Commission noted that in Exhibit E (SOL White Paper) of NERC's petition, NERC stated that, with regard to the SOL concept, the SOL White Paper brings "clarity and consistency to the notion of establishing SOLs, exceeding SOLs, and implementing Operating Plans to mitigate SOL exceedances."¹⁹ The Commission further noted that IROs, as defined by NERC, are a subset of SOLs that, if violated, could lead to instability, uncontrolled separation, or cascading outages that adversely impact the reliability of the bulk electric system. The Commission agreed with NERC that clarity and consistency are important with respect to establishing and implementing operating plans to mitigate SOL and IRO exceedances. However, the Commission noted that NERC, in its 2015 State of Reliability report, had stated that the Western Interconnection reliability coordinator definition of an IROL has additional criteria that may not exist in other reliability coordinator areas.²⁰ The

¹⁹ NERC Petition, Exhibit E, "White Paper on System Operating Limit Definition and Exceedance Clarification" at 1.

²⁰ NOPR, 151 FERC ¶ 61,236 at P 51, citing NERC 2015 State of Reliability report at 44, available at www.nerc.com. See also WECC Reliability Coordination System Operating Limits Methodology for the Operations Horizon, Rev. 7.0 (effective March 3, 2014) at 18 (stating that "SOLs

¹⁴ See Order No. 788, 145 FERC ¶ 61,147.

¹⁵ See, e.g., Order No. 748, 134 FERC ¶ 61,213, at PP 39-40.

¹⁶ See Remand NOPR, 145 FERC ¶ 61,158 at P 85. Further, currently-effective Reliability Standard IRO-009-1, Requirement R4 states that "[w]hen actual system conditions show that there is an instance of exceeding an IROL in its Reliability Coordinator Area, the Reliability Coordinator shall, without delay, act or direct others to act to mitigate the magnitude and duration of the instance of exceeding that IROL within the IROL's Tv."

¹⁷ NERC Petition at 17-18.

¹⁸ Remand NOPR, 145 FERC ¶ 61,158 at P 90.

Commission stated that it is unclear whether NERC regions apply a consistent approach to identifying IROLs. The Commission, therefore, sought comment on (1) identification of all regional differences or variances in the formulation of IROLs; (2) the potential reliability impacts of such differences or variations, and (3) the value of providing a uniform approach or methodology to defining and identifying IROLs.

Comments

22. Commenters generally agree that there are variations in IROL formulation but maintain that the flexibility is needed due to different system topographies and configurations. EEI and other commenters, also suggest that, to the extent there are variations, such resolution should be addressed by NERC and the Regional Entities in a standard development process rather than by a Commission directive. NERC requests that the Commission refrain from addressing these issues in this proceeding. NERC contends that the TOP and IRO Reliability Standards do not address the methods for the development and identification of SOLs and IROLs and that requirements governing the development and identification of SOLs and IROLs are included in the Facilities Design, Connections and Maintenance (FAC) Reliability Standards. NERC states that the current FAC Reliability Standards provide reliability coordinators flexibility in the manner in which they identify IROLs.²¹ NERC adds that it recently initiated a standards development project (Project 2015–09 Establish and Communicate System Operating Limits) to evaluate and modify the FAC Reliability Standards that address the development and identification of SOLs and IROLs. NERC explains that the Project 2015–09 standard drafting team will address the clarity and consistency of the requirements for establishing both SOLs and IROLs. According to NERC, it would be premature for NERC or the Commission to address issues regarding the identification of IROLs in this proceeding without the benefit of the complete analysis of the Project 2015–09 standard drafting team. NERC

qualify as IROLs when . . . studies indicate that instability, Cascading, or uncontrolled separation may occur resulting in uncontrolled interruption of load equal to or greater than 1000 MW”), available at <https://www.wecc.biz/Reliability/PhaseII%20WECC%20RC%20SOL%20Methodology%20FINAL.pdf>.

²¹ See also Peak Comments at 4–5. Peak points to Reliability Standards FAC–011–2 and FAC–014–2 as support for regional variation in establishing IROLs.

commits to working with stakeholders and Commission staff during the Project 2015–09 standards development process to address the issues raised in the NOPR.

23. ERCOT comments that the existing Reliability Standards provide a consistent but flexible structure for IROL identification that provides maximum benefit to interconnected transmission network. ERCOT believes that the Reliability Standards should continue to permit regional variations that will encourage flexibility for consideration of system-specific topology and characteristics as well as the application of operational experience and engineering judgment. ERCOT states that regional differences exist in terms of the specific processes and methodologies utilized to identify IROLs. However, according to ERCOT, appropriate consistency in IROL identification is driven by the definition of an IROL, the Reliability Standards associated with the identification of SOLs, and the communication and coordination among responsible entities. Further, ERCOT argues that allowing regional IROL differences benefits the bulk electric system by allowing the entities with the most operating experience to recognize the topology and operating characteristics of their areas, and to incorporate their experience and judgment into IROL identification.

24. Peak supports allowing regions to vary in their interpretation and identification of IROLs based on the level of risk determined by that region, as long as that interpretation is transparent and consistent within that region. Peak understands the definition of IROL to recognize regional differences and variances in the formulation of IROLs. Peak contends that such regional variation is necessary due to certain physical system differences. Thus, according to Peak, a consistent approach from region to region is not required, and may not enhance the overall reliability of the system. Peak explains that, in the Western United States, the evaluation of operating limits and stability must take into account the long transmission lines and greater distance between population centers, a situation quite different than the dense, interwoven systems found in much of the Eastern Interconnection. Peak adds that the Western Interconnection more frequently encounters localized instability because of the sparsity of the transmission system and the numerous small load centers supplied by few transmission lines, and these localized instances of instability have little to no impact on

the overall reliability of the bulk electric system. Peak encourages the Commission to recognize that differences among the regions may require flexibility to determine, through its SOL methodology, the extent and severity of instability and cascading that warrant the establishment of an IROL.

25. While Peak supports retaining the flexibility of a region by region application of the IROL definition, Peak notes that the current definition is not without some confusing ambiguity in the application of IROL that should be addressed, including ambiguity and confusion around the term “instability,” the phrase “that adversely impact the reliability of the Bulk Electric System” and “cascading.” Peak suggests that one method to eliminate confusion on the definition and application of IROLs would be to expand NERC’s whitepaper to address concerns more specific to IROLs. Peak contends that further guidance from NERC in the whitepaper may remedy the confusion on the limits on the application of IROLs for widespread versus localized instability.

26. Peak requests that, if the Commission or NERC determines that a one-size-fits all approach is necessary for the identification of IROLs and eliminates the current flexibility for regional differences, that the Commission recognizes the limitations this will place on reliability coordinators to evaluate the specific conditions within their reliability coordinator area. The Commission should require that any standardized application of the IROL definition would need to address specific thresholds and implementation triggers for IROLs based on the risk profile and challenges facing specific regions, to avoid the downfalls of inaccurate or overbroad application, as discussed above.

Commission Determination

27. While it appears that regional discrepancies exist regarding the manner for calculating IROLs, we accept NERC’s explanation that this issue is more appropriately addressed in NERC’s Facilities Design, Connections and Maintenance or “FAC” Reliability Standards. NERC indicates that an ongoing FAC-related standards development project—NERC Project 2015–09 (Establish and Communicate System Operating Limits)—will address the development and identification of SOLs and IROLs. We conclude that NERC’s explanation, that the Project 2015–09 standard drafting team will address the clarity and consistency of the requirements for establishing both SOLs and IROLs, is reasonable.

Therefore, we will not direct further action on IROLs in the immediate TOP and IRO standard-related rulemaking. However, when this issue is considered in Project 2015–19, the specific regional difference of WECC’s 1,000 MW threshold in IROLs should be evaluated in light of the Commission’s directive in Order No. 802 (approving Reliability Standard CIP–014) to eliminate or clarify the “widespread” qualifier on “instability” as well as our statement in the Remand NOPR that “operators do not always foresee the consequences of exceeding such SOLs and thus cannot be sure of preventing harm to reliability.”²²

B. Monitoring of Non-Bulk Electric System Facilities

NOPR

28. In the NOPR the Commission proposed to find that the proposed Reliability Standards adequately address the 2011 Southwest Outage Blackout Report recommendation regarding monitoring sub-100 kV facilities, primarily because of the responsibility of the reliability coordinator under proposed Reliability Standard IRO–002–4, Requirement R3 to monitor non-bulk electric system facilities to the extent necessary. The Commission noted, however, that “the transmission operator may have a more granular perspective than the reliability coordinator of its necessary non-bulk electric system facilities to monitor,” and it is not clear whether or how the transmission operator would provide information to the reliability coordinator regarding which non-BES facilities should be monitored.²³ The Commission sought comment on how NERC will ensure that the reliability coordinator will receive such information.

29. The Commission stated that including such non-bulk electric system facilities in the definition of bulk electric system through the NERC Rules of Procedure exception process could be an option to address any potential gaps for monitoring facilities but notes that there may be potential efficiencies gained by using a more expedited method to include non-bulk electric

system facilities that requires monitoring. The Commission sought comment on whether the BES exception process should be used exclusively in all cases. Alternatively, the Commission sought comment on whether this concern can be addressed through a review process of the transmission operators’ systems to determine if there are important non-bulk electric system facilities that require monitoring.

Comments

30. Nearly all commenters support the Reliability Standards as proposed as sufficient for identifying and monitoring non-bulk electric system facilities, and do not support the alternatives offered by the Commission in the NOPR.²⁴ NERC submits that the proposed data specification and collection Reliability Standards IRO–010–2 and TOP–003–3, in addition to the exceptions process will help ensure that the reliability coordinator can work with transmission operators, and other functional entities, to obtain sufficient information to identify the necessary non-bulk electric system facilities to monitor. In support, NERC points to Reliability Standard IRO–010–2, which provides a mechanism for the reliability coordinator to obtain the information and data it needs for reliable operations and to help prevent instability, uncontrolled separation, or cascading outages. Further, NERC cites Reliability Standard TOP–003–3, which allows transmission operators to obtain data on non-bulk electric system facilities, necessary to perform their operational planning analyses, real-time monitoring, and real-time assessments from applicable entities. NERC explains that any data that the transmission operator obtains regarding non-bulk electric system facilities under Reliability Standard TOP–003–3 can be passed on to the reliability coordinator pursuant to a request under proposed Reliability Standard IRO–010–2. Accordingly, NERC states that it would be premature to develop an alternative process before the data specification and bulk electric system exception process are allowed to work.

31. EEI states that this issue has been thoroughly studied by NERC through Project 2010–17 Phase 2 (Revisions to the Definition of Bulk Electric System) that led to modification of the definition of bulk electric system. EEI believes that the current process provides all of the necessary tools and processes to ensure that insights by TOPs are fully captured and integrated into existing monitoring

systems that would ensure that all non-BES elements that might impact BES reliability are fully monitored. EEI does not support the alternative process proposed by the Commission. EEI warns that an alternative, parallel review process of the transmission operators’ systems to determine if there are important non-bulk electric system facilities that require monitoring would either circumvent the revised bulk electric system definition process or arbitrarily impose NERC requirements (*i.e.*, monitoring) onto non-bulk electric system elements.

32. APS agrees with the Commission that there would be a reliability benefit for the reliability coordinator to be able to identify facilities within the transmission operators’ areas that may have a material impact on reliability. APS believes this benefit can be achieved using the method deployed in the Western Interconnection by the Western Electricity Coordinating Council (WECC). APS explains that the WECC planning coordination committee has published a bulk electric system inclusion guideline that categorizes non-bulk electric system facilities that are to be identified by each planning authority and transmission planner when performing their system planning and operations reliability assessments, and the identified facilities are then reported to NERC. APS proposes a similar exception process be used in all cases. According to APS, each reliability coordinator would publish a guideline on how to identify non-bulk electric system facilities critical to reliability appropriate for their reliability coordinator area, and each planning coordinator and transmission planner would run studies according to the reliability coordinator guideline at least once every three years.

33. ERCOT states that performance of sufficient studies and evaluations of reliability coordinator areas occurs in cooperation and coordination with associated transmission operators, rendering an additional review process unnecessary. However, to avoid any potential gaps in monitoring non-bulk electric system facilities and ensure that existing agreements and monitoring processes are respected, ERCOT states that the Commission should direct NERC to modify the TOP and IRO Reliability Standards to refer not only to sub-100 kV facilities identified as part of the bulk electric system through the Rules of Procedure exception process, but also to other sub-100 kV facilities as requested or agreed by the responsible entities.²⁵ ERCOT also states that

²² *Physical Security Reliability Standard*, Order No. 802, 149 FERC ¶ 61,140 (2014) and Remand NOPR, 145 FERC ¶ 61,158 at P 52. *See also* FPA section 215(a)(4) defining Reliable Operation as “operating the elements of the bulk-power system within equipment and electric system thermal, voltage, and stability limits so that instability, uncontrolled separation, or cascading failures of such system will not occur as a result of a sudden disturbance, including a cybersecurity incident, or unanticipated failure of system elements.”

²³ NOPR, 151 FERC ¶ 61,236 at P 58.

²⁴ *E.g.* NERC, EEI, TAPS, Occidental, and NIPSCO.

²⁵ *See also* ISO/RTOs Comments at 3.

because “non-bulk electric system facilities” fall outside the scope of the NERC Reliability Standards, use of this terminology should be avoided. ERCOT advocates for the Commission to permit monitoring of other sub-100 kV facilities to be undertaken as agreed to between the reliability coordinator and the transmission operator. ERCOT and ISO/RTOs suggest that the phrase “non-BES facilities” in Reliability Standard IRO-002-4, Requirement R3 should be replaced with “sub-100 kV facilities identified as part of the BES through the BES exception process or as otherwise agreed to between the Reliability Coordinator and Transmission Operator” and the phrase “non-BES data” in Reliability Standards IRO-010-2 (Requirement R1.1) and TOP-003-3 (Requirement R1.1) should be replaced with “data from sub-100 kV facilities identified as part of the BES through the BES exception process, as otherwise requested by the Responsible Entity, or as agreed to between the Transmission Operator and the Responsible Entity.”²⁶

34. ITC does not support the Commission’s proposal. ITC states that transmission operators are required to incorporate any non-bulk electric system data into operational planning analysis and real-time assessments and monitoring, which therefore requires transmission operators to regularly review their models to identify impacting non-bulk electric system facilities. Conversely, ITC explains that conducting a one-time or periodic review and analysis of a transmission operator’s model ignores the fact that changes in system conditions can cause the list of impacting non-bulk electric system facilities to change frequently.

Commission Determination

35. We agree with NERC, TAPS, and EEI that the BES exception process can be a mechanism for identifying non-BES facilities to be included in the BES definition.²⁷ Indeed, *once* a non-BES facility is included in the BES definition under the BES exception process, the “non-BES facility” becomes a BES “Facility” under TOP-001-3, Requirement R10, and real-time monitoring is required of “Facilities.”²⁸

²⁶ See also ISO/RTOs Comments at 4-6.

²⁷ NERC TOP/IRO Petition, Exh. G at 9 states in response to the 2011 Southwest Outage Recommendation #17, “If a non-BES facility impacts the BES, such as by contributing to an SOL or IROL, then the SDT expects that facility to be incorporated into the BES through the official BES Exception Process and it would be covered in proposed TOP-001-3, Requirement R10, Parts 10.1 and 10.2 by use of the defined term ‘Facilities.’”

²⁸ NERC Glossary of Terms defines Facility as: “A set of electrical equipment that operates as a single

However, we are concerned that in some instances the absence of real-time monitoring of non-BES facilities by the transmission operator within and outside its TOP area as necessary for determining SOL exceedances in proposed TOP-001-3, Requirement R10 creates a reliability gap. As the 2011 Southwest Outage Report indicates, the Regional Entity “should lead other entities, including TOPs and BAs, to ensure that all facilities that can adversely impact BPS reliability are either designated as part of the BES or otherwise incorporated into planning and operations studies and *actively monitored* and alarmed in [real-time contingency analysis] systems.”²⁹ Such monitoring of non-BES facilities could provide a “stop gap” during the period where a sub-100 kV facility undergoes analysis as a possible BES facility, allowing for monitoring in the interim until such time the non-bulk electric system facilities become “BES Facilities” or the transmission operator determines that a non-bulk electric system facility is no longer needed for monitoring to determine a system operating limit exceedance in its area.³⁰ We believe that the operational planning analyses and real-time assessments performed by the transmission operators as well as the reliability coordinators will serve as the basis for determining which “non-BES facilities” require monitoring to determine system operating limit and interconnection reliability operating limit exceedances. In addition, we believe that monitoring of certain non-BES facilities that are occasional system operating limit exceedance performers may not qualify as a candidate for inclusion in the BES definition, yet should be monitored for reliability purposes.³¹ Accordingly, pursuant to

Bulk Electric System Element (e.g., a line, a generator, a shunt compensator, transformer, etc.)”

²⁹ NOPR, 151 FERC ¶ 61,236 at P 55, citing Recommendation 17 of the 2011 Southwest Outage Blackout Report (emphasis added).

³⁰ NERC’s BES Frequently Asked Questions, Version 1.6, February 25, 2015, Section 5.6. “How long will the process take?” at page 14 states: “In general, assuming a complete application, no appeals, and taking the allotted time for each subtask, the process could take up to 11.5 months, but is anticipated to be shorter for less complicated Exception Requests. If the Exception Request is appealed to the NERC Board of Trustees Compliance Committee pursuant to Section 1703 of the NERC Rules of Procedure, the process could take an additional 8.5 months, totaling 20 months. This does not include timing related to an appeal to the applicable legal authority or Applicable Governmental Authority. A Regional Entity, upon consultation with NERC, may extend the time frame of the substantive review process. . . .” <http://www.nerc.com/pa/RAPA/BES%20DL/BES%20FAQs.pdf>.

³¹ See, e.g., NERC TOP/IRO Petition at 18 and 27-28.

section 215(d)(5) of the FPA, we direct NERC to revise Reliability Standard TOP-001-3, Requirement R10 to require real-time monitoring of non-BES facilities. We believe this is best accomplished by adopting language similar to Reliability Standard IRO-002-4, Requirement R3, which requires reliability coordinators to monitor non-bulk electric system facilities to the extent necessary. NERC can develop an equally efficient and effective alternative that addresses our concerns.³²

36. To be clear, we are not directing that all current “non-BES” facilities that a transmission operator considers worthy of monitoring also be included in the bulk electric system. We believe that such monitoring may result in some facilities becoming part of the bulk electric system through the exception process; however it is conceivable that others may remain non-BES because they are occasional system operating limit exceedance performers that may not qualify as a candidate for inclusion in the BES definition.

C. Removal of Load-Serving Entity Function From TOP-001-3

NOPR

37. NERC proposed the removal of the load-serving entity function from proposed Reliability Standard, TOP-001-3, Requirements R3 through R6, as a recipient of an operating instruction from a transmission operator or balancing authority. NERC supplemented its initial petition with additional explanation for the removal of the load-serving entity function from proposed Reliability Standard TOP-001-3.³³ NERC explained that the proposed standard gives transmission operators and balancing authorities the authority to direct the actions of certain other functional entities by issuing an operating instruction to maintain reliability during real-time operations.

38. In the NOPR, the Commission noted that NERC was required to make a compliance filing in Docket No. RR15-4-000, regarding NERC’s Risk-Based Registration initiative, and that the Commission’s decision on that filing

³² Reliability Standard IRO-002-4, Requirement R3 states: Each Reliability Coordinator shall monitor Facilities, the status of Special Protection Systems, and non-BES facilities identified as necessary by the Reliability Coordinator, within its Reliability Coordinator Area and neighboring Reliability Coordinator Areas to identify any System Operating Limit exceedances and to determine any Interconnection Reliability Operating Limit exceedances within its Reliability Coordinator Area.

³³ The Commission also notes that Reliability Standards TOP-003-3 and IRO-010-2 also include “load-serving entity” as an applicable entity.

will guide any action in this proceeding. On March 19, 2015, the Commission approved, in part, NERC's Risk-Based Registration initiative, but denied, without prejudice, NERC's proposal to eliminate the load-serving entity function from the registry process, finding that NERC had not adequately justified its proposal.³⁴ In doing so, the Commission directed NERC to provide additional information to support this aspect of its proposal to address the Commission's concerns. On July 17, 2015, NERC submitted a compliance filing in response to the March 19 Order.

Comments

39. NERC states that while load-serving entities play a role in facilitating interruptible (or voluntary) load curtailments, that role is to simply communicate requests for voluntary load curtailments and does not necessitate requiring load-serving entities to comply with a transmission operator's or balancing authority's operating instructions issued pursuant to Reliability Standard TOP-001-3. In short, the load-serving entity's role in carrying out interruptible load curtailment is not the type of activity that rises to the level of requiring an operating instruction. EEI and TAPS contend it is appropriate to omit the load-serving entity function from TOP-001-3 applicability. TAPS explains that because the load-serving entity function does not own or operate equipment, the load-serving entity function cannot curtail load or perform other corrective actions subject to reliability standards. Dominion asserts that a load-serving entity does not own or operate bulk electric system facilities or equipment or the facilities or equipment used to serve end-use customers and is not aware of any entity, registered solely as a load-serving entity, which is responsible for operating one or more elements or facilities.

Commission Determination

40. In an October 15, 2015 order in Docket No. RR15-4-001, the Commission accepted a NERC compliance filing, finding that NERC complied with the March 17 Order with respect to providing additional information justifying the removal of the load-serving entity function.³⁵ The Commission also found that NERC addressed the concerns expressed regarding an accurate estimate of the

load-serving entities to be deregistered and the reliability impact of doing so, and how load data will continue to be available and reliability activities will continue to be performed even after load-serving entities would no longer be registered.³⁶ Because the load-serving entity category is no longer a NERC registration function, no further action is required in this proceeding.³⁷

D. Data Exchange Capabilities

41. The Commission approved Reliability Standards COM-001-2 (Communications) and COM-002-4 (Operating Personnel Communications Protocols) in Order No. 808, and noted that in the NOPR underlying that order (COM NOPR) it had raised concerns as to whether Reliability Standard COM-001-2 addresses facilities that directly exchange or transfer data.³⁸ In response to that concern in the COM NOPR, NERC clarified that Reliability Standard COM-001-2 did not need to include requirements regarding data exchange capability because such capability is covered under other existing and proposed standards. Based on that explanation, the Commission decided not to make any determinations in Order No. 808 and stated that it would address the issue in this TOP and IRO rulemaking proceeding.³⁹

NOPR

42. In the NOPR, the Commission stated that facilities for data exchange capabilities appear to be addressed in NERC's TOP/IRO petition. However, the Commission sought additional explanation from NERC regarding how it addresses data exchange capabilities in the TOP and IRO Standards in the following areas: (a) Redundancy and diverse routing; and (b) testing of the alternate or less frequently used data exchange capability.

1. Redundancy and Diverse Routing of Data Exchange Capabilities

NOPR

43. In the NOPR, the Commission agreed that proposed Reliability Standard TOP-001-3, Requirements

³⁶ *Id.*

³⁷ In its response to comments in Docket No. RR15-4-000, NERC stated that, once the Commission approved the proposed deactivation of the load-serving entity registration function, it would make any needed changes to the Reliability Standards through the Reliability Standard Development Process. See January 26, 2016, NERC Motion to File Limited Answer at 6 in Docket No. RR15-4-000.

³⁸ See NOPR, 151 FERC ¶ 61,236 at P 67, citing *Communications Reliability Standards*, Order No. 808, 151 FERC ¶ 61,039 (2015).

³⁹ *Id.* citing Order No. 808, 151 FERC ¶ 61,039 at P 54.

R19 and R20 require some form of "data exchange capabilities" for the transmission operator and balancing authority and that proposed Reliability Standard TOP-003-3 addresses the operational data itself needed by the transmission operator and balancing authority. In addition, the Commission agreed that Reliability Standard IRO-002-4, Requirement R1 requires "data exchange capabilities" for the reliability coordinator and that proposed Reliability Standard IRO-010-2 addresses the operational data needed by the reliability coordinator and that proposed Reliability Standard IRO-002-4 Requirement R4 requires a redundant infrastructure for system monitoring. However, the Commission was concerned that it is not clear whether redundancy and diverse routing of data exchange capabilities were adequately addressed in proposed Reliability Standards TOP-001-3 and IRO-002-4 for the reliability coordinator, transmission operator, and balancing authority and sought explanation or clarification on how the standards address redundancy and diverse routing or an equally effective alternative. The Commission also stated that, if NERC or others believe that redundancy and diverse routing are not addressed, they should address whether there are associated reliability risks of the interconnected transmission network for any failure of data exchange capabilities that are not redundant and diversely routed.

Comments

44. NERC and EEI state that the requirements in the TOP and IRO Reliability Standards covering data exchange are results-based, articulating a performance objective without dictating the manner in which it is met. NERC adds that, in connection with their compliance monitoring activities, NERC and the Regional Entities will review whether applicable entities have met that objective, and will consider whether the applicable entity has redundancy and diverse routing, and whether the applicable entity tests these capabilities. EEI also argues that Reliability Standard EOP-008-1, Requirements R1, R1.2, R1.2.2, R7, and EOP-001-2.1b, Requirements R6 and R6.1 provide specific requirements for maintaining or specifying reliable back-up data exchange capability necessary to ensure BES Reliability and the testing of those capabilities.

45. ERCOT asserts that the Reliability Standards already appropriately provide for redundancy and diversity of routing of data exchange capabilities, as both the existing and proposed standards

³⁴ *North American Electric Reliability Corp.* 150 FERC ¶ 61,213 (2015) (March 19 Order).

³⁵ *North American Electric Reliability Corp.* 153 FERC ¶ 61,024 (2015).

either explicitly or implicitly require responsible entities to ensure availability of data and data exchange capabilities. ERCOT states that, should the Commission seek to provide further clarification on this issue, such clarification should be consistent with existing explicit requirements regarding the redundancy of data exchange capabilities, such as Requirement R4 of Reliability Standard IRO-002-4.

46. ISOs/RTOs and ERCOT explain the suite of currently-effective standards and the proposed TOP and IRO standards establish performance-based requirements for reliability coordinators, balancing authorities, and transmission operators, that create the need for those entities to have diverse and redundantly routed data communication systems. In the event of a failure of data communications, ISOs/RTOs explain that the functional entity should be able to rely on the redundant and diversely routed *voice capabilities* required in the COM standards.

Commission Determination

47. We agree with NERC and other commenters that there is a reliability need for the reliability coordinator, transmission operator and balancing authority to have data exchange capabilities that are redundant and diversely routed. However, we are concerned that the TOP and IRO Standards do not clearly address redundancy and diverse routing so that registered entities will unambiguously recognize that they have an obligation to address redundancy and diverse routing as part of their TOP and IRO compliance obligations. NERC's comprehensive approach to establishing communications capabilities necessary to maintain reliability in the COM standards is applicable to data exchange capabilities at issue here.⁴⁰ Therefore, pursuant to section 215(d)(5) of the FPA, we direct NERC to modify Reliability Standards TOP-001-3, Requirements R19 and R20 to include the requirement that the data exchange capabilities of the transmission operators and balancing authorities

require redundancy and diverse routing. In addition, we direct NERC to clarify that "redundant infrastructure" for system monitoring in Reliability Standards IRO-002-4, Requirement R4 is equivalent to redundant and diversely routed data exchange capabilities.

48. Further, we disagree with commenter arguments that Reliability Standard EOP-008-1 provides alternatives to data exchange redundancy and diverse routing. The NERC standard drafting team that developed the COM standards addressed this issue in the standards development process, responding to a commenter seeking clarification on the relationship between communication capabilities, alternative communication capabilities, primary control center functionality and backup control center functionality. The standard drafting team responded that "Interpersonal Communication and Alternative Interpersonal Communication *are not related to EOP-008*," even though Reliability Standard EOP-008-1 Requirement R1 applies equally to data communications and voice communications.⁴¹ To the extent the standard drafting team asserted that Reliability Standard EOP-008 did not supplant the redundancy requirements of the COM Reliability Standards, we believe the same is true for data communications. Redundancy for data communications is no less important than the redundancy explicitly required in the COM standards for voice communications.

2. Testing of the Alternate or Less Frequently Used Data Exchange Capability

NOPR

49. In the NOPR, the Commission expressed concern that the proposed TOP and IRO Reliability Standards do not appear to address testing requirements for alternative or less frequently used mediums for data exchange to ensure they would properly function in the event that the primary or more frequently used data exchange capabilities failed. Accordingly, the Commission sought comment on whether and how the TOP and IRO Reliability Standards address the testing of alternative or less frequently used data exchange capabilities for the transmission operator, balancing authority and reliability coordinator.

⁴¹ See NERC COM Petition, Exh. M, (Consideration of Comments on Initial Ballot, February 25-March 7, 2011) at 30 (emphasis added).

Comments

50. Commenters assert that the existing standards have sufficient testing requirements. NERC points to Reliability Standard EOP-008-1, Requirement R7, which requires that applicable entities conduct annual tests of their operating plan that demonstrates, among other things, backup functionality. Similarly, EEI cites EOP-008-1 Requirements R1, R1.2, R1.2.2, R7 and EOP-001-2.1b Requirements R6 and R6.1 as providing specific requirements for maintaining and testing of data exchange capabilities. ITC suggests that NERC's proposed Standard TOP-001-3 provides ample assurance that the data exchange capabilities are regularly tested and also points to Reliability Standards EOP-001-2.1b and EOP-008-1 which require entities, including those covered by TOP-001-3, to maintain reliable back-up data exchange capability as necessary to ensure reliable BES operations, and require that such capabilities be thoroughly and regularly tested.

Commission Determination

51. We agree with NERC and other commenters that there is a reliability need for the reliability coordinator, transmission operator and balancing authority to test alternate data exchange capabilities. However, we are not persuaded by the commenters' assertions that the need to test is implied in the TOP and IRO Standards. Rather, we determine that testing of alternative data exchange capabilities is important to reliability and should not be left to what may or may not be implied in the standards.⁴² Therefore, pursuant to section 215(d)(5) of the FPA, we direct NERC to develop a modification to the TOP and IRO standards that addresses a data exchange capability testing framework for the data exchange capabilities used in the primary control centers to test the alternate or less frequently used data exchange capabilities of the reliability coordinator, transmission operator and balancing authority. We believe that the structure of Reliability Standard COM-001-2, Requirement R9 could be a

⁴² In NERC's COM Petition, Exh. M, (Consideration of Comments, Index to Questions, Comments and Responses) at 35, the standard drafting team stated that the "requirement [COM-001-2, Requirement R9 which addresses testing of alternative interpersonal communication] applies to the primary control center" and "EOP-008 applies to the back up control center."

⁴⁰ See, e.g., Order No. 808, 151 FERC ¶ 61,039 at P 8: "NERC stated in its [COM] petition that Reliability Standard COM-001-2 establishes requirements for Interpersonal Communication capabilities necessary to maintain reliability. NERC explained that proposed Reliability Standard COM-001-2 applies to reliability coordinators, balancing authorities, transmission operators, generator operators, and distribution providers. The proposed Reliability Standard includes eleven requirements and two new defined terms, "Interpersonal Communication" and "Alternative Interpersonal Communication," that, according to NERC, collectively provide a comprehensive approach to establishing communications capabilities necessary to maintain reliability."

model for use in the TOP and IRO Standards.⁴³

E. Other Issues Raised by Commenters

1. Emergencies and Emergency Assistance Under Reliability Standard TOP-001-3

52. Reliability Standard TOP-001-3, Requirement R7 requires each transmission operator to assist other transmission operators within its reliability coordinator area, if requested and able, provided that the requesting transmission operator has implemented its comparable emergency procedures. NIPSCO contends that this requirement limits the ability of an adjacent transmission operator that is located along the seam in another reliability coordinator area from rendering assistance in an emergency because Requirement R7 only requires each transmission operator to assist other transmission operators within its reliability coordinator area. NIPSCO points to Reliability Standard IRO-014-3, Requirement R7 which requires each reliability coordinator to assist other reliability coordinators and, according to NIPSCO, a similar requirement in Reliability Standard TOP-001-3 will make the two sets of requirements consistent with each other.

53. In addition, Reliability Standard TOP-001-3, Requirement R8 states:

Each Transmission Operator shall inform its Reliability Coordinator, known impacted Balancing Authorities, and known impacted Transmission Operators of its actual or expected operations that result in, or could result in, an Emergency.

BPA contends that the phrase “could result in” in Requirement R8 of TOP-001-3 is overly broad and suggests corrective language underscored below:

Each Transmission Operator shall inform its Reliability Coordinator, known impacted Balancing Authorities, and known impacted Transmission Operators of its actual or expected operations that result in an Emergency, or could result in an Emergency *if a credible Contingency were to occur.*

As an alternative to changing the language of the requirement, BPA asks the Commission to clarify that it is in the transmission operator’s discretion to determine what “could result” in an emergency, based on the transmission operator’s experience and judgment.

⁴³ 43 COM-001-2, Requirement R9 states: “Each Reliability Coordinator, Transmission Operator, and Balancing Authority shall test its Alternative Interpersonal Communication capability at least once each calendar month. If the test is unsuccessful, the responsible entity shall initiate action to repair or designate a replacement Alternative Interpersonal Communication capability within 2 hours.”

Commission Determination

54. With regard to NIPSCO’s concern, we do not believe that the requirements as written limit the ability of an adjacent transmission operator located along the seam in another reliability coordinator area from rendering assistance in an emergency. We agree with NIPSCO that proposed Reliability Standard TOP-001-3, Requirement R7 requires each transmission operator to assist other transmission operators within its reliability coordinator area and further agree with NIPSCO that proposed Reliability Standard IRO-014-3, Requirement R7 requires each reliability coordinator to assist other reliability coordinators.⁴⁴ In addition, we understand that an adjacent transmission operator in another reliability coordinator area can render assistance when directed to do so by its own reliability coordinator.⁴⁵ Having a similar requirement in Reliability Standard TOP-001-3 compared to Reliability Standard IRO-014-3, Requirement R7 is unnecessary and could complicate the clear decision-making authority NERC developed in the TOP and IRO Reliability Standards. Thus, we determine that no further action is required.

55. With regard to clarification of emergencies in Reliability Standard TOP-001-3, Requirement R8, we do not see a need to modify the language as suggested by BPA. The requirement as written implies that the transmission operator has discretion to determine what could result in an emergency, based on its experience and judgment. In addition, we note that the transmission operators’ required next-day operational planning analysis, real-time assessments and real-time monitoring under the TOP Reliability Standards provide evaluation, assessment and input in determining what “could result” in an emergency.

2. Reliability Coordinator Authority in Next-Day Operating Plans

56. Reliability Standard TOP-002-4, Requirements R2 and R4 require transmission operators and balancing authorities to have operating plans. Reliability Standard TOP-002-4, Requirements R6 and R7 require transmission operators and balancing authorities to provide their operating plans to their reliability coordinators and Reliability Standard IRO-008-2, Requirement R2 requires reliability coordinators to develop a coordinated

⁴⁴ See Reliability Standards TOP-001-3 and IRO-014-3.

⁴⁵ See Reliability Standard IRO-001-4, Requirement R2.

operating plan that considers the operating plans provided by the transmission operators and balancing authorities.

57. NIPSCO is concerned about the absence of any required direct coordination between transmission operators and balancing authorities as well as the absence of any guidance regarding the resolution of potential conflicts between the transmission operator and balancing authority operating plans. NIPSCO contends that the Reliability Standards provide only a limited coordination process in which reliability coordinators are required to notify those entities identified with its coordinated operating plan of their roles. NIPSCO argues that there is no provision for modifications to operating plans based on the reliability coordinator’s coordinated operating plan or based on potential conflicts between the transmission operator and balancing authority operating plans. NIPSCO is concerned that a potential disconnect between operating plans could lead to confusion or a failure of coordination of reliable operations.

Commission Determination

58. We believe that proposed Reliability Standards TOP-002-4 and IRO-008-2 along with NERC’s definition of reliability coordinator address NIPSCO’s concern.⁴⁶ Although the transmission operator and balancing authority develop their own operating plans for next-day operations, both the transmission operator and balancing authority notify entities identified in the operating plans as to their role in those plans. Further, each transmission operator and balancing authority must provide its operating plan for next-day operations to its reliability coordinator.⁴⁷ In Reliability Standard IRO-008-2, Requirement R2, the reliability coordinator must have a coordinated operating plan for next-day operations to address potential SOL and IROL exceedances while considering the operating plans for the next-day provided by its transmission operators

⁴⁶ NERC Glossary of Terms defines the Reliability Coordinator as “The entity that is the highest level of authority who is responsible for the reliable operation of the Bulk Electric System, has the Wide Area view of the Bulk Electric System, and has the operating tools, processes and procedures, including the authority to prevent or mitigate emergency operating situations in both next-day analysis and real-time operations. The Reliability Coordinator has the purview that is broad enough to enable the calculation of Interconnection Reliability Operating Limits, which may be based on the operating parameters of transmission systems beyond any Transmission Operator’s vision.”

⁴⁷ Reliability Standard TOP-002-4 (Operations Planning).

and balancing authorities. Also, Reliability Standard IRO-008-2, Requirement R3 requires that the reliability coordinator notify impacted entities identified in its operating plan as to their role in such plan. Based on the notification and coordination processes of Reliability Standards TOP-002-4 (for the transmission operator and balancing authority) and IRO-008-2 (for the reliability coordinator) for next-day operating plans, as well as the fact that the reliability coordinator is the entity that is the highest level of authority who is responsible for the reliable operation of the bulk electric system, we believe that the reliability coordinator has the authority and necessary next-day operational information to resolve any next-day operational issues within its reliability coordinator area. Accordingly, we deny NIPSCO's request.

3. Reliability Coordinator Authority in Next-Day Operations and the Issuance of Operating Instructions

59. NIPSCO is concerned with the elimination of the explicit requirement in currently-effective Reliability Standard IRO-004-2 that each transmission operator, balancing authority, and transmission provider comply with the directives of a reliability coordinator based on next-day assessment in the same manner as would be required in real-time operating conditions. NIPSCO claims that, while the Reliability Standards appear to address the Commission's concerns regarding directives issued in other than emergency conditions through the integration of the term "operating instruction," the standards only allow for the issuance of directives in real-time. NIPSCO points to Reliability Standard TOP-001-3, Requirements R1 and R2, and IRO-001-4, Requirement R1, where transmission operators, balancing authorities, and reliability coordinators are explicitly given authority and responsibility to issue operating instructions to address reliability in their respective areas. NIPSCO states that "operating instruction" is "clearly limited to real-time operations" as it underscored below:

A command by operating personnel responsible for the *Real-time operation* of the interconnected Bulk Electric System to *change or preserve the state, status, output, or input of an Element* of the Bulk Electric System or Facility of the Bulk Electric System. (A discussion of general information and of potential options or alternatives to resolve Bulk Electric System operating concerns is not a command and is not considered an Operating Instruction.)

NIPSCO contends that there are no clear requirements addressing potential conflicts between operating plans, no clear requirements authorizing the issuance of a directive to address issues identified in next-day planning, and no clear requirement to comply with any directive so issued. NIPSCO is concerned that this raises the possibility that potential next-day problems identified in the operational planning analyses may not get resolved in the next-day planning period because the reliability coordinator's authority to issue operating instructions is limited to real-time operation. According to NIPSCO, this limitation undermines some of the usefulness of the next-day planning and the performance of operational planning analyses.

Commission Determination

60. We do not share NIPSCO's concern. Rather, we believe that, because the reliability coordinator is required to have a coordinated operating plan for the next-day operations, the reliability coordinator will perform its task of developing a coordinated operating plan in good faith, with inputs not only from its transmission operators and balancing authorities, but also from its neighboring reliability coordinators.⁴⁸ A reliability coordinator has a wide-area view and bears the ultimate responsibility to maintain the reliability within its footprint, "including the authority to prevent or mitigate emergency operating situations in both next-day analysis and real-time operations."⁴⁹

61. In addition, we do not agree with NIPSCO's claim that operating instructions are "clearly limited to real-time operations." The phrase "real-time operation" in the definition of operating instruction as emphasized by NIPSCO applies to the entity that issues the operating instruction which is "operating personnel responsible for the Real-time operation." The definition of operating instruction is "[a] command by operating personnel responsible for the Real-time operation of the interconnected Bulk Electric System. . . ." In addition, the time horizons associated with the issuance of or compliance with an operating instruction are not found in the definition of operating instructions, but found in the individual requirement(s) applicable to issuing an operating instruction. For example, Reliability Standard TOP-001-3, Requirements R1

through R6 and IRO-001-4, Requirements R1 through R3 are all requirements associated with the issuance or compliance of operating instructions. In all nine requirements, the defined time horizon is "same-day operations" and "real-time operations."⁵⁰ Accordingly, we deny NIPSCO's request on this issue.

4. Updating Operational Planning Analyses and Real-Time Assessments

62. NIPSCO is concerned that the proposed Reliability Standards are not clear as to whether updates or additional analyses are required. NIPSCO points to Reliability Standards IRO-008-2 and TOP-002-4, which require reliability coordinators to perform—and transmission operators and balancing authorities to have—an operational analysis for the next-day, but do not specify when such analysis must be performed or if it needs to be updated in next-day planning based on any change in inputs. Similarly, NIPSCO asserts that the proposed Reliability Standards require the performance of a real-time assessment every 30 minutes but do not address the need to potentially update operating plans based on changes in system conditions (including unplanned outages of protection system degradation) and do not require the performance of additional real-time assessments or other studies with more frequency based on changes in system conditions. NIPSCO explains that it is not clear if or when, based on the operational planning analysis results, some type of additional study or analysis would need to be undertaken prior to the development of an operating plan. According to NIPSCO, the text of the requirements and the definition do not specifically require additional studies; however, it seems that when issues associated with protection system degradation or outages are identified, further study of these issues would be required and/or additional analyses required to update results as protection system status or transmission or generation outages change.

Commission Determination

63. We do not share NIPSCO's concern. Reliability Standards IRO-008-2 and TOP-002-4 require reliability coordinators to perform and

⁴⁸ See Reliability Standards IRO-008-2, Requirements R1 and R2, and IRO-014-3, Requirement R1.

⁴⁹ See *supra* n. 46.

⁵⁰ NERC's "Time Horizons" document defines "Same-Day Operations" time horizon as "routine actions required within the timeframe of a day, but not real-time" and defines "Real-Time Operations" time horizon as "actions required within one hour or less to preserve the reliability of the bulk electric system." See http://www.nerc.com/files/Time_Horizons.pdf.

transmission operators to have an operational planning analysis to assess whether its planned operations for next-day will exceed any of its SOLs (for the transmission operator) and SOLs/IROLs (for the reliability coordinator). Both are required to have an operating plan(s) to address potential SOL and/or IROL exceedances based on its operational planning analysis results. We believe that, if the applicable inputs of the operational planning analysis change from one operating day to the next operating day, and because an operational planning analysis is an "evaluation of projected system conditions," a new operational planning analysis must be performed to include the change in applicable inputs. Based on the results of the new operational planning analysis for next-day, operating plans may need updating to reflect the results of the new operational planning analysis. Likewise with the real-time assessment, as system conditions change and the applicable inputs to the real-time assessment change, a new assessment would be needed to accurately reflect applicable inputs, as stated in the real-time assessment definition.⁵¹

5. Performing a Real-Time Assessment When Real-Time Contingency Analysis Is Unavailable

64. Reliability Standard TOP-001-3, Requirement R13 requires transmission operators to ensure a real-time assessment is performed at least every 30 minutes. NIPSCO states that NERC's definition of real-time assessment anticipates that real-time assessments must be performed through the use of either an internal tool or third-party service.⁵² NIPSCO believes that compliance with the requirement to perform a real-time assessment should not be dependent on the availability of a system or tool. According to NIPSCO, if a transmission operators' tools are unavailable for 30 minutes or more, they should be permitted to meet the requirement to assess existing conditions through other means.

⁵¹ Real-time assessment is defined as "An evaluation of system conditions using Real-time data to assess existing (pre-Contingency) and potential (post-Contingency) operating conditions. The assessment shall reflect applicable inputs including, but not limited to: Load, generation output levels, known Protection System and Special Protection System status or degradation, Transmission outages, generator outages, Interchange, Facility Ratings, and identified phase angle and equipment limitations. (Real-time Assessment may be provided through internal systems or through third-party services)."

⁵² See *supra* n. 48.

Commission Determination

65. Reliability Standard TOP-001-3, Requirement R13 requires the transmission operator to ensure the assessment is performed at least once every 30 minutes, but does not state that the transmission operator on its own must perform the assessment and does not specify a system or tool. This gives the transmission operator flexibility to perform its real-time assessment. Further supporting this flexibility, NERC's definition of real-time assessment states that a real-time assessment "may be provided through internal systems or through third-party services."⁵³ Therefore, we believe that Reliability Standard TOP-001-3, Requirement R13 does not specify the system or tool a transmission operator must use to perform a real-time assessment. In addition, NERC explains that Reliability Standard TOP-001-3, Requirement R13 and the definition of real-time assessment "do not specify the manner in which an assessment is performed nor do they preclude Reliability Coordinators and Transmission Operators from taking 'alternative actions' and developing procedures or off-normal processes to mitigate analysis tool (RTCA) outages and perform the required assessment of their systems. As an example, the Transmission Operator could rely on its Reliability Coordinator to perform a Real-time Assessment or even review its Reliability Coordinator's Contingency analysis results when its capabilities are unavailable and vice-versa."⁵⁴ Accordingly, we conclude that TOP-001-3 adequately addresses NIPSCO's concern, namely, if a transmission operators' tools are unavailable for 30 minutes or more, the transmission operator has the flexibility to meet the requirement to assess system conditions through other means.

6. Valid Operating Limits

66. IESO is concerned that the revised TOP standards do not compel an entity to verify existing limits or re-establish limits following an event that results in conditions not previously assessed within an acceptable time frame as is specified in the currently-effective Reliability Standard TOP-004-2 Requirement R4.⁵⁵ IESO disagrees that

⁵³ NERC TOP/IRO Petition at 18.

⁵⁴ NERC TOP/IRO Petition, Exh. K (Summary of Development History and Complete Record of Development), Consideration of Comments May 19, 2014 through July 2, 2014) at 61.

⁵⁵ Requirement R4 states: "If a Transmission Operator enters an unknown operating state (*i.e.* any state for which valid operating limits have not been determined), it will be considered to be in an emergency and shall restore operations to respect

this is sufficient because there is no requirement in the Reliability Standard TOP-001-3 standard to derive a new set of limits, particularly transient stability limits, or verify that an existing set of limits continue to be valid for the prevailing conditions within an established timeframe. IESO contends that a real-time assessment is useful only if the system conditions are assessed against a valid set of limits and is unable to verify or re-establish stability-restricted SOLs with which to assess system conditions to address reliability concerns. IESO believes that an explicit requirement to verify or re-establish SOLs when entering into an unstudied state must therefore be imposed to fill this reliability gap.

67. Further, IESO asserts that implementing operating plans to mitigate an SOL exceedance does not require transmission operators to determine a valid set of limits with which to compare the prevailing system conditions (*i.e.* whether or not the limits are exceeded). While the IESO supports performing a real-time assessment every 30 minutes, it asserts that performing an assessment without first validating the current set of limits or re-establishing a new set of limits as the boundary conditions leaves a reliability gap.

Commission Determination

68. We agree with IESO that valid operating limits, including transient stability limits, are essential to the reliable operation of the interconnected transmission network and that a transmission operator must not enter into an unknown operating state. Further, we agree with IESO that Reliability Standard TOP-001-3 has no requirements to derive a new set of limits or verify an existing set of limits for prevailing operating conditions within an established timeframe. However, IESO's concerns regarding the establishment of transient stability operating limits are addressed collectively through proposed Reliability Standard TOP-001-3, certain currently-effective Facilities Design, Connections, and Maintenance (FAC) Reliability Standards and NERC's Glossary of Terms definition of SOLs.

69. In its SOL White Paper, NERC stated that the intent of the SOL concept is to bring clarity and consistency for establishing SOLs, exceeding SOLs, and implementing operating plans to mitigate SOL exceedances.⁵⁶ In

proven reliable power system limits within 30 minutes."

⁵⁶ NERC Petition, Exh. E (White Paper on System Operating Limit Definition and Exceedance Clarification) at 1. NIPSCO requests clarification as to how NERC's SOL White Paper can be used in

addition, “transient stability ratings” are included in the SOL definition. Further, in the SOL White Paper, NERC states that the “concept of SOL determination is not complete without looking at the approved NERC FAC standards FAC-008-3, FAC-011-2 and FAC-014-2.”⁵⁷ Specific to IESO’s concerns of establishing transient stability limits, we agree with NERC that approved Reliability Standard FAC-011-2, Requirement R2 requires that the reliability coordinator’s SOL methodology include a requirement that SOLs provide a certain level of bulk electric system performance including among other things, that the “BES shall demonstrate transient, dynamic and voltage stability” and that “all Facilities shall be within their . . . stability limits” for both pre- and post-contingency conditions.⁵⁸ In addition, we note that currently-effective Reliability Standard FAC-011-2, Requirement R2.1 states that “[i]n the determination of SOLs, the BES condition used shall reflect current or expected system conditions and shall reflect changes to system topology such as Facility outages.”⁵⁹

70. With respect to Reliability Standard TOP-001-3, we agree with NERC that Requirement R13 specifies that transmission operators must perform a real-time assessment at least once every 30 minutes, which by

definition is an evaluation of system conditions to assess existing and potential operating conditions. The real-time assessment provides the transmission operator with the necessary knowledge of the system operating state to initiate an operating plan, as specified in Requirement R14, when necessary to mitigate an exceedance of SOLs. In addition, the SOL White Paper provides technical guidance for including timelines in the required operating plans to return the system to within prescribed ratings and limits.⁶⁰ Accordingly, we conclude that the establishment of transient stability operating limits is adequately addressed collectively through proposed Reliability Standard TOP-001-3, currently-effective Reliability Standards FAC-011-2 and FAC-014-2 and NERC’s Glossary of Terms definition of SOLs.⁶¹

III. Information Collection Statement

71. The collection of information contained in this Final Rule is subject to review by the Office of Management and Budget (OMB) regulations under section 3507(d) of the Paperwork Reduction Act of 1995 (PRA).⁶² OMB’s regulations require approval of certain informational collection requirements imposed by agency rules.⁶³ Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing

requirements of a rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

Public Reporting Burden: The number of respondents below is based on an estimate of the NERC compliance registry for the balancing authority, transmission operator, generator operator, distribution provider, generator owner, load-serving entity, purchasing-selling entity, transmission service provider, interchange authority, transmission owner, reliability coordinator, planning coordinator, and transmission planner functions. The Commission based its paperwork burden estimates on the NERC compliance registry as of May 15, 2015. According to the registry, there are 11 reliability coordinators, 99 balancing authorities, 450 distribution providers, 839 generator operators, 80 purchasing-selling entities, 446 load-serving entities, 886 generator owners, 320 transmission owners, 24 interchange authorities, 75 transmission service providers, 68 planning coordinators, 175 transmission planners and 171 transmission operators. The estimates are based on the change in burden from the current standards to the standards approved in this Final Rule. The following table illustrates the burden to be applied to the information collection:

RM15–16–000 (TRANSMISSION OPERATIONS RELIABILITY STANDARDS, INTERCONNECTION RELIABILITY OPERATIONS AND COORDINATION RELIABILITY STANDARDS)

	Number of respondents ⁶⁴	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ⁶⁵	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC–725A						
TOP–001–3	196 (TOP & BA)	1	196	96 hrs., \$6,369	18,816 hrs., \$1,248,441.	96 hrs., \$6,369.
TOP–002–4	196 (TOP & BA)	1	196	284 hrs., \$18,843	55,664 hrs., \$3,693,306.	284 hrs., \$18,843.
TOP–003–3	196 (TOP & BA)	1	196	230 hrs., \$15,260	45,080 hrs., \$2,991,058.	230 hrs., \$15,260.
Sub-Total for FERC–725A.	123,252 hrs., \$7,932,806.	

determining compliance. NIPSCO requests that any substantive content that is treated as containing enforceable compliance requirements be filed with the Commission for approval. NERC developed the SOL White Paper as a guidance document which provides links between relevant reliability standards and reliability concepts to establish a common understanding necessary for developing effective operating plans to mitigate SOL

exceedances. Guidelines are illustrative but not mandatory and enforceable compliance requirements. See, e.g. *North American Electric Reliability Corp.*, 143 FERC ¶ 61,271, at P 15 (2013). Accordingly, we see no need for further revisions to the Reliability Standards to incorporate the SOL White Paper as requested by NIPSCO.

⁵⁷ NERC Petition, Exh. E at 1.

⁵⁸ *Id.* at 2. See also Reliability Standard FAC-011-2, Requirement R2.

⁵⁹ Reliability Standard FAC-011-1, Requirement R2.1 (emphasis added).

⁶⁰ NERC Petition at 57–58.

⁶¹ See Reliability Standard FAC-014-2, Requirement R2.

⁶² 44 U.S.C. 3507(d) (2012).

⁶³ 5 CFR 1320.11.

RM15-16-000 (TRANSMISSION OPERATIONS RELIABILITY STANDARDS, INTERCONNECTION RELIABILITY OPERATIONS AND COORDINATION RELIABILITY STANDARDS)—Continued

	Number of respondents ⁶⁴	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ⁶⁵	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC-725Z						
IRO-001-4 ⁶⁶	177 (RC & TOP) ...	1	177	0 hrs. \$0	0 hrs. \$0	0 hrs. \$0.
IRO-002-4	11 (RC)	1	11	24 hrs., \$1,592	264 hrs., \$17,516 ..	24 hrs., \$1,592.
IRO-008-2	11 (RC)	1	11	228 hrs., \$15,127	2,508 hrs., \$166,405.	228 hrs., \$15,127.
IRO-010-2	11 (RC)	1	11	36 hrs., \$2,388	396 hrs., \$26,274 ..	36 hrs., \$2,388.
IRO-014-3	11 (RC)	1	11	12 hrs., \$796	132 hrs., \$8,758	12 hrs., \$796.
IRO-017-1	180 (RC, PC, & TP).	1	180	218 hrs., \$14,464	39,240 hrs., \$2,603,574.	218 hrs., \$14,464.
Sub-Total for FERC-725Z.	42,540 hrs., \$2,822,529.00.
Retirement of current standards currently in FERC-725A.	457(RC, TOP, BA, TSP, LSE, PSE, & IA).	1	457	-223 hrs., -\$14,796	-101,911 hrs., -\$6,761,794.	-223 hrs., -\$14,796.
NET TOTAL of NOPR in RM15-16.	63,881 hrs., \$3,993,540.

Title: FERC-725Z, Mandatory Reliability Standards: IRO Reliability Standards, and FERC-725A, Mandatory Reliability Standards for the Bulk-Power System.

Action: Proposed Changes to Collections.

OMB Control Nos: 1902-0276 (FERC-725Z); 1902-0244 (FERC-725A).

Respondents: Business or other for-profit and not-for-profit institutions.

Frequency of Responses: On-going.

72. Necessity of the Information and Internal review: The Commission has reviewed the requirements of Reliability Standards TOP-001-3, TOP-002-4, TOP-003-3, IRO-001-4, IRO-002-4, IRO-008-2, IRO-010-2, IRO-014-3, and IRO-017-1 and made a determination that the standards are necessary to implement section 215 of the FPA. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

73. Interested persons may obtain information on the reporting

requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, email: DataClearance@ferc.gov, phone: (202) 502-8663, fax: (202) 273-0873].

74. Comments on the requirements of this rule may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: oir_submission@omb.eop.gov. Please reference OMB Control Nos. 1902-0276 (FERC-725Z) and 1902-0244 (FERC-725A) in your submission.

IV. Environmental Analysis

75. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.⁶⁷ The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the

regulations being amended.⁶⁸ The actions approved herein fall within this categorical exclusion in the Commission's regulations.

V. Regulatory Flexibility Act Analysis

76. The Regulatory Flexibility Act of 1980 (RFA) generally requires a description and analysis of Proposed Rules that will have significant economic impact on a substantial number of small entities.⁶⁹ The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.⁷⁰ The SBA revised its size standard for electric utilities (effective January 22, 2014) to a standard based on the number of employees, including affiliates (from a standard based on megawatt hours).⁷¹ Reliability Standards TOP-001-3, TOP-002-4, TOP-003-3, IRO-001-4, IRO-002-4, IRO-008-2, IRO-010-2, IRO-014-3, and IRO-017-1 are expected to impose an additional burden on 196 entities (reliability coordinators, transmission operators, balancing authorities, transmission service providers, and planning authorities). Comparison of the applicable entities with the Commission's small business data indicates that approximately 82 of these entities are small entities that will be

⁶⁴ the number of respondents is the number of entities for which a change in burden from the current standards to the proposed exists, not the total number of entities from the current or proposed standards that are applicable.

⁶⁵ The estimated hourly costs (salary plus benefits) are based on Bureau of Labor Statistics (BLS) information, as of April 1, 2015, for an electrical engineer (\$66.35/hour). These figures are available at http://blsgov/oes/current/naics3_221000.htm#17-0000.

⁶⁶ IRO-001-4 is a revised standard with no increase in burden.

⁶⁷ *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regulations Preambles 1986-1990 ¶ 30,783 (1987).

⁶⁸ 18 CFR 380.4(a)(2)(ii).

⁶⁹ 5 U.S.C. 601-12.

⁷⁰ 13 CFR 121.101.

⁷¹ SBA Final Rule on "Small Business Size Standards: Utilities," 78 FR 77343 (Dec. 23, 2013).

affected by the proposed Reliability Standards.⁷² As discussed above, Reliability Standards TOP-001-3, TOP-002-4, TOP-003-3, IRO-001-4, IRO-002-4, IRO-008-2, IRO-010-2, IRO-014-3, and IRO-017-1 will serve to enhance reliability by imposing mandatory requirements for operations planning, system monitoring, real-time actions, coordination between applicable entities, and operational reliability data. The Commission estimates that each of the small entities to whom the proposed Reliability Standards TOP-001-3, TOP-002-4, TOP-003-3, IRO-001-4, IRO-002-4, IRO-008-2, IRO-010-2, IRO-014-3, and IRO-017-1 applies will incur costs of approximately \$147,364 (annual ongoing) per entity. The Commission does not consider the estimated costs to have a significant economic impact on a substantial number of small entities.

VI. Document Availability

77. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

78. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

79. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

⁷² The Small Business Administration sets the threshold for what constitutes a small business. Public utilities may fall under one of several different categories, each with a size threshold based on the company's number of employees, including affiliates, the parent company, and subsidiaries. For the analysis in this NOPR, we are using a 750 employee threshold for each affected entity to conduct a comprehensive analysis.

VII. Effective Date and Congressional Notification

80. This final rule is effective January 26, 2016. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.
Issued: November 19, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-30110 Filed 11-25-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF DEFENSE

Department of the Navy

[No. USN-2013-0011]

RIN 0703-AA92

32 CFR Part 776

Professional Conduct of Attorneys Practicing Under the Cognizance and Supervision of the Judge Advocate General; Correction

AGENCY: Department of the Navy, DoD.

ACTION: Final rule; correction.

SUMMARY: On November 4, 2015, the Department of the Navy (DoN) published a final rule to comport with current policy as stated in JAG Instruction 5803.1 (Series) governing the professional conduct of attorneys practicing under the cognizance and supervision of the Judge Advocate General. The content of one of its CFRs is better codified as an appendix, and this correction amends the CFR accordingly.

DATES: This correction is effective December 4, 2015.

FOR FURTHER INFORMATION CONTACT: Commander Noreen A. Hagerty-Ford, JAGC, U.S. Navy, Office of the Judge Advocate General (Administrative Law), Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374-5066, telephone: 703-614-7408.

SUPPLEMENTARY INFORMATION: The DoN published a rule at 80 FR 68388 on November 4, 2015, to revise 32 CFR part 776, to comport with current policy as stated in JAG Instruction 5803.1 (Series) governing the professional conduct of attorneys practicing under the cognizance and supervision of the Judge Advocate General. The content of

§ 776.94 is more appropriate as an appendix, and this correction amends the CFR accordingly, redesignating § 776.94 as an appendix to subpart D. In addition, because § 776.94 becomes an appendix to its subpart, DoN is redesignating § 776.95 in the November 4 rule as § 776.94.

Correction

In FR Rule Doc. 2015-26982 appearing on page 68388 in the **Federal Register** of Wednesday, November 4, 2015, the following corrections are made:

- 1. On page 68390, in the first column, third line, revise "776.94 Outside Law Practice Questionnaire and Request." to read "Appendix to Subpart D of Part 776—Outside Law Practice Questionnaire and Request." and in the seventh line, revise "776.95 Relations with Non-USG Counsel." to read "776.94 Relations with Non-USG Counsel.";
- 2. On page 68408, in the third column, second line, revise "§ 776.94 of this part" to read "appendix to subpart D of part 776";
- 3. On page 68408, in the third column, revise the section heading "§ 776.94 Outside Law Practice Questionnaire and Request." to read "Appendix to Subpart D of Part 776—Outside Law Practice Questionnaire and Request."; and
- 4. On page 68409, in the second column under the Subpart E heading, revise "§ 776.95 Relations with Non-USG Counsel." to read "§ 776.94 Relations with Non-USG Counsel.".

Dated: November 20, 2015.

N.A. Hagerty-Ford,

Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015-30190 Filed 11-25-15; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

34 CFR Parts 600, 602, 603, 668, 682, 685, 686, 690, and 691

[Docket ID ED-2010-OPE-0004]

RIN 1840-AD02

Program Integrity Issues

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Final regulations; clarification and additional information.

SUMMARY: On October 29, 2010, the Department of Education published in the **Federal Register** final regulations for improving integrity in the programs authorized under title IV of the Higher

Education Act of 1965, as amended (HEA) (October 29, 2010, final regulations). The preamble to those regulations was revised in a **Federal Register** notice of March 22, 2013. This document clarifies and provides additional information about the October 29, 2010, final regulations.

DATES: This clarification and additional information apply to the October 29, 2010, regulations (75 FR 66832), which were generally effective July 1, 2011.

FOR FURTHER INFORMATION CONTACT: Scott Filter, U.S. Department of Education, 1990 K Street NW., Room 8014, Washington, DC 20006. Telephone: (202) 219-7031 or by email at Scott.Filter@ed.gov.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the contact person listed in this section.

SUPPLEMENTARY INFORMATION: The October 29, 2010, final regulations (75 FR 66832) amended the regulations for Institutional Eligibility Under the HEA, the Secretary's Recognition of Accrediting Agencies, the Secretary's Recognition Procedures for State Agencies, the Student Assistance General Provisions, the Federal Family Education Loan (FFEL) Program, the William D. Ford Federal Direct Loan Program, the Teacher Education Assistance for College and Higher Education (TEACH) Grant Program, the Federal Pell Grant Program, and the Academic Competitiveness Grant (AGC) and the National Science and Mathematics Access to Retain Talent Grant (National Smart Grant) Programs. On March 22, 2013 (78 FR 17598), the Department revised the preamble discussion to the October 29, 2010, final regulations in response to the remand in *Ass'n of Private Sector Colls. & Univs. (APSCU) v. Duncan*, 681 F.3d 427 (D.C. Cir. 2012) (78 FR 17598). This document clarifies and provides additional information about the October 29, 2010, final regulations in accordance with a subsequent district court order in *APSCU v. Duncan*, 70 F. Supp. 3d 446 (D.D.C. 2014).

Electronic Access to This Document

The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal

Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys.

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Clarification and Additional Information

Graduation-Based and Completion-Based Compensation. In *APSCU v. Duncan*, 70 F. Supp. 3d 446 (D.D.C. 2014), the district court determined that the Department had not adequately explained or supported its decision to ban compensation to an educational institution's recruiters of students based on the students' graduation from or completion of educational programs offered by the institution. The regulations at 34 CFR 668.14(b)(22), implementing the statutory ban on enrollment-based compensation to recruiters of students, 20 U.S.C. 1094(a)(20), do not contain a ban on graduation-based or completion-based compensation. Although the Department removed the safe harbor that permitted certain graduation-based or completion-based compensation and previously indicated that it interpreted the amended regulations to ban such compensation, *see, e.g.*, 75 FR 66874, the Department hereby indicates, in response to the district court's decision, that the Department has reconsidered its interpretation and does not interpret the regulations to proscribe compensation for recruiters that is based upon students' graduation from, or completion of, educational programs. Correspondingly, the Department will not view the references in the regulations to recruiter enrollment activities that may occur "through completion" by a student of an educational program, 34 CFR 668.14(b)(22)(iii)(B) (introduction), and (iii)(B)(2)(ii), as prohibiting graduation-based or completion-based compensation to recruiters.

The Department has changed its interpretation because, at this time, it lacks sufficient evidence to demonstrate that schools are using graduation-based or completion-based compensation as a proxy for enrollment-based

compensation. In assessing the legality of a compensation structure, the Department will focus on the substance of the structure rather than on the label given the structure by an institution. Thus, although compensation based on students' graduation from, or completion of, educational programs is not *per se* prohibited, the Department reserves the right to take enforcement action against institutions if compensation labeled by an institution as graduation-based or completion-based compensation is merely a guise for enrollment-based compensation, which is prohibited. Compensation that is based upon success in securing enrollments, even if one or more other permissible factors are also considered, remains prohibited.

Impact on Minority Enrollment. The district court found that the Department failed to respond adequately to two commenters who questioned whether the amended regulations "might adversely affect minority outreach." *Id.* at 456; *see also APSCU v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012). The district court remanded the matter for the Department to address "the potential effect on minority recruitment, *i.e.*, whether minority enrollment could decline under the new regulations." *APSCU v. Duncan*, 70 F. Supp. 3d at 456.

The particular comments were included in two submissions that also included comments on other aspects of the proposed regulations. The first commenter asked:

Can schools increase compensation to personnel involved in diversity outreach programs for successfully assembling a diverse student body? Does the Department intend to foreclose schools' ability to compensate their staffs for successfully managing outreach programs for students from disadvantaged backgrounds like the eight TRIO programs administered by the Department?

DeVry to Jessica Finkel (August 1, 2010), AR—3386. The second commenter asked:

How will the new regulations apply to employees who are not involved in general student recruiting, but who are involved in recruiting certain types of students? Examples would include college coaches who recruit student athletes, and employees in college diversity offices who recruit minority students. We see nothing in the proposed regulations that excludes these types of employees from the scope of the incentive compensation law. Thus, coaches who recruit student athletes would not be able to be compensated, in any part, on the number or caliber of students they recruited or the volume of university revenue generated by the teams on which the athletes played. Similarly, employees responsible for

recruiting minority students would not be able to be compensated, in any part, on an increase in minority students who enroll at the college. We believe both of these practices are widespread and promote desirable goals, and are another example of how unclear, and potentially far-reaching, the Department's proposed regulations are. We request the Department's guidance on how to apply the law to compensation of these particular practices.

Career Education Corporation to Jessica Finkel (August 1, 2010) AR-3308.

The ban on the payment of incentive compensation precludes institutions from paying their recruiters, or enrollment counsellors, bonuses based upon the number of students they enroll, irrespective of the student's minority or other status and irrespective of whether the goal of the recruiters is to increase diversity. The statute and accompanying regulations address the powerful incentive that such pay provides for the recruiter to close the sale—whether or not the training offered is really what the individual needs. The ban exists to shelter all students from abusive practices that have historically occurred when recruiters were rewarded based on the number of students enrolled, as opposed to a more fulsome evaluation of a student's particular needs and an institution's capacity to meet those needs. Congress had no basis to expect (nor do we) that recruiters paid by incentive-based compensation who focus their recruitment efforts on minorities (or any other group, including athletes) would disregard their personal gain as they persuade individuals to enroll.

Minority student enrollment is not a goal in itself; minority student success matters, not just enrollment. Although the ban on incentive compensation may cause minority student enrollment numbers to decline, we expect that the minority students who do ultimately enroll will have a better chance at success, because they will have enrolled based on a decision made free of pressured sales tactics, and they presumably would be a good fit for the school they select. Indeed, as the Department has stated, “[m]inority and low income students are often the targeted audience of recruitment abuses, and our regulatory changes are intended to end that abuse. It is our expectation and objective that enrollment of students, including minority students, against their best educational interests would be reduced with the elimination of improper incentive compensation.” 78 FR 17600 (2013).

In response to the district court's remand and the commenters' questions, the Department hereby acknowledges

that the amended regulations could negatively affect outreach and enrollment generally, as well as student outreach that is specifically targeted at promoting diversity, which could result in fewer minority students recruited and enrolled. However, neither the statute nor any information presented by the commenters or in the administrative record provides a basis for treating a recruitment program directed at minority students differently than an institution's general or other specific recruitment programs. And, as explained below, there are ample ways for schools to maintain or increase their enrollment of minority students (and other students) that are likely to achieve a positive result from their enrollment besides providing compensation based on recruiters' enrollment numbers.

For several reasons, estimating how significant the effect on minority recruitment or enrollment may be is difficult. A robust assessment of the effect of incentive-based compensation on minority outreach and enrollment would require a comparison between schools with similar characteristics, one group of which paid its recruiters with incentive-based compensation for minority enrollments, and the other group which did not. We have not conducted such an experiment, and we have found no such study or analysis of this issue in the literature.

Another way to estimate the effect of the incentive compensation ban on institutions' recruitment of minority students would be to estimate how schools that pay incentive compensation to staff who recruit minorities would change their practices as a result of the ban on enrollment-based incentive compensation. If recruiting minority students is more difficult than recruiting other students, we expect schools would need to take steps to achieve the same level of success achieved by paying recruiters compensation based on the number of minority students they enroll, and that this would include, among other things, hiring more recruiters or changing their salary schedules in order to attract more talented recruiters, or both. We believe that schools that devote special efforts to recruit minority students and that used incentive compensation payments to drive those efforts in the past devoted significant resources to those payments, though we have no data quantifying those costs. We would expect those schools to redirect those resources if they wanted to ensure continued success in recruiting and enrolling minority students. Such steps could include increasing salaries to attract more capable recruiters or developing

new or enhancing existing outreach activities. We expect that those for-profit schools that currently enroll substantial numbers and high percentages of minority students would take such steps.

Accepting for purposes of this analysis the assertion that efforts to recruit minority students are specialized and thus require more resources than ordinary recruiting efforts generally used, we consider it reasonable to expect that some schools may conclude that the cost of those resources outweighs the benefits of maintaining or increasing special recruiting efforts for minority students. The group of schools more likely to choose not to allocate the added resources needed for specialized minority recruiting would appear to be those schools which depend less on minority enrollments, specifically: For-profit schools that offer longer programs (2 year and 4 year programs), and public or non-profit institutions. Minority enrollment might decline at some institutions in this group, because institutions in this group, compared to those for-profit institutions offering shorter programs, appear to depend less on minority enrollment than for-profit institutions offering shorter programs. They would be more likely to consider the expenses of increasing salaries or adding staff for specialized minority recruiting to outweigh the benefits of maintaining their minority recruiting efforts at the same level as before the ban. Nevertheless, the size of reductions in minority enrollments that would be fairly attributable to the ban—as opposed to other causes—remains difficult to predict.

Next, we would need to determine to what extent recruiters engaged under any revised schemes would be likely to succeed in recruiting minority students without the sales tactics that the ban is intended to deter. Last, for schools affected by the ban, we would need to distinguish those effects that are fairly attributed to the incentive compensation ban itself from those effects that could be attributed to other factors such as competitors' minority student recruitment efforts or a program's performance under the Department's gainful employment regulations, which apply to the same kinds of programs at for-profit schools that are being promoted by such recruiters. No data exists from which one can make these determinations.

While there is uncertainty about the size of any adverse effect of the ban on institutions' recruitment of minority students, the evidence that is available does not support an assertion that the Department's rule will seriously

undermine efforts to obtain educational diversity. In “For Profit Higher Education: The Failure to Safeguard the Federal Investment and Ensure Student Success,”¹ the Senate HELP Committee referred to GAO’s 2011 study of student outcomes at for-profit schools. In that study, GAO observed that African American and Hispanic students already comprised some 48 percent of all students enrolled in for-profit schools—more than the percent of students enrolled at for-profit schools who are non-Hispanic white (46 percent; Asian-Pacific Islanders and other non-Hispanic white students account for the other 6 percent of for-profit school students), double the percentage of students enrolled at private non-profit schools who are minority students, and far more than the percentage (28 percent) of students enrolled in public institutions who are minority students.² In addition, we note that the pattern observed in the GAO report continued in succeeding years, and was reflected at each credential level.³ These data demonstrate that for-profit schools at each credential level already enroll disproportionately large percentages of minority students compared to non-minority students and therefore call into question one of the commenter’s claims that minority recruitment efforts by the for-profit institutions to which the ban applies are needed to successfully assemble a diverse student body. (AR –3386, 3429, 3430). For-profit schools clearly already have diverse student bodies, dramatically different than student bodies at public or private non-profit institutions.

¹ For Profit Higher Education: The Failure to Safeguard the Federal Investment and Ensure Student Success, Senate HELP Committee, Majority Committee Staff Report, July 30, 2012, at 46, 47.

² *Id.*

³ Smith, Peter & Parrish, Leslie (2014), Do Students of Color Profit from For-Profit College? Poor Outcomes and High Debt Hamper Attendees’ Futures, Center for Responsible Lending, at 9, available at <http://higherednotdebt.org/tag/center-for-responsible-lending>. 2011 data show that of African Americans who enroll in schools that offer only short-term (non-degree) programs (less than 2-year), 91 percent do so at for-profit schools; of Hispanic students who enrolled in those schools, 85 percent enrolled at for-profit schools, but of white students in such programs, only 76 percent enrolled at for-profit schools. Of students who enroll at 2-year institutions, the pattern continues: 10 percent of African Americans and 8 percent of Hispanic students who enroll in 2-year institutions do so at for-profit schools, while only 5 percent of white students who enroll in 2-year schools do so at for-profit schools. Of African American and Hispanic students who enroll at 4-year institutions, 28 percent and 15 percent, respectively, enroll at for-profit schools, while only 10 percent of white students who enroll at 4-year institutions do so. *Id.* at 9.

Although the data show that for-profit schools already enrolled a significant percentage of minority students, estimating whether this diversity has been the result of the payment of incentive compensation, and whether the incentive compensation ban will negatively affect this already very diverse enrollment, would require a reliable estimate of the prevalence of incentive-based compensation in recruiting efforts directed at these minority students, as opposed to other students. The Department has no evidence to show what percentage of these minority students were enrolled on account of incentive-based compensation, as opposed to other features of for-profit schools.⁴ However, we do know that the percentage of enrolled students who were minority students in degree-granting institutions increased from fall 2010 to fall 2013, after the regulations became effective: minority enrollment as a percentage of all enrollment increased from 39.5 percent in 2010 to 43.1 percent in 2013.⁵ Similarly, minority student enrollment as a percentage of total

⁴ Although the percentage of revenue spent by for-profit institutions on advertising and recruiting, the numbers of recruiters, and the abusive recruiting tactics used by for-profit schools have been reported in, e.g., the HELP committee report, that report simply states variously that “some companies” or “many companies” used the practice. *Id.*, at 3, 4, 50, 51. A commenter asserted that incentive compensation payments are “widespread” (AR 3308).

⁵ National Center for Education Statistics (NCES) (2014) Digest of Education Statistics (Table 306.50) available at http://nces.ed.gov/programs/digest/d14/tables/dt14_306.50.asp, and NCES (2011) Digest of Education Statistics (Table 241), available at http://nces.ed.gov/programs/digest/d11/tables/dt11_241.asp. The numbers of students are those identified as the “fall enrollment” students, from the Integrated Postsecondary Education Data System (IPEDS) maintained by the National Center for Education Statistics and derived from periodic reports from postsecondary institutions. The fall enrollment is the annual component of IPEDS that collects data on the number of students enrolled in the fall at postsecondary institutions. Students reported are those enrolled in courses creditable toward a degree or other formal award; students enrolled in courses that are part of a vocational or occupational program, including those enrolled in off-campus or extension centers; and high school students taking regular college courses for credit. Institutions report annually the number of full—and part-time students, by gender, race/ethnicity, and level (undergraduate, graduate, first-professional); the total number of undergraduate entering students (first-time, full-and part-time students, transfer-ins, and non-degree students); and retention rates. In even-numbered years, data are collected for State of residence of first-time students and for the number of those students who graduated from high school or received high school equivalent certificates in the past 12 months. Also in even-numbered years, 4-year institutions are required to provide enrollment data by gender, race/ethnicity, and level for selected fields of study. In odd-numbered years, data are collected for enrollment by age category by student level and gender. <http://nces.ed.gov/ipeds/glossary/?charindex=F>

enrollments in for-profit degree-granting institutions increased from fall 2010 to fall 2013: from 49.3 percent (4-year institutions) and 56 percent (2-year institutions) in 2010 to 54 percent (4-year institutions) and 61 percent (2-year institutions) in 2013.⁶ These changes may be the result of many factors that are difficult to weigh or distinguish with respect to their effects on enrollment, including that institutions have already made changes needed to recruit in a manner compliant with the ban. However, these data do not support a claim that the incentive compensation ban has in fact negatively affected minority enrollment.

The Department continues to support all lawful efforts to promote diversity in enrollment, and nothing in the amended regulations changes that fact. Schools can implement effective recruiting programs generally, and effective minority outreach programs specifically, without compensating recruiters based on the number of students enrolled. Considerable efforts have already been made by this and other agencies, and non-governmental entities, to explore techniques to reach minority students and persuade them that postsecondary education is both available to them and worth their investment.⁷ It is beyond the scope of this clarification and additional information to incorporate that literature or summarize the findings. The commenters did not seek Department guidance on how to conduct outreach to minority students, and any institution interested in methods of such outreach can access resources and information on methods of outreach through Department and other sources.⁸ The commenters directly asked only for guidance about how to apply the compensation ban to minority recruitment practices, and we respond simply that the ban prohibits compensating those performing outreach and recruitment activities for minority students on the basis of the number of students enrolled. As we note above, minority students are often the target of recruitment practices that lead

⁶ *Id.* Some of the data cited here post-dates the promulgation of the final regulations, but the Department is including such data for illustrative purposes.

⁷ In addition, as one commenter notes, Title IV of the Higher Education Act authorizes the Trio Grant Programs to finance activities to encourage “qualified individuals from disadvantaged backgrounds” to prepare for and enroll in postsecondary education, and that for-profit institutions qualify for grants under these programs. 20 U.S.C. 1070a–11 *et seq.*

⁸ See, e.g., list of resources on minority student outreach available through the Department’s Web site: <http://findit.ed.gov/search?utf8=%E2%9C%93&affiliate=ed.gov&query=minority+outreach+>

to enrollment in courses of study that do not further their educational or vocational goals and are contrary to their economic interests, and the rule is intended to reduce that occurrence.

We acknowledge that some institutions may need to revise their diversity outreach operations if they depend more on the financial motivation of the recruiter than the design of the recruiting or outreach plan or the relative value of the programs touted by the recruiter. The regulations address only the payment of incentives to recruiters, not the activities the school requires recruiters to perform. Thus, the regulations do not prevent an institution from holding a recruiter accountable for implementing an effective recruiting or minority outreach plan adopted by the institution.

In sum, the Department acknowledges that the amended regulations may result in some negative impact on minority recruitment and enrollment. But neither the statute nor any information presented by the commenters or in the administrative record provides a basis for treating a recruitment program directed at minority students differently than an institution's general or other specific recruitment programs.

List of Subjects

34 CFR Part 600

Colleges and universities, Foreign relations, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Student aid, Vocational education.

34 CFR Part 602

Colleges and universities, Reporting and recordkeeping requirements.

34 CFR Part 603

Colleges and universities, Vocational education.

34 CFR Part 668

Administrative practice and procedure, Aliens, Colleges and universities, Consumer protection, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Selective Service System, Student aid, Vocational education.

34 CFR Part 682

Administrative practice and procedure, Colleges and universities, Loan programs-education, Reporting and recordkeeping requirements, Student aid, Vocational education.

34 CFR Part 685

Administrative practice and procedure, Colleges and universities,

Loan programs-education, Reporting and recordkeeping requirements, Student aid, Vocational education.

34 CFR Part 686

Administrative practice and procedure, Colleges and universities, Education, Elementary and secondary education, Grant programs-education, Reporting and recordkeeping requirements, Student aid.

34 CFR Part 690

Colleges and universities, Education of disadvantaged, Grant programs-education, Reporting and recordkeeping requirements, Student aid.

34 CFR Part 691

Colleges and universities, Elementary and secondary education, Grant programs-education, Student aid.

Dated: November 23, 2015.

Arne Duncan,
Secretary of Education.

[FR Doc. 2015-30158 Filed 11-25-15; 8:45 am]

BILLING CODE 4000-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2015-0686; FRL-9939-38-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revision to the Definition of Volatile Organic Compound

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the Commonwealth of Virginia's State Implementation Plan (SIP). The revision adds a compound to the list of substances not considered to be volatile organic compounds (VOCs). EPA is approving this revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: This rule is effective on January 26, 2016 without further notice, unless EPA receives adverse written comment by December 28, 2015. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2015-0686 by one of the following methods:

A. www.regulations.gov. Follow the on-line instructions for submitting comments.

B. *Email:* fernandez.cristina@epa.gov.

C. *Mail:* EPA-R03-OAR-2015-0686, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2015-0686. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through www.regulations.gov or email. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in

www.regulations.gov or may be viewed during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814-2166, or by email at shandruk.irene@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Tropospheric ozone, commonly known as smog, is formed when VOCs and nitrogen oxides react in the atmosphere in the presence of sunlight. Because of the harmful health effects of ozone, EPA and state governments limit the amount of VOCs that can be released into the atmosphere. VOCs have different levels of reactivity, that is, some VOCs react slowly or form less ozone, and therefore, changes in their emissions have limited effects on local or regional ozone pollution episodes. It has been EPA's policy that VOCs with a negligible level of reactivity should be excluded from the regulatory definition of VOC contained at 40 CFR 51.100(s) so as to focus control efforts on compounds that do significantly increase ozone concentrations. This is accomplished by adding the substance to a list of compounds not considered to be VOCs, and thus, excluded from the definition of VOC. EPA believes that exempting such compounds creates an incentive for industry to use negligibly reactive compounds in place of more highly reactive compounds that are regulated as VOCs. On March 27, 2014 (79 FR 17037), EPA revised the definition of VOC contained in 40 CFR 51.100 to exclude one substance from the definition of VOC. The compound excluded from the definition of VOC is 2-amino-2-methyl-1-propanol (AMP).

II. Summary of SIP Revision

On September 17, 2015, the Commonwealth of Virginia (Virginia) submitted a formal revision to its SIP which consists of adding AMP to the list of substances that are not considered VOCs found at 9VAC5-10-20. The September 17, 2015 SIP revision will allow the Virginia SIP to mirror the Federal definition of VOC. EPA believes that by excluding this negligibly reactive compound from the definition of VOC an incentive is created for industry to use negligibly reactive compounds in place of more highly reactive compounds; therefore, the air quality in Virginia will not be negatively

affected by the approval of this SIP revision particularly as EPA has found this compound negligibly reactive for ozone formation.

III. Final Action

EPA is approving the SIP revision to the definition of VOC submitted by Virginia on September 17, 2015. EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse comment. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on *January 26, 2016* without further notice unless EPA receives adverse comment by *December 28, 2015*. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1-1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the

assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege Law, Va. Code § 10.1-1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . ." The opinion concludes that "[r]egarding § 10.1-1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval." Virginia's Immunity law, Va. Code Sec. 10.1-1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity."

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or

any, state audit privilege or immunity law.

V. Incorporation by Reference

In this rulemaking action, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the definition of VOC. EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or may be viewed at the EPA Region III office (see the **ADDRESSES** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this

action must be filed in the United States Court of Appeals for the appropriate circuit by January 26, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking action. This action, revising Virginia's definition of VOC, may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 12, 2015.

Shawn M. Garvin,
Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart VV—Virginia

- 2. In § 52.2420, the table in paragraph (c) is amended by adding an entry for "Section 5-10-20" after the entry for "Section 5-10-20" (with the State effective date of 3/12/15) to read as follows:

§ 52.2420 Identification of plan.

*	*	*	*	*
(c) * * *				

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation	Title/Subject	State effective date	EPA Approval date	Explanation [former SIP citation]
*	*	*	*	*
9 VAC 5, Chapter 10 General Definitions [Part I]				
*	*	*	*	*
5-10-20	Terms Defined	7/30/15	11/27/15 [Insert Federal Register Citation].	Definition of VOC is revised by adding 2-amino-2-methyl-1-propanol to the list of substances not considered to be VOCs.
*	*	*	*	*

* * * * *
 [FR Doc. 2015-30108 Filed 11-25-15; 8:45 am]
 BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1632-CN2]

RIN 0938-AS41

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Extensions of the Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule and interim final rule with comment period; correction.

SUMMARY: This document corrects technical and typographical errors in the correcting document that appeared in the October 5, 2015 **Federal Register**, entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to the Electronic Health Record Incentive Program; Extensions of the

Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals; Correction.”

DATES: *Effective date:* This correcting document is effective November 25, 2015. *Applicability date:* This correcting document is applicable to discharges beginning October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, (410) 786-4487.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2015-19049 which appeared in the August 17, 2015 **Federal Register** (80 FR 49326), entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to the Electronic Health Record Incentive Program; Extensions of the Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals” (hereinafter referred to as the FY 2016 IPPS/LTCH PPS final rule), there were a number of technical and typographical errors. Therefore, we published a correcting document that appeared in the October 5, 2015 **Federal Register** (80 FR 60055) to correct those errors (hereinafter referred to as the FY 2016 IPPS/LTCH PPS correcting document). The provisions of the FY 2016 IPPS/LTCH PPS correcting document were effective as if they had been included in the FY 2016 IPPS/LTCH PPS final rule that appeared in the August 17, 2015 **Federal Register**. Accordingly, those corrections were effective October 1, 2015.

II. Summary of Errors and Corrections to Tables Posted on the CMS Web Site

Since publication of the FY 2016 IPPS/LTCH PPS correcting document, we discovered technical and typographic errors to data that appeared in that document. Therefore, we are correcting the errors in the following IPPS tables that are listed on page 49808 of the FY 2016 IPPS/LTCH PPS final rule, that were discussed on pages 60056 and 60057 and corrected in the FY 2016 IPPS/LTCH PPS correcting document. These tables are available on the Internet on the CMS Web site at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html):

Table 2—CASE MIX INDEX AND WAGE INDEX TABLE BY CCN—FY 2016 CORRECTION NOTICE. In the FY 2016 IPPS/LTCH PPS correcting document, we inadvertently changed the reclassification status for two hospitals (CCNs 050152 and 050228). In Table 2 of the FY 2016 IPPS/LTCH PPS final rule, prior to the revisions based on the FY 2016 IPPS/LTCH PPS correcting document, the reclassification status for CCNs 050152 and 050228 correctly reflected an MGCRB reclassification to Reclassified/Redesignated CBSA 36084. For these two hospitals, the “MGCRB Reclass” column value will be corrected by adding a “Y” and the “Reclassified/Redesignated CBSA” column value will be corrected by adding “36084.”

Also, in Table 2 that was posted on the Internet in conjunction with the FY 2016 IPPS/LTCH PPS correcting document, we inadvertently listed the “County Name” and “County Code” values for CCN 050B21 as “FAIRFIELD” and “07000”, and for CCN 070B22 as “FRESNO” and “05090”. The “County Name” and “County Code” values for CCN 050B21 should be “FRESNO” and

“05090”, and for CCN 070B22 should be “FAIRFIELD” and “07000.” Therefore, the “County Name” and “County Code” for CCN 050B21 will be corrected to read “FRESNO” and “05090”, respectively; and the “County Name” and “County Code” for CCN 070B22 will be corrected to read “FAIRFIELD” and “07000”, respectively.

Table 3—WAGE INDEX TABLE BY CBSA—FY 2016 CORRECTION NOTICE. As described previously, the reclassifications for two hospitals (CCNs 050152 and 050228) to CBSA 36084 were not properly listed and are being corrected in Table 2. Therefore, we are making corresponding changes to the “Reclassified Wage Index” and “Reclassified GAF” column values for CBSA 36084 in Table 3.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

We believe that this correcting document does not constitute a rule that would be subject to the APA notice and comment or delayed effective date requirements. This correcting document corrects technical and typographic errors in the tables referenced in the FY 2016 IPPS/LTCH PPS final rule as revised by the FY 2016 IPPS/LTCH PPS correcting document but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this correcting document is intended to ensure that the tables referenced in the FY 2016 IPPS/LTCH PPS final rule accurately reflect the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment

procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public’s interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the FY 2016 IPPS/LTCH PPS final rule accurately reflects our policies. Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply implementing correctly the policies that we previously proposed, received comment on, and subsequently finalized. This correcting document is intended solely to ensure that the FY 2016 IPPS/LTCH PPS final rule accurately reflects these payment methodologies and policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

Dated: November 18, 2015.

Madhura Valverde,

*Executive Secretary to the Department,
Department of Health and Human Services.*

[FR Doc. 2015–30248 Filed 11–25–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 150826781–5999–02]

RIN 0648–BF33, 0648–BE91

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; 2016 Red Snapper Commercial Quota Retention

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). This final rule withholds 4.9 percent of the 2016 red snapper commercial quota prior to the annual distribution of red snapper allocation to

the Individual Fishing Quota (IFQ) program shareholders on January 1, 2016. This final rule allows the allocations being established through Amendment 28 to the FMP (Amendment 28) to be effective for the 2016 fishing year should Amendment 28 be approved by the Secretary of Commerce (Secretary) in 2016. This final rule also makes a technical correction to re-insert regulatory text that a previous rulemaking inadvertently omitted, which specifies that the recreational annual catch limit (ACL) for red snapper is equal to the total recreational quota.

DATES: This rule is effective December 28, 2015.

ADDRESSES: Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office (SERO) Web site at http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2015/rs_framework_2016_quota/documents/pdfs/retain_2016_red_snapper_commercial_quota_ea.pdf.

FOR FURTHER INFORMATION CONTACT: Richard Malinowski, NMFS SERO, telephone: 727–824–5305, or email: rich.malinowski@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico (Gulf) reef fish fishery is managed under the FMP. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On October 19, 2015, NMFS published a proposed rule for the framework action and requested public comment (80 FR 63190). The proposed rule and the framework action outline the rationale for the actions contained in this final rule. A summary of the actions implemented by the framework action and this final rule is provided below.

Management Measures Contained in This Final Rule

This final rule withholds 4.9 percent of the 2016 red snapper commercial quota, equal to 352,000 lb (159,665 kg), round weight, and 317,117 lb (143,842 kg), gutted weight, prior to the annual distribution of allocation to the IFQ program shareholders on January 1, 2016. The framework procedures of the FMP include the authority to retain a portion of an annual quota in anticipation of future regulatory changes during the same fishing year. This final rule allows the allocations being

established through Amendment 28 to be effective for the 2016 fishing year should the Secretary approve Amendment 28 in 2016. If NMFS does not implement Amendment 28, NMFS will distribute the withheld 4.9 percent of the 2016 red snapper commercial quota to shareholders based on the shares held as of the date of distribution.

Other Changes to the Codified Text

This final rule fixes an error in § 622.41(q)(2)(i) for the recreational sector of Gulf red snapper. This final rule re-inserts a sentence of regulatory text originally published in the final rule implementing Amendment 40 to the FMP (80 FR 22422, April 22, 2015), which specifies that the recreational ACL for red snapper is equal to the total recreational quota. The regulatory text was inadvertently omitted in a subsequent correcting amendment (80 FR 58219, September 28, 2015) to a final rule for a framework action that increased the commercial and recreational quotas for Gulf red snapper in the 2015, 2016, and 2017 fishing years (80 FR 24832, May 1, 2015). This final rule corrects the error by re-inserting the regulatory text into § 622.41(q)(2)(i). This action is unrelated to the actions described in this framework action.

Comments and Responses

NMFS received 46 comment submissions from individuals, commercial fishermen, and a commercial fishermen's association on the framework action and the proposed rule, along with other issues. Many of the comments NMFS received were about Amendment 28 and alternative management strategies for red snapper, for example, expanding state waters and advocating for state rather than Federal management. Such comments were beyond the scope of the proposed rule and, therefore, have not been addressed in this final rule. The comments that relate to the framework action and the proposed rule are summarized and responded to below.

Comment 1: The red snapper commercial quota should not be withheld until Amendment 28 is approved and implemented by NMFS. The resulting reallocation of the red snapper commercial quota would then apply to the 2017 fishing year.

Response: NMFS disagrees that the commercial quota necessary to implement Amendment 28 in the 2016 fishing year should not be withheld. The Council approved Amendment 28 for review and implementation in August 2015 with the expectation that

the revised allocations and quotas would be implemented in 2016, if approved by the Secretary. This will not be possible unless that portion of the commercial quota is not distributed to shareholders on January 1, 2016, the date on which NMFS distributes annual red snapper allocation to shareholders. If Amendment 28 is not approved by the Secretary, the withheld red snapper commercial quota will be distributed as soon as possible to the current red snapper IFQ shareholders based on their current shares held as of the date of distribution.

Comment 2: Withholding IFQ allocation cannot be accomplished through framework procedures. NMFS regulations at 50 CFR 622.42(a) list actions that can be established or modified in accordance with the framework procedures of the FMP. Withholding IFQ allocation in anticipation of reallocation is not one of the described actions that can be accomplished by framework procedures. NMFS and the Council are not modifying approved framework items such as the red snapper quotas or the ACLs through this framework action; that is what Amendment 28 would do if and when it is approved. NMFS, therefore, lacks authority to implement this action using framework procedures.

Response: NMFS disagrees. The regulations at 50 CFR 622.42(a) refer to the framework procedures of the FMP and list quotas as one of the management measures that may be modified. The framework procedures for the FMP that were established with the Generic ACL and Accountability Measures Amendment (76 FR 82044, December 29, 2011; http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/generic_archives/generic_acl_am_amend_sept_2011.pdf) list the regulatory changes that may be implemented and expressly include "retention of portion of an annual quota in anticipation of future regulatory changes during the same fishing year." Thus, this framework action and regulations are in accordance with the FMP (as revised through the Generic ACL and Accountability Measures Amendment), and regulations at 50 CFR 622.42(a).

Comment 3: Reducing each shareholder's allocation of red snapper by approximately five percent could reduce access to quota that was leased out to the grouper fishery for bycatch coverage. This would result in negative biological consequences that are not analyzed in the framework action.

Response: NMFS disagrees. Withholding the red snapper commercial quota until a decision to

approve or disapprove Amendment 28 is made does not restrict the ability of the shareholders to continue to contribute to the private quota bank they developed. Any long-term impacts on bycatch mortality anticipated from a permanent shift in allocation to the recreational sector would be a consequence of Amendment 28 and its implementing regulations, not this rule.

Comment 4: Withholding a portion of an individual's quota indefinitely disrupts fishermen's business plans, particularly for fishermen who harvest large portions or all of their allocation early in the year, leading to inefficiencies in the allocation leasing marketplace which would reduce profitability and introduce economic and social costs to the IFQ program.

Response: NMFS disagrees. As stated in the proposed rule for this framework action, withholding a portion of the commercial quota may result in a reduction in normal total revenue, alteration of the flow of receipts, and disruption of normal business operation, consistent with the comment. These effects, however, are expected to be minor because of the small amount of quota withheld (4.9 percent) and the likely short timeframe during which withholding occurs. Thus, the full value of the quota being withheld would not be lost. Because red snapper commercial harvest occurs throughout the year, and is not subject to "race to fish" (derby) conditions, withholding this small portion is not expected to severely limit the availability of allocation for purchase or trade early in the year, nor result in a market glut if allocation is subsequently returned to shareholders. This action only applies to the 2016 fishing year. As a result, the economic and social consequences are of limited scope and duration and are not expected to harm individual businesses or the industry beyond as already described. If Amendment 28 is approved by the Secretary of Commerce and the quota is not returned to shareholders, this would be a consequence of the rule for Amendment 28 and not this current framework action and final rule.

Classification

The Regional Administrator, Southeast Region, NMFS has determined that this final rule is consistent with the framework action, the FMP, the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting

Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule.

The Chief Counsel for Regulation of the Department of Commerce (DOC) certified to the Chief Counsel for advocacy of the Small Business Administration (SBA) during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. NMFS received no significant comments regarding the certification. However, one general comment on the expected economic effects of this rule is addressed in the Comments and Response section of this rule. As a result, a final regulatory flexibility analysis was not required and was not prepared.

As discussed in the background section of this final rule, this rule also re-inserts a sentence of regulatory text originally published in the final rule implementing Amendment 40 (80 FR 22422, April 22, 2015). The regulatory text was inadvertently omitted in a subsequent correcting amendment (80 FR 58219, September 28, 2015) to a final rule that implemented a framework amendment for red snapper in the Gulf reef fish fishery (80 FR 24832, May 1, 2015). The DOC Chief Counsel for Regulation certified to the Chief Counsel for advocacy of the SBA that the final rules implementing both Amendment 40 and the framework amendment would not have a significant economic impact on a substantial number of small entities. The re-insertion of this regulatory text is not expected to have direct adverse economic effects on a substantial number of small entities because it is an administrative correcting action. The final rule that originally published the regulation was certified to not have a significant economic impact on a substantial number of small entities, and the public may believe the omitted text is already included in the regulations. This change is needed to ensure that the public is aware of the correct recreational harvest limit (quota) and accountability measures for recreationally-caught Gulf red snapper.

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA, finds good cause to waive prior notice and opportunity for additional public comment for this correcting action because it would be unnecessary and contrary to the public interest. Such procedures are unnecessary because the

public received notice and an opportunity to comment on the proposed rules for the framework amendment and Amendment 40 and the final rule for Amendment 40 included this regulatory text. This final rule reinstates the regulatory text that was inadvertently omitted from the correcting amendment that published on September 28, 2015 (80 FR 58219). If this final rule was delayed to allow for notice and opportunity for public comment, it could cause confusion because the public believes that the omitted text is already included in the regulations.

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Gulf of Mexico, Recreational, Red snapper, Reef fish.

Dated: November 23, 2015.

Eileen Sobeck,
Assistant Administrator for Fisheries,
National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

- 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

- 2. In § 622.39, add paragraphs (a)(1)(i)(B)(1) and (2) to read as follows:

§ 622.39 Quotas.

* * * * *

- (a) * * *
- (1) * * *
- (i) * * *
- (B) * * *

(1) NMFS will withhold distribution of 4.9 percent of the 2016 IFQ allocation of red snapper commercial quota on January 1, 2016, totaling 352,000 lb (159,665 kg), round weight, of the 2016 red snapper commercial quota specified in this paragraph (a)(1)(i)(B).

(2) As determined by NMFS, remaining 2016 IFQ allocation of red snapper will be distributed to the current shareholders based on their current shares held as of the date of distribution.

* * * * *

- 3. In § 622.41, revise paragraph (q)(2)(i) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

- (q) * * *
- (2) * * *

(i) The recreational ACL is equal to the total recreational quota specified in § 622.39(a)(2)(i)(A). The AA will determine the length of the red snapper recreational fishing season, or recreational fishing seasons for the Federal charter vessel/headboat and private angling components, based on when recreational landings are projected to reach the recreational ACT, or respective recreational component ACT specified in paragraph (q)(2)(iii) of this section, and announce the closure date(s) in the **Federal Register**. These seasons will serve as in-season accountability measures. On and after the effective date of the recreational closure or recreational component closure notifications, the bag and possession limit for red snapper or for the respective component is zero. When the recreational sector or Federal charter vessel/headboat component is closed, this bag and possession limit applies in the Gulf on board a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued, without regard to where such species were harvested, *i.e.*, in state or Federal waters.

* * * * *

[FR Doc. 2015-30194 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 101206604-1758-02]

RIN 0648-XE326

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; 2015-2016 Accountability Measure and Closure for King Mackerel in the Florida West Coast Northern Subzone

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for commercial king mackerel in the Florida west coast northern subzone of the eastern zone of the Gulf of Mexico (Gulf exclusive economic zone (EEZ) through this temporary final rule. NMFS has determined that the commercial quota for king mackerel in the eastern zone, Florida west coast northern subzone of the Gulf EEZ will be reached by

November 28, 2015. Therefore, NMFS closes the Florida west coast northern subzone to commercial king mackerel fishing on November 28, 2015, to protect the Gulf king mackerel resource.

DATES: The closure is effective noon, local time, November 28, 2015, until 12:01 a.m., local time, on July 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Susan Gerhart, NMFS Southeast Regional Office, telephone: 727-824-5305, email: susan.gerhart@noaa.gov.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, and cobia) is managed under the Fishery Management Plan for Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The Gulf migratory group king mackerel is divided into western and eastern zones. The Gulf's eastern zone for king mackerel is further divided into the Florida west coast northern and southern subzones that have separate quotas. The quota for the Florida west coast northern subzone is 178,848 lb (81,124 kg) (50 CFR 622.384(b)(1)(i)(B)(2)).

Regulations at 50 CFR 622.388(a)(1) require NMFS to close the commercial sector for Gulf migratory group king mackerel in the Florida west coast northern subzone when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. Based on the best scientific information available, NMFS has determined the commercial quota of 178,848 lb (81,124 kg) for Gulf migratory group king mackerel in the Florida west coast northern subzone will be reached by November 28, 2015. Accordingly, the Florida west coast northern subzone is closed effective noon, local time, November 28, 2015, through June 30, 2016, the end of the current fishing year, to commercial fishing for Gulf migratory group king mackerel.

Except for a person aboard a charter vessel or headboat, during the closure, no person aboard a vessel for which a commercial permit for king mackerel has been issued may fish for or retain Gulf group king mackerel in the EEZ in the closed subzone (50 CFR 622.384(e)(1) and (e)(2)). A person aboard a vessel that has a valid charter vessel/headboat permit for coastal

migratory pelagic fish may continue to retain king mackerel in or from the closed subzone under the bag and possession limits set forth in 50 CFR 622.382(a)(1)(ii) and (a)(2), provided the vessel is operating as a charter vessel or headboat. A charter vessel or headboat that also has a commercial king mackerel permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, king mackerel from the closed subzone, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to king mackerel from the closed zones or subzones that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(3)).

The Florida west coast northern subzone is that part of the EEZ between 26°19.8' N. latitude (a line directly west from the boundary between Lee and Collier Counties, FL) and 87°31.1' W. longitude (a line directly south from the state boundary of Alabama and Florida).

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of Gulf migratory group king mackerel and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.388(a)(1) and 50 CFR 622.384(e) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for Fisheries, NOAA (AA), finds that the need to immediately implement this action to close the Florida west coast northern subzone of the Gulf eastern zone to commercial king mackerel fishing constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary, because the rule implementing the commercial quota and the associated requirement for closure of the commercial harvest when the quota

is reached or is projected to be reached has already been subject to notice and public comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because the capacity of the fishing fleet allows for rapid harvest of the quota, and there is a need to immediately implement this action to protect the king mackerel resource. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 23, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015-30192 Filed 11-23-15; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 130708597-4380-01]

RIN 0648-XE329

Pacific Island Pelagic Fisheries; 2015 CNMI Longline Bigeye Tuna Fishery; Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is closing the U.S. pelagic longline fishery for bigeye tuna in the western and central Pacific Ocean as a result of the fishery reaching the 2015 allocation limit for the Commonwealth of the Northern Mariana Islands (CNMI). This action is necessary to comply with regulations managing this fish stock.

DATES: Effective November 30, 2015, through December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS PIRO Sustainable Fisheries, 808-725-5176.

SUPPLEMENTARY INFORMATION: On August 5, 2015, NMFS restricted the retention, transshipment and landing of bigeye tuna captured by longline gear in the western and central Pacific Ocean (WCPO) as a result of the U.S. longline fishery reaching the 2015 U.S. bigeye

tuna limit of 3,502 mt (80 FR 44883, July 28, 2015). Regulations at 50 CFR 300.224(d) provide an exception to this closure for bigeye tuna caught by U.S. longline vessels identified in a valid specified fishing agreement under 50 CFR 665.819(c). Further, 50 CFR 665.819(c)(9) authorized NMFS to attribute catches of bigeye tuna made by U.S. longline vessels identified in a valid specified fishing agreement to the U.S. territory to which the agreement applies.

Effective on October 9, 2015, NMFS specified a 2015 catch limit of 2,000 mt of longline-caught bigeye tuna for the CNMI (80 FR 61767, October 14, 2015). NMFS also authorized the CNMI to allocate up to 1,000 mt of its 2,000 mt bigeye tuna limit to U.S. longline fishing vessels permitted to fish under the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP).

On October 9, 2015, the Western Pacific Fishery Management Council, through its Executive Director, transmitted to NMFS a specified fishing agreement between the CNMI and Quota Management, Inc. (QMI), dated September 16, 2015, and amended on October 15, 2015, by adding one vessel. NMFS reviewed the agreement, as amended, and determined that it was consistent with the requirements at 50 CFR 665.819, the FEP, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable laws. The criteria that a specified fishing agreement must meet, and the process for attributing longline-caught bigeye tuna, followed the procedures in 50 CFR 665.819—Territorial catch and fishing effort limits.

In accordance with 50 CFR 300.224(d) and 50 CFR 665.819(c)(9), NMFS began attributing bigeye tuna caught in the WCPO by vessels identified in the CNMI/QMI agreement to the CNMI, beginning on October 9, 2015. NMFS monitored catches of longline-caught bigeye tuna by the CNMI longline fisheries, including catches made by U.S. longline vessels operating under the CNMI/QMI agreement. Based on this monitoring, NMFS forecasted that the CNMI territorial allocation limit of 1,000 mt will be reached by the end of

November 2015, and is, as an accountability measure, prohibiting the catch and retention of longline-caught bigeye tuna by vessels in the CNMI/QMI agreement.

Notice of Closure and Temporary Rule

On November 30, 2015, through December 31, 2015, NMFS closes the U.S. pelagic longline fishery for bigeye tuna in the western and central Pacific Ocean as a result of the fishery reaching the 2015 allocation limit of 1,000 mt for the CNMI.

During the closure, a U.S. fishing vessel operating under the CNMI/QMI agreement may not retain on board, transship, or land bigeye tuna captured by longline gear in the WCPO, except that any bigeye tuna already on board a fishing vessel upon the effective date of the restrictions may be retained on board, transshipped, and landed, provided that they are landed within 14 days of the start of the closure, that is, by December 14, 2015. Additionally, U.S. fishing vessels operating under the CNMI/QMI agreement are also prohibited from transshipping bigeye tuna caught in the WCPO by longline gear to any vessel other than a U.S. fishing vessel with a valid permit issued under 50 CFR 660.707 or 665.801.

During the closure, all other restrictions and requirements NMFS established on August 5, 2015, as a result of the U.S. longline fishery reaching the 2015 U.S. bigeye tuna limit of 3,502 mt (80 FR 44883, July 28, 2015) shall remain valid and effective.

NMFS notes that there is a pending case in litigation—*Conservation Council for Hawai'i, et al., v. NMFS* (D. Hawaii); *case no. 14-cv-528*—that challenges the framework process for allocations from the territories to U.S. longline fishing vessels.

Classification

There is good cause to waive the prior notice and public comment requirement of the Administrative Procedure Act, and make this rule effective immediately upon publication in the **Federal Register**. This rule closes the U.S. longline fishery for bigeye tuna in the WCPO as a result of reaching the bigeye tuna allocation limit established

by the 2015 specification for catch and allocation limits of bigeye tuna for the CNMI, and the specified fishing agreement between the Government of the CNMI and QMI dated September 16, 2015, amended on October 15, 2015.

NMFS forecasts that the fishery will reach the 2015 limit by the end of November 2015. Fishermen have been subject to longline bigeye tuna limits in the western and central Pacific since 2009. They have received ongoing, updated information about the 2015 catch and progress of the fishery in reaching the Convention Area limit via the NMFS Web site, social media, and other means. The publication timing of this rule, moreover, provides longline fishermen with seven days' advance notice of the closure date, and allows two weeks to return to port and land their catch of bigeye tuna. This action is intended to comply with regulations managing this stock, and, accordingly NMFS finds it impracticable and contrary to the public interest to have prior notice and public comment.

For the reasons stated above, there is also good cause to waive the 30-day delay requirement of the Administrative Procedure Act for this notice and temporary rule. NMFS must close the fishery as soon as possible to ensure that fishery does not exceed the allocation limit. NMFS implemented the catch and allocation limits for the CNMI consistent with management objectives to sustainably manage the bigeye tuna stock and restore the stock to levels capable of producing maximum sustainable yield on a continuing basis. Failure to close the fishery immediately would be inconsistent with bigeye tuna management objections and in violation of Federal law.

This action is required by 50 CFR 665.819(d), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 23, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–30193 Filed 11–23–15; 4:15 pm]

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Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2635

RIN 3209-AA04

Standards of Ethical Conduct for Employees of the Executive Branch; Amendment to the Standards Governing Solicitation and Acceptance of Gifts From Outside Sources

AGENCY: Office of Government Ethics (OGE).

ACTION: Proposed rule.

SUMMARY: The Office of Government Ethics is proposing to revise the portions of the Standards of Ethical Conduct for Executive Branch Employees that govern the solicitation and acceptance of gifts from outside sources. The proposed amendments modify the existing regulations to more effectively advance public confidence in the integrity of Federal officials. The proposed amendments would also incorporate past interpretive guidance, add and update regulatory examples, improve clarity, update citations and make technical corrections.

DATES: Written comments are invited and must be received on or before January 26, 2016.

ADDRESSES: You may submit comments, in writing, to OGE on this proposed rule, identified by RIN 3209-AA04, by any of the following methods:

Email: usoge@oge.gov. Include the reference "Proposed Amendments to Subpart B" in the subject line of the message.

Fax: (202) 482-9237.

Mail/Hand Delivery/Courier: Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005-3917, Attention: "Proposed Amendments to Subpart B."

Instructions: All submissions must include OGE's agency name and the Regulation Identifier Number (RIN), 3209-AA04, for this proposed rulemaking. All comments, including attachments and other supporting materials, will become part of the public

record and subject to public disclosure. Comments may be posted on OGE's Web site, www.oge.gov. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT:

Christopher J. Swartz, Assistant Counsel, or Vincent J. Salamone, Associate Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005-3917; Telephone: 202-482-9300; TTY: 800-877-8339; FAX: 202-482-9237.

SUPPLEMENTARY INFORMATION:

I. Background

On August 7, 1992, the U.S. Office of Government Ethics (OGE) published the Standards of Ethical Conduct for Employees of the Executive Branch (Standards), which are codified at 5 CFR part 2635. *See* 57 FR 35005-35067, as amended. Subpart B of part 2635 sets forth the regulations governing the solicitation and acceptance of gifts from outside sources by officers and employees of the Executive Branch. These regulations implement the gift restrictions set forth in 5 U.S.C. 7353 and section 101(d) of Executive Order 12674, as modified by Executive Order 12731.

Pursuant to section 402 of the Ethics in Government Act of 1978, Public Law 95-521, codified at 5 U.S.C. Appendix IV, sec. 402, the Director of OGE is responsible for periodically reviewing, evaluating and updating the rules and regulations that pertain to ethics in the Executive Branch. In accordance with section 402, OGE has reviewed the regulations found in subpart B and is proposing changes in light of OGE's experience gained from application of the Standards since they became effective in February 1993.

In formulating this proposed rule, OGE has consulted with the Department of Justice and the Office of Personnel Management pursuant to section 201(a) of Executive Order 12674, as modified by Executive Order 12731, and the authorities contained in title IV of the Ethics in Government Act of 1978, as amended. Prior to promulgating this proposed rule, OGE solicited the views of Executive Branch agency ethics officials through an electronic survey

and multiple in-person meetings. OGE has considered the input received from these agency ethics officials and has incorporated many of their comments and suggestions into the proposed rule.

II. Regulatory Amendments to Subpart B

Technical Changes

OGE proposes amending the Table of Contents to subpart B of the Standards to conform to the proposed substantive amendments to subpart B, which are explained elsewhere in this document. OGE also proposes a number of general technical and non-substantive changes that would apply throughout subpart B to enhance clarity and readability and to remove gender-specific terms from the substantive regulatory text. OGE also proposes to replace the term "shall" as used throughout the regulation with the terms "will," "must," or "does" where the term is used to indicate an affirmative obligation or requirement, and to replace the term "shall not" with the terms "may not" or "does not" as appropriate. These changes are intended to enhance clarity and do not constitute a substantive change to the regulation.

Proposed § 2635.201 Overview and Considerations For Declining Otherwise Permissible Gifts

Proposed § 2635.201(a) reiterates the language that is contained in current § 2635.201, and includes a new subheading "Overview." Proposed § 2635.201(b) is new to the Standards. This section is entitled "Considerations for declining otherwise permissible gifts." OGE is proposing the addition of this section because it is OGE's experience that employees and ethics officials sometimes focus on whether a regulatory exception permits the acceptance of an otherwise impermissible gift, and not on whether acceptance of the gift could affect the perceived integrity of the employee or the credibility and legitimacy of the agency's programs. To counter this tendency, OGE is proposing to add § 2635.201(b)(1), which sets out a flexible, non-binding standard that employees are encouraged to use when deciding whether to accept a gift that would otherwise be permitted by this subpart. Specifically, this section encourages employees to consider the potential that a "reasonable person" would question their integrity if they

were to accept the gift. In a circumstance where an employee concludes that a reasonable person would question his or her integrity, the employee is encouraged to consider declining the gift.

To assist employees in making this determination, OGE has added proposed § 2635.201(b)(2), which sets out some factors that employees can consider when evaluating whether they should decline an otherwise permissible gift because acceptance might cause a reasonable person with knowledge of the relevant facts to question their integrity. Employees are not, however, required to consider these factors in every case; these factors are merely intended to be illustrative of the types of considerations that are relevant to this determination. In addition, because the regulatory exceptions represent OGE's determination that, in most cases, acceptance of a gift under the relevant exception will not adversely affect public confidence, and because the factors are inherently subjective, the proposed rule clarifies that an employee has not violated the subpart by accepting a gift under an exception found in § 2635.204. The section concludes by encouraging employees to seek advice from an appropriate agency ethics official when making this determination or where there are questions related to other provisions of this subpart.

Proposed § 2635.202 General Prohibition on Solicitation or Acceptance of Gifts

OGE proposes revising the heading of § 2635.202 to "General prohibition on solicitation or acceptance of gifts." OGE proposes to move the provisions setting forth the limitations on use of the exceptions set out in current § 2635.202(c) to redesignated § 2635.205. OGE believes that reordering the regulations to place the rules establishing limitations on the exceptions after the regulatory exceptions will produce a more logical and understandable ordering of the regulation.

OGE proposes to revise current § 2635.202(a) by moving the prohibitions on accepting gifts and soliciting gifts into separate paragraphs. OGE is proposing this revision to emphasize that the prohibition on soliciting gifts from prohibited sources, or that are to be given because of the employee's official position, is an independent restriction from the prohibition on accepting gifts that are restricted under subpart B.

OGE proposes to reword current § 2635.202(b) to increase clarity and

readability. OGE also proposes to move this paragraph to § 2635.202(c). This section describes the relationship between the Standards found in subpart B and the illegal gratuities statute, 18 U.S.C. 201(c)(1)(B). This revision is technical in nature and does not affect the substance of the regulation, which has been consistent since the issuance of the Standards in 1992. OGE also proposes to include a statement reminding employees that, notwithstanding any exception provided in the subpart, no gift may be solicited or accepted if to do so would violate the federal bribery statute, 18 U.S.C. 201(b). OGE proposes to add a new *Example 1 to paragraph (c)* to illustrate a circumstance in which an employee's acceptance of a gift would violate the new § 2635.202(c).

Proposed § 2635.203 Definitions

OGE proposes a number of changes to § 2635.203(b), which defines the term "gift" as well as provides exclusions from that definition.

OGE proposes to amend current § 2635.203(b)(2), which excludes from the definition of the term "gift" certain presentation items with little intrinsic value, to permit employees to accept items that are "primarily" for presentation as opposed to only those that are "solely" for presentation. OGE believes distinguishing between items intended for presentation based on whether the item hypothetically could have some independent use is not intuitive or necessary, so long as the presentation item is truly of "little intrinsic value." Items such as watches, artwork, items containing precious metals or gemstones, fine crystal, or that otherwise have significant independent value would not qualify for this exclusion, even if they were inscribed or otherwise adorned with personalized information (such as the name of the donor, the date of an event, or the name of the recipient).

Proposed § 2635.203(b)(6) would clarify that continued participation in an employee welfare or benefit plan with a current or former employer would not constitute a gift for purposes of subpart B.

OGE proposes to delete the Note following current paragraph (b)(7) stating that employees are prohibited from accepting certain frequent flyer program benefits that are earned from Government-financed travel, as it no longer reflects current law.

Proposed § 2635.203(b)(8) is new as an exclusion, and excludes from the definition of "gift" certain offers of free attendance to an event provided to a speaker on the day of his or her

presentation. Such offers of free attendance are currently treated as gifts that employees are permitted to accept pursuant to an exception set out in current § 2635.204(g)(1). As described in current § 2635.204(g)(1), OGE views the employee's attendance in these circumstances as customary and necessary to allow the employee to carry out his or her assignment, and therefore views such offers of free attendance as not constituting a gift to either the agency or the employee. Moving the exception at § 2635.204(g)(1) to the exclusion section at § 2635.203(b)(8) reflects that long-time understanding. Advice OGE has previously provided on the application of current § 2635.204(g)(1) would continue to be applicable to proposed § 2635.203(b)(8).

OGE has also provided that an offer of free attendance provided to an employee's spouse or another accompanying guest on the day the employee is presenting is also excluded from the gift rules in certain circumstances, which accords with the current exception for such attendees under § 2635.204(g)(6). Likewise, OGE has excluded from the definition of "gift" an offer of free attendance to certain personnel, such as security details or press officers, who are assigned by the agency to perform official duties in support of the presenting employee. This regulatory exclusion accords with OGE's longstanding interpretation of current § 2635.204(g)(1). See OGE DAEOgram DO-10-003 (Feb. 18, 2010). OGE also proposes simplifying the language of the exclusion to cover "Free attendance to an event provided by the sponsor of an event to . . . an employee who is assigned to *present information* on behalf of the agency . . ." (emphasis added). Current § 2635.204(g)(1) provides that an employee may accept an offer of free attendance to an event when he or she is assigned to participate as a speaker or panel participant or *otherwise to present information* on behalf of the agency. See also OGE Legal Advisory LA-12-05 (Sept. 7, 2012). The proposed regulation is consistent with this advice.

OGE proposes to include ten examples to § 2635.203(b) to provide clarification to the regulatory exclusions to the definition of "gift." These examples are not intended to be comprehensive. Proposed *Example 1 to paragraph (b)(1)* clarifies that the exclusion for "modest items of food and refreshment" would not cover alcoholic beverages served at a Government contractor's holiday party. Proposed *Example 1, Example 2, and Example 3 to paragraph (b)(2)* clarify the meaning

of “items with little intrinsic value . . . which are intended primarily for presentation.” Proposed *Example 1* and *Example 2 to paragraph (b)(5)* both clarify the exclusion for rewards and prizes given to participants in contests or events open to the public. *Example 1 to paragraph (b)(7)* emphasizes that employees may accept certain travel-related benefits, such as frequent flyer miles, pursuant to an applicable statute or regulation. OGE proposes to move *Example 4* following current § 2635.204(g) to *Example 1 to paragraph (b)(8)* following proposed § 2635.203(b)(8). OGE proposes to add *Example 2* and *Example 3 to paragraph (b)(8)* to provide additional guidance on what constitutes “present[ing] information” on behalf of an employee’s agency.

OGE is proposing to revise the first sentence of § 2635.203(c), which sets out the definition of “market value” as used throughout the subpart. The current definition states that “Market value means the retail cost the employee would incur to purchase the gift.” OGE has found that this definition can lead to confusion and in certain circumstances may not be applicable at all if the gift does not have a “retail” price, e.g., if the gift takes the form of services or intangibles. As OGE stated in 1992, the purpose of including a definition of “market value” was to “ensure that the employee pays the fair value” of the gift and to allow the employee to “determine the value or the amount to be reimbursed without having to consult the donor as to the donor’s cost.” 57 FR 35006, 35014 (Aug. 7, 1992); see also OGE Informal Advisory Opinion 96 x 20. To better accord with OGE’s intent that the term “market value” reflect the price the employee would pay for the gift if he or she were to purchase it at fair value and on the open market, OGE has amended the first sentence of the definition to read: “Market value means the cost that a member of the general public would reasonably expect to incur to purchase the gift.” The proposed change also reflects OGE’s interpretation that the “market value” of a gift is the cost the recipient would incur to purchase the item on the open market, not the cost that the donor paid to acquire the gift. This principle is illustrated in proposed *Example 1* and new *Example 2 to paragraph (c)*. Proposed *Example 1 to paragraph (c)* also illustrates OGE’s longstanding guidance that the market value of a gift is not eliminated or significantly diminished because the item has been inscribed or otherwise adorned with the donor or recipient’s

name or information related to an event at which the gift was presented. Proposed *Example 3 to paragraph (c)* is current *Example 2* following § 2635.203(c) without substantive change. *Example 4* and *Example 5 to paragraph (c)* are provided to clarify how to calculate the market value of certain gifts that are not available for retail purchase, such as free admission to a private skybox or an invitation-only event where an entry fee is not charged to attendees.

OGE proposes to modify the formatting of § 2635.203(e) and § 2635.203(f) to enhance clarity. OGE also proposes to amend § 2635.203(f)(1) to expand the definition of “indirectly solicited or accepted” gifts to include gifts that are given to “a member of the employee’s household” on the basis of the person’s relationship with the employee and with the employee’s knowledge and acquiescence. OGE proposes to amend § 2635.203(f)(2) to clarify that employees who solicit or accept funds or other support for a charitable organization in accordance with subpart H of the Standards have not indirectly solicited or accepted a gift under subpart B. Proposed *Example 1 to paragraph (e)* is current *Example 1* following § 2635.203(e). Proposed *Example 2 to paragraph (e)* is current *Example 2* following § 2635.203(e). Proposed *Example 1 to paragraph (f)(2)* is current *Example 1* following § 2635.203(f).

OGE proposes removing current § 2635.203(g), defining the term “vendor promotional training.” The term is no longer used in the substantive provisions of the subpart, and the definition is therefore unnecessary.

OGE proposes to add a new § 2635.203(g) defining the term “free attendance” as used throughout the subpart. The language found in this definition is based on the definition of “free attendance” currently found in § 2635.204(g)(4). Because the term is used throughout the subpart, OGE believes it is more logical for the definition to appear in § 2635.203. OGE has amended the definition as it is currently found in § 2635.204(g)(4) to permit employees who are presenters at an event to accept meals outside of a group context, so long as the meal is open to all presenters and is hosted by the sponsor of the event. OGE is aware that it is customary for the sponsors of an event to provide a separate luncheon or dinner for participating presenters. OGE believes that these meals are often beneficial to the agency because the agency employee is able to interact with other presenters, receive instructions, and hear about program goals or

changes. OGE believes that where a meal is provided to all other presenters, the meal does not constitute a separate gift for the personal benefit of the employee.

OGE has determined that the explanatory Note that follows current § 2635.204(g) is unnecessary. OGE therefore proposes to remove the Note.

Proposed § 2635.204 Exceptions to the Prohibition on Acceptance of Certain Gifts

OGE proposes retitling this section to provide additional clarity as to the substantive regulatory text. OGE also proposes amending the introductory clause to improve readability.

OGE is proposing to revise and add a number of examples to § 2635.204(a) to clarify the application of the rule in various contexts. Proposed *Examples 1 through 5 to paragraph (a)* are unchanged except for technical modification. Proposed *Example 6 to paragraph (a)* is new and emphasizes that an employee may not rely on the exception for gifts of \$20 or less to accept a group gift with an aggregate market value in excess of \$20. Proposed *Example 7 to paragraph (a)* is new and incorporates OGE’s advice that store gift cards that are worth \$20 or less may be accepted under § 2635.204(a), but that general-use prepaid gift cards may not be accepted under the exception, even if their value is below the regulatory threshold. See OGE Legal Advisory LA–15–04 (April 30, 2015). General-use prepaid cards operate similarly to debit cards in practice and are therefore akin to gifts of cash. See *id.*

OGE proposes amending § 2635.204(b) to incorporate OGE’s longstanding interpretation that the exception for gifts based on a personal relationship applies only to gifts provided by an individual. As used in the Standards, the term “individual” refers only to a natural person, i.e., a human being. See 5 CFR 2635.102(k) (defining “person” to include an “individual” as well as a “corporation” “company” or “other organization or institution”). This accords with the common understanding of the term. See *Mohammed v. Palestinian Authority*, 132 S. Ct. 1702, 1707 (2012). OGE also proposes amending § 2635.204(b) to make explicit that in determining whether a gift is motivated by a personal relationship, employees and agencies may consider not only the “history of the relationship” but also the “nature of the relationship.” This amendment accords with advice that OGE has issued on this exception in the past. See OGE Informal Advisory Opinion 06 x 3 (Mar. 21, 2006).

Proposed *Example 1 to paragraph (b)* is revised to reflect circumstances that arise more frequently. Proposed *Example 2 to paragraph (b)* has no substantive change. Proposed *Example 3 to paragraph (b)* is new and provides guidance on the application of the exception at § 2635.204(b) to personal contacts made through social media networking Web sites.

OGE is proposing to revise § 2635.204(c)(1) to clarify that an employee may accept a reduction or waiver of membership or other fees to an organization where the only restriction on membership is related to professional qualifications and the reduction or waiver is available to all Government employees or all uniformed military personnel. OGE proposes to amend § 2635.204(c)(2) to explain that “opportunities and benefits” under this section may include free attendance or participation at an event if the other criteria of the section are met. OGE also proposes to amend § 2635.204(c)(3) to provide that the general prohibition on an employee accepting for personal use a benefit to which the Government is entitled does not apply when the employee is specifically authorized by statute or regulation to retain the benefit. Proposed *Example 1 to paragraph (c)(2)* illustrates circumstances under which an employee would not be able to accept a discount under § 2635.204(c)(2)(i), as it would be related to the employee’s Government employment. Proposed *Example 2* and *Example 3 to paragraph (c)(2)* and *Example 1 to paragraph (c)(3)* are renumbered but not substantively changed.

OGE proposes to restructure § 2635.204(d), *Awards and honorary degrees*, to clarify this exception. Proposed § 2635.204(d)(l) covers awards. The elements are the same as currently set forth in § 2635.204(d), but are reordered for clarity. Proposed § 2635.204(d)(2) defines an “Established program of recognition.” Proposed § 2635.204(d)(3), entitled “Honorary degrees,” is current § 2635.204(d)(2). As proposed, this paragraph updates the citation for the definition of an institution of higher education found at 20 U.S.C. 1001 and provides that employees may also accept honorary degrees from “similar foreign institution[s] of higher education.” For purposes of this exception, a “foreign institution of higher education” would include an institution of higher education that is physically located outside of the United States if it is accredited by a recognized quality assurance or accreditation organization. OGE proposes to add a note following

§ 2635.204(d)(3) reminding agency ethics officials that before approving the acceptance of an honorary degree from a foreign institution of higher education, the agency should also consider the potential applicability of the Emoluments Clause of the U.S. Constitution and the Foreign Gifts and Decorations Act.

Proposed § 2635.204(d)(4) is similar to current § 2635.204(d)(3), but is reworded to clarify that, for the purpose of determining whether the value of an award exceeds \$200 (and therefore is subject to additional restrictions), the value of the free attendance at the event does not need to be included but the cost of any travel expenses do. This is consistent with OGE’s current interpretation, as reflected in *Example 3* in the awards section of the current regulation.

OGE also proposes to amend the examples to § 2635.204(d) by adding one new example and updating the remaining example designations. Proposed *Example 1 to paragraph (d)(1)*, *Example 3 to paragraph (d)(1)*, and *Example 1 to paragraph (d)(3)* are currently in the regulation, and OGE proposes no substantive amendment to these examples. Proposed *Example 2 to paragraph (d)(1)* is a new example added to emphasize the existing rule that even where there is an “established program of recognition,” an employee may not accept the award if the entity that is giving the award has interests that may be substantially affected by the performance or nonperformance of the employee’s official duties.

OGE proposes to amend § 2635.204(e) by moving the definition of “employment” currently found at § 2635.204(e)(4) to a new § 2635.204(e)(5). Currently the term “employment” is defined by cross-reference to the definition of “employment” in § 2635.603(a). New § 2635.204(e)(5) removes the cross-reference and incorporates the substantive definition found in § 2635.603(a), *i.e.*, “‘employment’ means any form of non-Federal employment or business relationship involving the provision of personal services.” OGE is also proposing to add a new subparagraph (e)(4) providing that an employee may accept an invitation from his or her former employer to attend a reception or similar event, and accept benefits that are provided at the event, if other former employees have also been invited to attend and it is clear that these benefits are not being offered or enhanced because of the employee’s official position. There is currently some ambiguity in this regard because of the phrasing of the existing

paragraph. OGE does not believe a distinction should be made between events based on current and former business or employment activities. Under either situation, the invitation and any benefits must clearly be offered because of the employee’s former or current non-Government position and not because of Federal employment or the official’s status. Proposed *Example 1 to paragraph (e)(4)* illustrates this provision. There are no substantive changes to the other examples to paragraph (e).

OGE proposes to amend § 2635.204(f) to clarify that a gift that may be accepted in connection with certain political activities includes offers of free attendance to an accompanying spouse and other guests. Proposed *Example 1 to paragraph (f)* is currently *Example 1* following § 2635.204(f). There is no substantive change to this example.

OGE is proposing a number of substantive revisions to § 2635.204(g). As described above, OGE proposes to remove § 2635.204(g)(1), *Speaking and similar engagements*. The substance of the exception will be included in a new exclusion from the definition of “gift” at proposed § 2635.203(b)(8). Proposed § 2635.204(g) will focus on when an employee may accept an invitation of free attendance at a “widely attended gathering.” Accordingly, OGE proposes re-titling § 2635.204(g) as “Gifts of free attendance at widely attended gatherings.” Proposed § 2635.204(g)(1) would set forth the rule for when an employee may accept an unsolicited gift of free attendance at such a gathering, while proposed subparagraphs (g)(2)–(g)(5) provide definitions and concepts that apply throughout § 2635.204(g). Proposed § 2635.204(g)(6) is similar to current § 2635.204(g)(6), but has been amended to clarify that an employee may bring only one accompanying guest under the authority found in that section. This has been OGE’s interpretation of the regulation since its promulgation in 1996. *See* 61 FR 42965, 42968 (Aug. 20, 1996).

Proposed § 2635.204(g)(1) provides that an employee may accept a gift of free attendance to attend a widely attended gathering only upon receiving a written authorization from the agency designee. This is a change from the current rule. Currently, a written determination is required only when the person extending the invitation has interests that may be substantially affected by the performance or non-performance of the employee’s official duties, or is an organization the majority of whose members have such interests.

Although OGE is sympathetic to agency concerns that requiring that all

determinations be made in writing may increase workload, OGE believes that increased access to certain technologies since the Standards were promulgated, such as the Internet and mobile devices, reduces this concern. Additionally, OGE believes that requiring a written authorization on all occasions will promote the public's confidence in Government operations.

Proposed § 2635.204(g)(2) defines "widely attended gatherings." This definition is similar to the definition that is used in current § 2635.204(g)(2). OGE is proposing to amend the current definition to highlight that an event does not qualify as a widely attended gathering unless it is "expected that . . . there will be an opportunity to exchange ideas and views among invited persons." OGE has long held that an event does not meet the criteria of this exception if an opportunity to exchange ideas and views is not available. *See, e.g.,* OGE Informal Advisory Opinion 08 x 1 (Jan. 30, 2008) (stating that "the 'widely attended gathering' exception cannot be used to justify free attendance at an event that is not structured to allow interchange among attendees"); OGE Informal Advisory Opinion 07 x 14 (Dec. 5, 2007) (stating that OGE "considers it fundamental that a WAG must provide the opportunity for 'an exchange of ideas' with a large and diverse group. . . . If an event is so structured that an employee has little opportunity to exchange views with a large and diverse number of persons, then the very purpose of the exception would be defeated."); OGE Informal Advisory Opinion 99 x 2 (March 15, 1999). This amendment is being proposed to codify OGE's long-standing interpretation.

Proposed § 2635.204(g)(3) describes the finding that the agency designee must make before authorizing an employee to accept an offer of free attendance at a widely attended gathering. The proposed rule does not require a particular degree of specificity in making this finding, but does require written evidence that the determination was made. For example, an email from the agency designee to the employee indicating the designee's approval would be sufficient. This section also sets out the limitations that apply when the gift of free attendance is from someone other than the sponsor, including restrictions on the aggregate value of such gifts. OGE has set the ceiling for nonsponsor gifts of free attendance to match the threshold set by the General Service Administration (GSA) as the "minimal value" level used in the regulations implementing the Foreign Gifts and Decorations Act, 5

U.S.C. 7342. OGE raises this threshold on a three-year basis to match the dollar value set by GSA. The last time the regulatory ceiling was raised was in 2014. *See, e.g.,* 79 FR 28605 (May 19, 2014).

As described above, OGE proposes removing § 2635.204(g)(4) and the explanatory Note following the regulation, which sets out the definition of "free attendance" for the purposes of § 2635.204(g), because there is now a proposed subpart-wide definition of "free attendance" at § 2635.203(g). OGE proposes adding a new § 2635.204(g)(4) establishing factors the agency designee may consider in determining whether the agency's interest in having the employee attend the event outweighs the potential that the employee may be, or may appear to be, improperly influenced in the performance of his or her duties by accepting the gift.

OGE proposes to reword § 2635.204(g)(5) to more clearly state the criteria that apply when making a determination that a gift is from a person other than the sponsor.

Because the exception for widely attended gatherings generates more questions than perhaps any other gift exception, OGE has provided eight examples to the regulation. Proposed *Example 1 to paragraph (g)* is part of current *Example 1* following § 2635.204(g), but has been modified to illustrate when acceptance would not be permitted under the exception because the value of the gift from a nonsponsor is in excess of the regulatory threshold. *Example 2 to paragraph (g)* is new, and illustrates when acceptance would not be permitted under the exception because the gift is from a nonsponsor and the event is not expected to be attended by more than 100 persons. *Example 3 to paragraph (g)* is part of current *Example 1* following § 2635.204(g), but has been modified to illustrate when acceptance could be permitted under the exception because the gift is from the sponsor of the event. *Example 4 to paragraph (g)* is current *Example 2* following § 2635.204(g) modified to account for changes in the regulatory dollar threshold. *Example 5 to paragraph (g)* is current *Example 3* following § 2635.204(g). *Example 6 to paragraph (g)* is current *Example 5* following § 2635.204(g). *Example 7 to paragraph (g)* is current *Example 6* following § 2635.204(g) modified to reflect that all widely attended gathering authorizations must be in writing. Proposed *Example 8 to paragraph (g)* is new, and explains that an employee may not accept gifts of transportation to or from an event pursuant to the exception at § 2635.204(g). This is

consistent with OGE's longstanding interpretation of the definition.

OGE proposes to revise § 2635.204(h) to clarify that an employee may accept an invitation to attend a social event permitted under the current rule only when that invitation is unsolicited. OGE also proposes clarifying that the gift exception includes food, refreshments, and entertainment that are provided to the employee's spouse or other accompanying guests. OGE further proposes to add a new § 2635.204(h)(3) to require an employee to receive a written determination that the employee's attendance at the event complies with the proposed standard set out at § 2635.201(b) when either the sponsor of the event or the person extending the invitation is not an individual. If the event is being hosted by an organization or the invitation is from an organization, as opposed to an individual, OGE believes that it is appropriate to require an independent written determination by an agency ethics official confirming that the employee's acceptance of free meals, refreshments, and entertainment would not cause a reasonable person to question the employee's integrity under the standard found in proposed § 2635.201(b). OGE proposes removing the examples following § 2635.204(h), and replacing them with new *Example 1 to paragraph (h)* illustrating a situation in which acceptance under this paragraph would be permitted.

OGE proposes to amend § 2635.204(i) to clarify that gifts of meals, refreshments, and entertainment provided in a foreign area may be accepted only when unsolicited. OGE has also updated the citations throughout the regulation.

OGE proposes revising § 2635.204(k) to include a cross-reference to § 2635.105, which sets forth the requirements that agencies must follow to promulgate supplemental agency regulations.

OGE proposes to revise § 2635.204(l) by removing the Note following paragraph (1), as it is not necessary for understanding the scope or substance of the exception.

OGE proposes to add a new gift exception for unsolicited gifts of informational materials at proposed § 2635.204(m). Executive Branch employees occasionally receive unsolicited gifts of books and periodicals. These items are often given with the goal of communicating the ideas and positions of the donor rather than personally benefitting the individual employee. The proposed gift exception would allow acceptance of these materials when either they are less

than \$100 or, if they are in excess of \$100, there has been a determination that their acceptance accords with the general standard found at proposed § 2635.201(b). An employee could not use the proposed exception to accept entertainment materials, such as novels, audio or video recordings of entertainment programs, or pictures, photographs, or artwork intended for display or decoration. Section (m)(2) provides guidance on what constitutes informational materials. OGE also proposes providing two new examples to illustrate this exception.

Proposed § 2635.205 Limitations on Use of Exceptions

As previously described, OGE is proposing to move the limitations on employees' ability to use and rely on the exceptions in § 2635.204, which were previously located at § 2635.202(c), to § 2635.205. OGE further proposes to revise the regulatory text of proposed § 2635.205(b), which is current § 2635.202(c)(2), by rewording this paragraph to prohibit an employee from "[u]s[ing], or permit[ing] the use of, the employee's Government position, or any authority associated with public office, to solicit or coerce the offering of a gift." This rewording is consistent with the language currently found in subpart G of the Standards, which broadly prohibits employees from using their public office for private gain. See 5 CFR 2635.702(a).

Some exceptions would permit employees to solicit certain gifts in limited circumstances where it is clear that they have not used their official positions to induce the offering of the gifts, as in the case of an employee who solicits a gift from his or her spouse even though the spouse is employed by a prohibited source, pursuant to the exception at § 2635.204(b). These exceptions include: § 2635.204(b) (Gifts based on a personal relationship); § 2635.204(c) (Discounts and similar benefits); § 2635.204(d) (Awards and honorary degrees); § 2635.204(e) (Gifts based on outside business or employment relationships); § 2635.204(f) (Gifts in connection with political activities permitted by the Hatch Act Reform Amendments); § 2635.204(j) (Gifts to the President or Vice President); § 2635.204(k) (Gifts authorized by supplemental agency regulation); and § 2635.204(l) (Gifts accepted under specific statutory authority). However, these exceptions would continue to prohibit employees from using the authority of their positions to solicit or coerce the offering of gifts. They would also continue to prohibit employees from soliciting gifts

to be given because of the employee's position.

Other exceptions would bar solicitation of gifts under any circumstances, even where employees have not used the authority of their positions to influence or induce the giving of the gift. To emphasize this broader prohibition, OGE retained, and in some cases added, language in these exceptions clarifying that they apply only to the acceptance of "unsolicited" gifts. These exceptions include: § 2635.204(a) (Gifts of \$20 or less); § 2635.204(g) (Gifts of free attendance at widely attended gatherings); § 2635.204(h) (Social invitations); § 2635.204(i) (Meals, refreshments and entertainment in foreign areas); and § 2635.204(m) (Gifts of informational materials).

OGE proposes to expand the description of the federal bribery statute, found at proposed § 2635.205(d)(1), to more closely follow the text of the law. OGE also proposes to add two new limitations on the use of the exceptions found at § 2635.204. Proposed § 2635.205(e) would bar an employee from relying on an exception to the general gift prohibition when the acceptance of the gift would be prohibited by Executive Order. Similarly, proposed § 2635.205(f) would bar an employee from relying on an exception to the general gift prohibition when the acceptance of the gift would be prohibited by supplemental agency regulation issued with the concurrence of OGE.

OGE proposes removing the limitation currently found at § 2635.202(c)(5) dealing with the acceptance of vendor promotional training. This limitation was originally included to ensure that any gift would be consistent with the guidelines on vendor promotional training in the Federal Information Resources Management Regulation, which was issued by the General Services Administration (GSA). See 57 FR 35006, 35012–13 (Aug. 7, 1992). However, that GSA regulation was rescinded in 1996.

Proposed *Example 1 to paragraph (c)* is current *Example 1* following § 2635.202(c)(3).

Proposed § 2635.206 Proper Disposition of Prohibited Gifts

OGE proposes to move the regulations pertaining to the proper disposition of prohibited gifts from § 2635.205 to § 2635.206.

OGE proposes to modify the language currently found at § 2635.205(a), and redesignated at § 2635.206(a), to enhance readability, to add headings to the subparagraphs, and to emphasize

that employees must promptly dispose of gifts that are accepted in violation of the subpart. OGE also proposes to add a sentence explaining that the obligation to dispose of prohibited gifts is independent of an agency's decision to initiate corrective or disciplinary action.

Currently, § 2635.205(a)(1) provides that an employee who receives a tangible gift that is prohibited by the subpart must either return the gift to the donor or pay the donor the market value. Proposed § 2635.206(a)(1) would amend the regulation to provide employees with the option of destroying gifts with a market value not in excess of \$100. OGE understands that on occasion it may be impossible, cost-prohibitive, or time-consuming for the employee or agency to return the prohibited gift. This could be the case, for example, if the donor was unknown or unreachable. In these cases, where the gift is a tangible item and the market value is \$100 or less, OGE believes the Government's interest may be better served by permitting an employee to destroy the gift. Destruction may be carried out by physical destruction or by permanently discarding the gift by placing it in a waste receptacle. OGE has provided examples illustrating proper gift disposition at the end of the relevant paragraphs.

OGE proposes revising § 2635.206(a)(2) for technical reasons. Proposed § 2635.206(a)(4) updates the citation that relates to disposition of gifts received from foreign governments or international organizations and strikes the language related to disposal of materials related to official travel. The latter provision has become obsolete following statutory changes occurring after the original promulgation of the Standards.

OGE proposes to add a new § 2635.206(d) to encourage employees to record any actions that they take to dispose of gifts that cannot be accepted under the subpart.

III. Matters of Regulatory Procedure

Regulatory Flexibility Act

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this proposed rule would not have a significant economic impact on a substantial number of small entities because it primarily affects current Federal Executive Branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that

require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 5, subchapter II), this proposed rule would not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (as adjusted for inflation) in any one year.

Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly this rule has been reviewed by the Office of Management and Budget.

Executive Order 12988

As Director of the Office of Government Ethics, I have reviewed this proposed rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects in 5 CFR Part 2635

Conflict of interests, Executive Branch standards of ethical conduct, Government employees.

Approved: November 9, 2015.

Walter M. Shaub, Jr.,

Director, Office of Government Ethics.

Accordingly, for the reasons set forth in the preamble, the Office of Government Ethics proposes to amend 5 CFR part 2635 as set forth below:

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 1. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Revise subpart B of part 2635 to read as follows:

Subpart B—Gifts From Outside Sources

Sec.

- 2635.201 Overview and considerations for declining otherwise permissible gifts.
- 2635.202 General prohibition on solicitation or acceptance of gifts.
- 2635.203 Definitions.
- 2635.204 Exceptions to the prohibition on acceptance of certain gifts.
- 2635.205 Limitations on use of exceptions.
- 2635.206 Proper disposition of prohibited gifts.

Subpart B—Gifts From Outside Sources

§ 2635.201 Overview and considerations for declining otherwise permissible gifts.

(a) *Overview.* This subpart contains standards that prohibit an employee from soliciting or accepting any gift from a prohibited source or any gift given because of the employee’s official position, unless the item is excluded from the definition of a gift or falls within one of the exceptions set forth in this subpart.

(b) *Considerations for declining otherwise permissible gifts.* (1) Every employee has a responsibility to the United States and its citizens to place loyalty to the Constitution, laws, and ethical principles above personal gain. An employee’s actions should promote the public’s trust that this fundamental responsibility is being met. Even when acceptance of a gift would be permitted by one of the exceptions contained in § 2635.204, it is frequently prudent for an employee to decline a gift offered by a prohibited source or because of the employee’s official position. In determining whether acceptance of a gift otherwise permitted by an exception set forth in § 2635.204 would be prudent, an employee should consider whether a reasonable person with knowledge of the relevant facts would question the employee’s integrity.

(2) In considering whether acceptance of a gift would lead a reasonable person to question the employee’s integrity, an employee may consider, among other factors:

- (i) Whether the gift has a high or low market value;
- (ii) Whether the gift was provided by a person or organization who has interests that may be affected substantially by the performance or nonperformance of the employee’s official duties;
- (iii) Whether acceptance of the gift would lead the employee to feel a sense of obligation to the donor;

(iv) Whether acceptance of the gift would reasonably create an appearance that the employee is providing the donor with preferential treatment or access to the Government;

(v) With regard to a gift of free attendance at an event, whether the Government is also providing persons with views or interests that differ from those of the donor with access to the Government;

(vi) With regard to a gift of free attendance at an event, whether the event is open to interested members of the public or representatives of the news media;

(vii) Whether acceptance of the gift would cause a reasonable person to question the employee’s ability to act impartially; and

(viii) Whether acceptance of the gift would interfere with the employee’s conscientious performance of official duties.

(3) Notwithstanding paragraph (b)(1) of this section, an employee who accepts a gift that qualifies for an exception under § 2635.204 does not violate this subpart or the Principles of Ethical Conduct set forth in § 2635.101(b).

(4) Employees who have questions regarding this subpart, including whether the employee should decline a gift that would otherwise be permitted under an exception found in § 2635.204, should seek advice from an agency ethics official. *See* § 2635.107(b).

§ 2635.202 General prohibition on solicitation or acceptance of gifts.

(a) *Prohibition on soliciting gifts.* Except as provided in this subpart, an employee may not, directly or indirectly:

- (1) Solicit a gift from a prohibited source; or
- (2) Solicit a gift to be given because of the employee’s official position.

(b) *Prohibition on accepting gifts.* Except as provided in this subpart, an employee may not, directly or indirectly:

- (1) Accept a gift from a prohibited source; or
- (2) Accept a gift given because of the employee’s official position.

(c) *Relationship to illegal gratuities statute.* A gift accepted pursuant to an exception found in this subpart will not constitute an illegal gratuity otherwise prohibited by 18 U.S.C. 201(c)(1)(B), unless it is accepted in return for being influenced in the performance of an official act. As more fully described in § 2635.205(d)(1), an employee may not solicit or accept a gift if to do so would be prohibited by the federal bribery statute, 18 U.S.C. 201(b).

Example 1 to paragraph (c): A government contractor who specializes in information technology software has offered an employee of the Department of Energy's information technology acquisition division a \$15 gift card to a local restaurant if the employee will allow the vendor to present a demonstration of the contractor's products at the division's staff meeting. Even though the gift card is less than \$20, the employee may not accept the gift under 5 CFR 2635.204(a) because it is conditional upon official action by the employee. Pursuant to §§ 2635.202(c) and 2635.205(a), notwithstanding any exception to the rule, an employee may not accept a gift in return for being influenced in the performance of an official act.

§ 2635.203 Definitions.

For purposes of this subpart, the following definitions apply:

(a) *Agency* has the meaning set forth in § 2635.102(a). However, for purposes of this subpart, an executive department, as defined in 5 U.S.C. 101, may, by supplemental agency regulation, designate as a separate agency any component of that department which the department determines exercises distinct and separate functions.

(b) *Gift* includes any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. The term excludes the following:

(1) Modest items of food and refreshments, such as soft drinks, coffee and donuts, offered other than as part of a meal;

Example 1 to paragraph (b)(1): A Department of Defense employee is invited to a defense contractor's holiday party. Alcoholic beverages are served at the party. Attendance at the party would be a gift to the employee because alcoholic beverages are not modest items of food or refreshment.

(2) Greeting cards and items with little intrinsic value, such as plaques, certificates, and trophies, which are intended primarily for presentation;

Example 1 to paragraph (b)(2): After giving a speech at the facility of a pharmaceutical company, a Government employee is presented with a glass paperweight in the shape of a pill capsule with the name of the company's latest drug and the date of the speech imprinted on the side. The employee may accept the paperweight because it is an item with little intrinsic value which is intended primarily for presentation.

Example 2 to paragraph (b)(2): After participating in a panel discussion hosted by an international media company, a Government employee is presented with an

inexpensive portable music player emblazoned with the media company's logo. The portable music player has a market value of \$25. The employee may not accept the portable music player as it has a significant independent use as a music player rather than being intended primarily for presentation.

Example 3 to paragraph (b)(2): After giving a speech at a conference held by a national association for miners, a Department of Commerce employee is presented with a block of granite that is engraved with the association's logo, a picture of the Appalachian Mountains, the date of the speech and the employee's name. The employee may accept this item because it is similar to a plaque, is designed primarily for presentation, and has little intrinsic value.

(3) Loans from banks and other financial institutions on terms generally available to the public;

(4) Opportunities and benefits, including favorable rates and commercial discounts, available to the public or to a class consisting of all Government employees or all uniformed military personnel, whether or not restricted on the basis of geographic considerations;

(5) Rewards and prizes given to competitors in contests or events, including random drawings, open to the public unless the employee's entry into the contest or event is required as part of the employee's official duties;

Example 1 to paragraph (b)(5): A Government employee is attending a free trade show on official time. The trade show is held in a public shopping area adjacent to the employee's office building. The employee voluntarily enters a drawing at an individual vendor's booth which is open to the public. She fills in an entry form on the vendor's display table and drops it into the contest box. The employee may accept the resulting prize because entry into the contest was not required by or related to her official duties.

Example 2 to paragraph (b)(5): All attendees at a conference, which is not open to the public, are entered in a drawing for a weekend getaway to Bermuda as a result of being registered for the conference. A Government employee who attends the conference in his official capacity at the Government's expense cannot accept the weekend getaway, which is a "door prize," because his entry in the contest was a result of registering for the conference as part of his official duties. Similarly, the employee could not accept the prize if entry into the drawing were restricted to those conference attendees who completed a conference evaluation, even if completing the evaluation was optional, because completing the evaluation was part of the conference and, therefore, incident to the performance of his official duties.

(6) Pension and other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a current or former employer;

(7) Anything which is paid for by the Government or secured by the Government under Government contract;

Example 1 to paragraph (b)(7): An employee at the Occupational Safety and Health Administration is assigned to travel away from her duty station to conduct an investigation of a collapse at a construction site. The employee's agency is paying for her travel expenses, including her airfare. The employee may accept and retain travel promotional items, such as frequent flyer miles, received as a result of her official travel, if done in accordance with 5 U.S.C. 5702, note, and 41 CFR part 301-53.

(8) Free attendance to an event provided by the sponsor of the event to:

(i) An employee who is assigned to present information on behalf of the agency at the event on any day when the employee is presenting;

(ii) An employee whose presence on any day of the event is deemed to be essential by the agency to the presenting employee's participation in the event, provided that the employee is accompanying the presenting employee; and

(iii) The spouse or one other guest of the presenting employee on any day when the employee is presenting, provided that others in attendance will generally be accompanied by a spouse or other guest, the offer of free attendance for the spouse or other guest is unsolicited, and the agency designee has authorized the presenting employee orally or in writing to accept.

Example 1 to paragraph (b)(8): An employee of the Department of the Treasury is assigned to participate in a panel discussion of economic issues as part of a one-day conference may accept the sponsor's waiver of the conference fee. Under the separate authority of § 2635.204(a), the employee may accept a token of appreciation for her speech having a market value of \$20 or less.

Example 2 to paragraph (b)(8): An employee of the Securities and Exchange Commission is assigned to present the agency's views at a roundtable discussion of an ongoing working group. The employee may accept free attendance to the meeting under § 2635.203(b)(8) because the employee has been assigned to present information at the meeting on behalf of the agency. If it is determined by the agency that it is essential that another employee accompany the presenting employee to the roundtable discussion, the accompanying employee may also accept free attendance to the meeting under § 2635.203(b)(8)(ii).

Example 3 to paragraph (b)(8): An employee of the United States Trade and Development Agency is invited to attend a cocktail party hosted by a prohibited source. The employee believes that while at the event he will have an opportunity to discuss official matters with other attendees. Although the employee may voluntarily

discuss official matters with other attendees, the employee has not been assigned to present information on behalf of the agency. The employee may not accept free attendance to the event under § 2635.203(b)(8).

(9) Any gift accepted by the Government under specific statutory authority, including:

(i) Travel, subsistence, and related expenses accepted by an agency under the authority of 31 U.S.C. 1353 in connection with an employee's attendance at a meeting or similar function relating to the employee's official duties which take place away from the employee's duty station, provided that the agency's acceptance is in accordance with the implementing regulations at 41 CFR chapter 304; and

(ii) Other gifts provided in-kind which have been accepted by an agency under its agency gift acceptance statute; and

(10) Anything for which market value is paid by the employee.

(c) *Market value* means the cost that a member of the general public would reasonably expect to incur to purchase the gift. An employee who cannot ascertain the market value of a gift may estimate its market value by reference to the retail cost of similar items of like quality. The market value of a gift of a ticket entitling the holder to food, refreshments, entertainment, or any other benefit is deemed to be the face value of the ticket.

Example 1 to paragraph (c): An employee who has been given a watch inscribed with the corporate logo of a prohibited source may determine its market value based on her observation that a comparable watch, not inscribed with a logo, generally sells for about \$50.

Example 2 to paragraph (c): During an official visit to a factory operated by a well-known athletic footwear manufacturer, an employee of the Department of Labor is offered a commemorative pair of athletic shoes manufactured at the factory. Although the cost incurred by the donor to manufacture the shoes was \$17, the market value of the shoes would be the \$100 that the employee would have to pay for the shoes on the open market.

Example 3 to paragraph (c): A prohibited source has offered a Government employee a ticket to a charitable event consisting of a cocktail reception to be followed by an evening of chamber music. Even though the food, refreshments, and entertainment provided at the event may be worth only \$20, the market value of the ticket is its \$250 face value.

Example 4 to paragraph (c): A company offers an employee of the Federal Communication Commission (FCC) free attendance for two to a private skybox at a ballpark to watch a major league baseball game. The skybox is leased annually by the company, which has business pending before the FCC. To determine the market value of

the tickets, the employee must add the market value of two of the most expensive publicly available tickets to the game and the market value of any food, parking or other tangible benefits provided in connection with the gift of attendance.

Example 5 to paragraph (c): An employee of the Department of Agriculture is invited to a reception held by a prohibited source. There is no entrance fee to the reception event or to the venue. To determine the market value of the gift, the employee must add the market value of any entertainment, food, beverages, or other tangible benefit provided to attendees in connection with the reception, but need not consider the cost incurred by the sponsor to rent or maintain the venue where the event is held. The employee may rely on a per-person cost estimate provided by the sponsor of the event, unless the employee or an agency designee has determined that a reasonable person would find that the estimate is clearly implausible.

(d) *Prohibited source* means any person who:

(1) Is seeking official action by the employee's agency;

(2) Does business or seeks to do business with the employee's agency;

(3) Conducts activities regulated by the employee's agency;

(4) Has interests that may be substantially affected by performance or nonperformance of the employee's official duties; or

(5) Is an organization a majority of whose members are described in paragraphs (d)(1) through (4) of this section.

(e) *Given because of the employee's official position.* A gift is given because of the employee's official position if the gift is from a person other than an employee and would not have been given had the employee not held the status, authority, or duties associated with the employee's Federal position.

Note to paragraph (e): Gifts between employees are subject to the limitations set forth in subpart C of this part.

Example 1 to paragraph (e): Where free season tickets are offered by an opera guild to all members of the Cabinet, the gift is offered because of their official positions.

Example 2 to paragraph (e): Employees at a regional office of the Department of Justice (DOJ) work in Government-leased space at a private office building, along with various private business tenants. A major fire in the building during normal office hours causes a traumatic experience for all occupants of the building in making their escape, and it is the subject of widespread news coverage. A corporate hotel chain, which does not meet the definition of a prohibited source for DOJ, seizes the moment and announces that it will give a free night's lodging to all building occupants and their families, as a public goodwill gesture. Employees of DOJ may accept, as this gift is not being given because of their Government positions. The donor's

motivation for offering this gift is unrelated to the DOJ employees' status, authority, or duties associated with their Federal position, but instead is based on their mere presence in the building as occupants at the time of the fire.

(f) *Indirectly solicited or accepted.* A gift which is solicited or accepted indirectly includes a gift:

(1) Given with the employee's knowledge and acquiescence to the employee's parent, sibling, spouse, child, dependent relative, or a member of the employee's household because of that person's relationship to the employee; or

(2) Given to any other person, including any charitable organization, on the basis of designation, recommendation, or other specification by the employee, except the employee has not indirectly solicited or accepted a gift by the raising of funds or other support for a charitable organization if done in accordance with § 2635.808.

Example 1 to paragraph (f)(2): An employee who must decline a gift of a personal computer pursuant to this subpart may not suggest that the gift be given instead to one of five charitable organizations whose names are provided by the employee.

(g) *Free attendance* includes waiver of all or part of the fee for an event or the provision of food, refreshments, entertainment, instruction or materials furnished to all attendees as an integral part of the event. It does not include travel expenses, lodgings, or entertainment collateral to the event. It does not include meals taken other than in a group setting with all other attendees, unless the employee is a presenter at the event and is invited to a separate meal for participating presenters that is hosted by the sponsor of the event. Where the offer of free attendance has been extended to an accompanying spouse or other guest, the market value of the gift of free attendance includes the market value of free attendance by both the employee and the spouse or other guest.

§ 2635.204 Exceptions to the prohibition on acceptance of certain gifts.

Subject to the limitations in § 2635.205, this section establishes exceptions to the prohibitions set forth in § 2635.202(a) and (b).

(a) *Gifts of \$20 or less.* An employee may accept unsolicited gifts having an aggregate market value of \$20 or less per source per occasion, provided that the aggregate market value of individual gifts received from any one person under the authority of this paragraph does not exceed \$50 in a calendar year. This exception does not apply to gifts of cash or of investment interests such as

stock, bonds, or certificates of deposit. Where the market value of a gift or the aggregate market value of gifts offered on any single occasion exceeds \$20, the employee may not pay the excess value over \$20 in order to accept that portion of the gift or those gifts worth \$20. Where the aggregate value of tangible items offered on a single occasion exceeds \$20, the employee may decline any distinct and separate item in order to accept those items aggregating \$20 or less.

Example 1 to paragraph (a): An employee of the Securities and Exchange Commission and his spouse have been invited by a representative of a regulated entity to a community theater production, tickets to which have a face value of \$30 each. The aggregate market value of the gifts offered on this single occasion is \$60, \$40 more than the \$20 amount that may be accepted for a single event or presentation. The employee may not accept the gift of the evening of entertainment. He and his spouse may attend the play only if he pays the full \$60 value of the two tickets.

Example 2 to paragraph (a): An employee of the National Geospatial-Intelligence Agency has been invited by an association of cartographers to speak about her agency's role in the evolution of missile technology. At the conclusion of her speech, the association presents the employee a framed map with a market value of \$18 and a ceramic mug that has a market value of \$15. The employee may accept the map or the mug, but not both, because the aggregate value of these two tangible items exceeds \$20.

Example 3 to paragraph (a): On four occasions during the calendar year, an employee of the Defense Logistics Agency (DLA) was given gifts worth \$10 each by four employees of a corporation that is a DLA contractor. For purposes of applying the yearly \$50 limitation on gifts of \$20 or less from any one person, the four gifts must be aggregated because a person is defined at § 2635.102(k) to mean not only the corporate entity, but its officers and employees as well. However, for purposes of applying the \$50 aggregate limitation, the employee would not have to include the value of a birthday present received from his cousin, who is employed by the same corporation, if he can accept the birthday present under the exception at § 2635.204(b) for gifts based on a personal relationship.

Example 4 to paragraph (a): Under the authority of 31 U.S.C. 1353 for agencies to accept payments from non-Federal sources in connection with attendance at certain meetings or similar functions, the Environmental Protection Agency (EPA) has accepted an association's gift of travel expenses and conference fees for an employee to attend a conference on the long-term effect of radon exposure. While at the conference, the employee may accept a gift of \$20 or less from the association or from another person attending the conference even though it was not approved in advance by the EPA. Although 31 U.S.C. 1353 is the

authority under which the EPA accepted the gift to the agency of travel expenses and conference fees, a gift of \$20 or less accepted under § 2635.204(a) is a gift to the employee rather than to her employing agency.

Example 5 to paragraph (a): During off-duty time, an employee of the Department of Defense (DoD) attends a trade show involving companies that are DoD contractors. He is offered software worth \$15 at X Company's booth, a calendar worth \$12 at Y Company's booth, and a deli lunch worth \$8 from Z Company. The employee may accept all three of these items because they do not exceed \$20 per source, even though they total more than \$20 at this single occasion.

Example 6 to paragraph (a): An employee of the Department of Defense (DoD) is being promoted to a higher level position in another DoD office. Six individuals, each employed by a different defense contractor, who have worked with the DoD employee over the years, decide to act in concert to pool their resources to buy her a nicer gift than each could buy her separately. Each defense contractor employee contributes \$20 to buy a desk clock for the DoD employee that has a market value of \$120. Although each of the contributions does not exceed the \$20 limit, the employee may not accept the \$120 gift because it is a single gift that has a market value in excess of \$20.

Example 7 to paragraph (a): During a holiday party, an employee of the Department of State is given a \$15 store gift card to a national coffee chain by an agency contractor. The employee may accept the card as the market value is less than \$20. The employee could not, however, accept a gift card that is issued by a credit card company or other financial institution, because such a card is equivalent to a gift of cash.

(b) *Gifts based on a personal relationship.* An employee may accept a gift given by an individual under circumstances which make it clear that the gift is motivated by a family relationship or personal friendship rather than the position of the employee. Relevant factors in making such a determination include the history and nature of the relationship and whether the family member or friend personally pays for the gift.

Example 1 to paragraph (b): An employee of the Federal Deposit Insurance Corporation (FDIC) has been dating an accountant employed by a member bank. As part of its "Work-Life Balance" program, the bank has given each employee in the accountant's division two tickets to a professional basketball game and has urged each to invite a family member or friend to share the evening of entertainment. Under the circumstances, the FDIC employee may accept the invitation to attend the game. Even though the tickets were initially purchased by the member bank, they were given without reservation to the accountant to use as she wished, and her invitation to the employee was motivated by their personal friendship.

Example 2 to paragraph (b): Three partners in a law firm that handles corporate mergers

have invited an employee of the Federal Trade Commission to join them in a golf tournament at a private club at the firm's expense. The entry fee is \$500 per foursome. The employee cannot accept the gift of one-quarter of the entry fee even though he and the three partners have developed an amicable relationship as a result of the firm's dealings with the FTC. As evidenced in part by the fact that the fees are to be paid by the firm, it is not a personal friendship but a business relationship that is the motivation behind the partners' gift.

Example 3 to paragraph (b): A Peace Corps employee enjoys using a social media site on the internet in his personal capacity outside of work. He has used the site to keep in touch with friends, neighbors, coworkers, professional contacts, and other individuals he has met over the years through both work and personal activities. One of these individuals works for a contractor that provides language services to the Peace Corps. The employee was acting in his official capacity when he met the individual at a meeting to discuss a matter related to the contract between their respective employers. Thereafter, the two communicated occasionally regarding contract matters. They later also granted one another access to join their social media networks through their respective social media accounts. However, they did not communicate further in their personal capacities, carry on extensive personal interactions, or meet socially outside of work. One day, the individual, whose employer continues to serve as a Peace Corps contractor, contacts the employee to offer him a pair of concert tickets worth \$30 apiece. Although the employee and the individual are connected through social media, the circumstances do not demonstrate that the gift was clearly motivated by a personal relationship, rather than the position of the employee, and therefore the employee may not accept the gift pursuant to § 2635.204(b).

(c) *Discounts and similar benefits.* In addition to those opportunities and benefits excluded from the definition of a gift by § 2635.203(b)(4), an employee may accept:

(1) A reduction or waiver of the fees for participation in organization activities offered to all Government employees or all uniformed military personnel by professional organizations if the only restrictions on membership relate to professional qualifications; and

(2) Opportunities and benefits, including favorable rates, commercial discounts, and free attendance or participation not precluded by paragraph (c)(3) of this section:

(i) Offered to members of a group or class in which membership is unrelated to Government employment;

(ii) Offered to members of an organization, such as an employees' association or agency credit union, in which membership is related to Government employment if the same

offer is broadly available to large segments of the public through organizations of similar size; or

(iii) Offered by a person who is not a prohibited source to any group or class that is not defined in a manner that specifically discriminates among Government employees on the basis of type of official responsibility or on a basis that favors those of higher rank or rate of pay.

Example 1 to paragraph (c)(2): A computer company offers a discount on the purchase of computer equipment to all public and private sector computer procurement officials who work in organizations with over 300 employees. An employee who works as the computer procurement official for a Government agency could not accept the discount to purchase the personal computer under the exception in § 2635.204(c)(2)(i). Her membership in the group to which the discount is offered is related to Government employment because her membership is based on her status as a procurement official with the Government.

Example 2 to paragraph (c)(2): An employee of the Consumer Product Safety Commission (CPSC) may accept a discount of \$50 on a microwave oven offered by the manufacturer to all members of the CPSC employees' association. Even though the CPSC is currently conducting studies on the safety of microwave ovens, the \$50 discount is a standard offer that the manufacturer has made broadly available through a number of employee associations and similar organizations to large segments of the public.

Example 3 to paragraph (c)(2): An Assistant Secretary may not accept a local country club's offer of membership to all members of Department Secretariats which includes a waiver of its \$5,000 membership initiation fee. Even though the country club is not a prohibited source, the offer discriminates in favor of higher ranking officials.

(3) An employee may not accept for personal use any benefit to which the Government is entitled as the result of an expenditure of Government funds, unless authorized by statute or regulation (e.g., 5 U.S.C. 5702, note, regarding frequent flyer miles).

Example 1 to paragraph (c)(3): The administrative officer for a field office of U.S. Immigration and Customs Enforcement (ICE) has signed an order to purchase 50 boxes of photocopy paper from a supplier whose literature advertises that it will give a free briefcase to anyone who purchases 50 or more boxes. Because the paper was purchased with ICE funds, the administrative officer cannot keep the briefcase which, if claimed and received, is Government property.

(d) *Awards and honorary degrees.*—(1) *Awards.* An employee may accept a bona fide award for meritorious public service or achievement and any item incident to the award, provided that:

(i) The award and any item incident to the award are not from a person who has interests that may be substantially affected by the performance or nonperformance of the employee's official duties, or from an association or other organization if a majority of its members have such interests; and

(ii) If the award or any item incident to the award is in the form of cash or an investment interest, or if the aggregate value of the award and any item incident to the award, other than free attendance to the event provided to the employee and to members of the employee's family by the sponsor of the event, exceeds \$200, the agency ethics official has made a written determination that the award is made as part of an established program of recognition.

Example 1 to paragraph (d)(1): Based on a written determination by an agency ethics official that the prize meets the criteria set forth in § 2635.204(d)(2), an employee of the National Institutes of Health may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.

Example 2 to paragraph (d)(1): A defense contractor, ABC Systems, has an annual award program for the outstanding public employee of the year. The award includes a cash payment of \$1,000. The award program is wholly funded to ensure its continuation on a regular basis for the next twenty years and selection of award recipients is made pursuant to written standards. An employee of the Department of the Air Force, who has duties that include overseeing contract performance by ABC Systems, is selected to receive the award. The employee may not accept the cash award because ABC Systems has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

Example 3 to paragraph (d)(1): An ambassador selected by a nonprofit organization as a recipient of its annual award for distinguished service in the interest of world peace may, together with his wife and children, attend the awards ceremony dinner and accept a crystal bowl worth \$200 presented during the ceremony. However, where the organization has also offered airline tickets for the ambassador and his family to travel to the city where the awards ceremony is to be held, the aggregate value of the tickets and the crystal bowl exceeds \$200, and he may accept only upon a written determination by the agency ethics official that the award is made as part of an established program of recognition.

(2) *Established program of recognition.* An award and an item incident to the award are made pursuant to an established program of recognition if:

(i) Awards have been made on a regular basis or, if the program is new,

there is a reasonable basis for concluding that awards will be made on a regular basis based on funding or funding commitments; and

(ii) Selection of award recipients is made pursuant to written standards.

(3) *Honorary degrees.* An employee may accept an honorary degree from an institution of higher education, as defined at 20 U.S.C. 1001, or from a similar foreign institution of higher education, based on a written determination by an agency ethics official that the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution.

Note to paragraph (d)(3): When the honorary degree is offered by a foreign institution of higher education, the agency may need to make a separate determination as to whether the institution of higher education is a foreign government for purposes of the Emoluments Clause of the U.S. Constitution (U.S. Const., art. I, § 9, cl. 8) which forbids employees from accepting emoluments, presents, offices, or titles from foreign governments, without the consent of Congress. The Foreign Gifts and Decorations Act, 5 U.S.C. 7342, however, may permit the acceptance of honorary degrees in some circumstances.

Example 1 to paragraph (d)(3): A well-known university located in the United States wishes to give an honorary degree to the Secretary of Labor. The Secretary may accept the honorary degree only if an agency ethics official determines in writing that the timing of the award of the degree would not cause a reasonable person to question the Secretary's impartiality in a matter affecting the university.

(4) *Presentation events.* An employee who may accept an award or honorary degree pursuant to paragraphs (d)(1) or (3) of this section may also accept free attendance to the event provided to the employee and to members of the employee's family by the sponsor of an event. In addition, the employee may also accept unsolicited offers of travel to and from the event provided to the employee and to members of the employee's family by the sponsor of the event. Travel expenses accepted under this paragraph must be added to the value of the award for purposes of determining whether the aggregate value of the award exceeds \$200.

(e) *Gifts based on outside business or employment relationships.* An employee may accept meals, lodgings, transportation and other benefits:

(1) Resulting from the business or employment activities of an employee's spouse when it is clear that such benefits have not been offered or enhanced because of the employee's official position;

Example 1 to paragraph (e)(1): A Department of Agriculture employee whose husband is a computer programmer employed by a Department of Agriculture contractor may attend the company's annual retreat for all of its employees and their families held at a resort facility. However, under § 2635.502, the employee may be disqualified from performing official duties affecting her husband's employer.

Example 2 to paragraph (e)(1): Where the spouses of other clerical personnel have not been invited, an employee of the Defense Contract Audit Agency whose wife is a clerical worker at a defense contractor may not attend the contractor's annual retreat in Hawaii for corporate officers and members of the board of directors, even though his wife received a special invitation for herself and her spouse.

(2) Resulting from the employee's outside business or employment activities when it is clear that such benefits are based on the outside business or employment activities and have not been offered or enhanced because of the employee's official status;

Example 1 to paragraph (e)(2): The members of an Army Corps of Engineers environmental advisory committee that meets six times per year are special Government employees. A member who has a consulting business may accept an invitation to a \$50 dinner from her corporate client, an Army construction contractor, unless, for example, the invitation was extended in order to discuss the activities of the advisory committee.

(3) Customarily provided by a prospective employer in connection with bona fide employment discussions. If the prospective employer has interests that could be affected by performance or nonperformance of the employee's duties, acceptance is permitted only if the employee first has complied with the disqualification requirements of subpart F of this part applicable when seeking employment; or

Example 1 to paragraph (e)(3): An employee of the Federal Communications Commission with responsibility for drafting regulations affecting all cable television companies wishes to apply for a job opening with a cable television holding company. Once she has properly disqualified herself from further work on the regulations as required by subpart F of this part, she may enter into employment discussions with the company and may accept the company's offer to pay for her airfare, hotel, and meals in connection with an interview trip.

(4) Provided by a former employer to attend a reception or similar event when other former employees have been invited to attend, the invitation and benefits are based on the former employment relationship, and it is clear that such benefits have not been offered or enhanced because of the employee's official position.

Example 1 to paragraph (e)(4): An employee of the Department of the Army is invited by her former employer, an Army contractor, to attend its annual holiday dinner party. The former employer traditionally invites both its current and former employees to the holiday dinner regardless of their current employment activities. Under these circumstances, the employee may attend the dinner because the dinner invitation is a result of the employee's former outside employment activities, other former employees have been asked to attend, and the gift is not offered because of the employee's official position.

(5) For purposes of paragraphs (e)(1) through (4) of this section, "employment" means any form of non-Federal employment or business relationship involving the provision of personal services.

(f) *Gifts in connection with political activities permitted by the Hatch Act Reform Amendments.* An employee who, in accordance with the Hatch Act Reform Amendments of 1993, at 5 U.S.C. 7323, may take an active part in political management or in political campaigns, may accept meals, lodgings, transportation, and other benefits, including free attendance at events, for the employee and an accompanying spouse or other guests, when provided, in connection with such active participation, by a political organization described in 26 U.S.C. 527(e). Any other employee, such as a security officer, whose official duties require him or her to accompany an employee to a political event, may accept meals, free attendance, and entertainment provided at the event by such an organization.

Example 1 to paragraph (f): The Secretary of the Department of Health and Human Services may accept an airline ticket and hotel accommodations furnished by the campaign committee of a candidate for the United States Senate in order to give a speech in support of the candidate.

(g) *Gifts of free attendance at widely attended gatherings.* (1) When authorized in writing by the agency designee pursuant to paragraph (g)(3) of this section, an employee may accept an unsolicited gift of free attendance at all or appropriate parts of a widely attended gathering. For an employee who is subject to a leave system, attendance at the event will be on the employee's own time or, if authorized by the employee's agency, on excused absence pursuant to applicable guidelines for granting such absence, or otherwise without charge to the employee's leave account.

(2) *Widely attended gatherings.* A gathering is widely attended if it is expected that a large number of persons will attend, that persons with a diversity of views or interests will be present, for

example, if it is open to members from throughout the interested industry or profession or if those in attendance represent a range of persons interested in a given matter, and that there will be an opportunity to exchange ideas and views among invited persons.

(3) *Written authorization by the agency designee.* The agency designee may authorize an employee or employees to accept a gift of free attendance at all or appropriate parts of a widely attended gathering only if the agency designee issues a written determination after finding that:

(i) The event is a widely attended gathering, as set forth in paragraph (g)(2) of this section;

(ii) The employee's attendance at the event is in the agency's interest because it will further agency programs and operations;

(iii) The agency's interest in the employee's attendance outweighs the concern that the employee may be, or may appear to be, improperly influenced in the performance of official duties; and

(iv) If a person other than the sponsor of the event invites or designates the employee as the recipient of the gift of free attendance and bears the cost of that gift, the event is expected to be attended by more than 100 persons and the value of the gift of free attendance does not exceed \$375.

(4) *Determination of agency interest.* In determining whether the agency's interest in the employee's attendance outweighs the concern that the employee may be, or may appear to be, improperly influenced in the performance of official duties, the agency designee may consider relevant factors including:

(i) The importance of the event to the agency;

(ii) The nature and sensitivity of any pending matter affecting the interests of the person who extended the invitation and the significance of the employee's role in any such matter;

(iii) The purpose of the event;

(iv) The identity of other expected participants;

(v) Whether acceptance would reasonably create the appearance that the donor is receiving preferential treatment;

(vi) Whether the Government is also providing persons with views or interests that differ from those of the donor with similar access to the Government; and

(vii) The market value of the gift of free attendance.

(5) *Cost provided by person other than the sponsor of the event.* The cost of the employee's attendance will be

considered to be provided by a person other than the sponsor of the event where such person designates the employee to be invited and bears the cost of the employee's attendance through a contribution or other payment intended to facilitate the employee's attendance. Payment of dues or a similar assessment to a sponsoring organization does not constitute a payment intended to facilitate a particular employee's attendance.

(6) *Accompanying spouse or other guest.* When others in attendance will generally be accompanied by a spouse or other guest, and where the invitation is from the same person who has invited the employee, the agency designee may authorize an employee to accept an unsolicited invitation of free attendance to an accompanying spouse or one other accompanying guest to participate in all or a portion of the event at which the employee's free attendance is permitted under paragraph (g)(1) this section. The authorization required by this paragraph must be provided in writing.

Example 1 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of \$800 and anticipates attendance of approximately 400. An Air Force contractor pays \$4,000 to the association so that the association can extend free invitations to five Air Force officials designated by the contractor. The Air Force officials may not accept the gifts of free attendance because (a) the contractor, rather than the association, provided the cost of their attendance; (b) the contractor designated the specific employees to receive the gift of free attendance; and (c) the value of the gift exceeds \$375 per employee.

Example 2 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of \$25 and anticipates attendance of approximately 50. An Air Force contractor pays \$125 to the association so that the association can extend free invitations to five Air Force officials designated by the contractor. The Air Force officials may not accept the gifts of free attendance because (a) the contractor, rather than the association, provided the cost of their attendance; (b) the contractor designated the specific employees to receive the gift of free attendance; and (c) the event was not expected to be attended by more than 100 persons.

Example 3 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of \$800 and anticipates attendance of approximately 400. An Air Force contractor pays \$4,000 in order that the association might invite any five Federal employees. An Air Force official to whom the sponsoring association, rather than the contractor, extended one of the five invitations could attend if the employee's participation were determined to be in the

interest of the agency and he received a written authorization.

Example 4 to paragraph (g): An employee of the Department of Transportation is invited by a news organization to an annual press dinner sponsored by an association of press organizations. Tickets for the event cost \$375 per person and attendance is limited to 400 representatives of press organizations and their guests. If the employee's attendance is determined to be in the interest of the agency, she may accept the invitation from the news organization because more than 100 persons will attend and the cost of the ticket does not exceed \$375. However, if the invitation were extended to the employee and an accompanying guest, the employee's guest could not be authorized to attend for free because the market value of the gift of free attendance would exceed \$375.

Example 5 to paragraph (g): An employee of the Department of Energy (DOE) and his spouse have been invited by a major utility executive to a small dinner party. A few other officials of the utility and their spouses or other guests are also invited, as is a representative of a consumer group concerned with utility rates and her spouse. The DOE official believes the dinner party will provide him an opportunity to socialize with and get to know those in attendance. The employee may not accept the free invitation under this exception, even if his attendance could be determined to be in the interest of the agency. The small dinner party is not a widely attended gathering. Nor could the employee be authorized to accept even if the event were instead a corporate banquet to which forty company officials and their spouses or other guests were invited. In this second case, notwithstanding the larger number of persons expected (as opposed to the small dinner party just noted) and despite the presence of the consumer group representative and her husband who are not officials of the utility, those in attendance would still not represent a diversity of views or interests. Thus, the company banquet would not qualify as a widely attended gathering under those circumstances either.

Example 6 to paragraph (g): An Assistant U.S. Attorney is invited to attend a luncheon meeting of a local bar association to hear a distinguished judge lecture on cross-examining expert witnesses. Although members of the bar association are assessed a \$15 fee for the meeting, the Assistant U.S. Attorney may accept the bar association's offer to attend for free, even without a determination of agency interest. The gift can be accepted under the \$20 gift exception at § 2635.204(a).

Example 7 to paragraph (g): An employee of the Department of the Interior authorized to speak on the first day of a four-day conference on endangered species may accept the sponsor's waiver of the conference fee for the first day of the conference under § 2635.203(b)(8). If the conference is widely attended, the employee may be authorized to accept the sponsor's offer to waive the attendance fee for the remainder of the conference if the agency designee has made a written determination that attendance is in the agency's interest.

Example 8 to paragraph (g): A military officer has been approved to attend a widely

attended gathering, pursuant to paragraph (g) of this section, that will be held in the same city as the officer's duty station. The defense contractor sponsoring the event has offered to transport the officer in a limousine to the event. The officer may not accept the offer of transportation because the definition of "free attendance" set forth in § 2635.203(g) excludes travel, and the market value of the transportation would exceed \$20.

(h) *Social invitations.* An employee may accept food, refreshments, and entertainment, not including travel or lodgings, for the employee and an accompanying spouse or other guests, at a social event attended by several persons if:

(1) The invitation is unsolicited and is from a person who is not a prohibited source;

(2) No fee is charged to any person in attendance; and

(3) If either the sponsor of the event or the person extending the invitation to the employee is not an individual, the agency designee makes a written determination after finding that the employee's attendance would not cause a reasonable person to question the employee's integrity. See § 2635.201(b).

Example 1 to paragraph (h): An employee of the White House Press Office has been invited to a social dinner for current and former White House Press Officers at the home of an individual who is not a prohibited source. The employee may attend even if she is being invited because of her official position.

(i) *Meals, refreshments, and entertainment in foreign areas.* An employee assigned to duty in, or on official travel to, a foreign area as defined in 41 CFR 300-3.1 may accept unsolicited food, refreshments, or entertainment in the course of a breakfast, luncheon, dinner, or other meeting or event provided:

(1) The market value in the foreign area of the food, refreshments or entertainment provided at the meeting or event, as converted to U.S. dollars, does not exceed the per diem rate for the foreign area specified in the U.S. Department of State's Maximum Per Diem Allowances for Foreign Areas, Per Diem Supplement Section 925 to the Standardized Regulations (GC-FA) available on the Internet at www.state.gov;

(2) There is participation in the meeting or event by non-U.S. citizens or by representatives of foreign governments or other foreign entities;

(3) Attendance at the meeting or event is part of the employee's official duties to obtain information, disseminate information, promote the export of U.S. goods and services, represent the United States, or otherwise further programs or

operations of the agency or the U.S. mission in the foreign area; and

(4) The gift of meals, refreshments, or entertainment is from a person other than a foreign government as defined in 5 U.S.C. 7342(a)(2).

Example 1 to paragraph (i): A number of local business owners in a developing country are eager for a U.S. company to locate a manufacturing facility in their province. An official of the Overseas Private Investment Corporation may accompany the visiting vice president of the U.S. company to a dinner meeting hosted by the business owners at a province restaurant where the market value of the food and refreshments does not exceed the per diem rate for that country.

(j) *Gifts to the President or Vice President.* Because of considerations relating to the conduct of their offices, including those of protocol and etiquette, the President or the Vice President may accept any gift on his or her own behalf or on behalf of any family member, provided that such acceptance does not violate § 2635.205(a) or (b), 18 U.S.C. 201(b) or 201(c)(3), or the Constitution of the United States.

(k) *Gifts authorized by supplemental agency regulation.* An employee may accept any gift when acceptance of the gift is specifically authorized by a supplemental agency regulation issued with the concurrence of the Office of Government Ethics, pursuant to 5 CFR 2635.105.

(l) *Gifts accepted under specific statutory authority.* The prohibitions on acceptance of gifts from outside sources contained in this subpart do not apply to any item which a statute specifically authorizes an employee to accept. Gifts which may be accepted by an employee under the authority of specific statutes include, but are not limited to:

(1) Free attendance, course or meeting materials, transportation, lodgings, food and refreshments or reimbursements therefor incident to training or meetings when accepted by the employee under the authority of 5 U.S.C. 4111 from an organization with tax-exempt status under 26 U.S.C. 501(c)(3) or from a person to whom the prohibitions in 18 U.S.C. 209 do not apply. The employee's acceptance must be approved by the agency in accordance with part 410 of this title; or

(2) Gifts from a foreign government or international or multinational organization, or its representative, when accepted by the employee under the authority of the Foreign Gifts and Decorations Act, 5 U.S.C. 7342. As a condition of acceptance, an employee must comply with requirements

imposed by the agency's regulations or procedures implementing that Act.

(m) *Gifts of informational materials.* (1) An employee may accept unsolicited gifts of informational materials when:

(i) The informational materials are primarily provided for educational or instructive purposes, rather than entertainment; and

(ii)(A) The aggregate market value of the informational materials is \$100 or less; or

(B) If the aggregate market value exceeds \$100, an agency designee makes a written determination that acceptance would not be inconsistent with the standard set forth in § 2635.201(b).

(2) *Informational materials.* Informational materials are writings, recordings, documents, records, or other items intended primarily to communicate information, not including images intended primarily for display or decoration, provided that the information relates in whole or in part to the following categories:

(i) The employee's official duties or position, profession, or field of study;

(ii) A general subject matter area, industry, or economic sector affected by or involved in the programs and operations of the agency; or

(iii) Another topic of interest to the agency or its mission.

Example 1 to paragraph (m): An analyst at the Agricultural Research Service receives an edition of an agricultural research journal in the mail from a consortium of private farming operations concerned with soil toxicity. The journal edition has a market value of \$75. The analyst may accept the gift.

Example 2 to paragraph (m): An inspector at the Mine Safety and Health Administration receives a popular novel with a market value of \$25 from a mine operator. Because the novel is primarily for entertainment purposes, the inspector may not accept the gift.

§ 2635.205 Limitations on use of exceptions.

Notwithstanding any exception provided in this subpart, other than § 2635.204(j), an employee may not:

(a) Accept a gift in return for being influenced in the performance of an official act;

(b) Use, or permit the use of, the employee's Government position, or any authority associated with public office, to solicit or coerce the offering of a gift;

(c) Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using the employee's public office for private gain;

Example 1 to paragraph (c): A purchasing agent for a Department of Veterans Affairs medical center routinely deals with

representatives of pharmaceutical manufacturers who provide information about new company products. Because of his crowded calendar, the purchasing agent has offered to meet with manufacturer representatives during his lunch hours Tuesdays through Thursdays, and the representatives routinely arrive at the employee's office bringing a sandwich and a soft drink for the employee. Even though the market value of each of the lunches is less than \$6 and the aggregate value from any one manufacturer does not exceed the \$50 aggregate limitation in § 2635.204(a) on gifts of \$20 or less, the practice of accepting even these modest gifts on a recurring basis is improper.

(d) Accept a gift in violation of any statute. Relevant statutes applicable to all employees include, but are not limited to:

(1) 18 U.S.C. 201(b), which prohibits a public official from, directly or indirectly, corruptly demanding, seeking, receiving, accepting, or agreeing to receive or accept anything of value personally or for any other person or entity in return for being influenced in the performance of an official act; being influenced to commit or aid in committing, or to collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or for being induced to do or omit to do any action in violation of his or her official duty. As used in 18 U.S.C. 201(b), the term "public official" is broadly construed and includes regular and special Government employees as well as all other Government officials; and

(2) 18 U.S.C. 209, which prohibits an employee, other than a special Government employee, from receiving any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a Government employee. The statute contains several specific exceptions to this general prohibition, including an exception for contributions made from the treasury of a State, county, or municipality;

(e) Accept a gift in violation of any Executive Order; or

(f) Accept any gift when acceptance of the gift is specifically prohibited by a supplemental agency regulation issued with the concurrence of the Office of Government Ethics, pursuant to 5 CFR 2635.105.

§ 2635.206 Proper disposition of prohibited gifts.

(a) Unless a gift is accepted by an agency acting under specific statutory authority, an employee who has received a gift that cannot be accepted under this subpart must dispose of the

gift in accordance with the procedures set forth in this section. The employee must promptly complete the authorized disposition of the gift. The obligation to dispose of a gift that cannot be accepted under this subpart is independent of an agency's decision regarding corrective or disciplinary action under § 2635.106.

(1) *Gifts of tangible items.* The employee must promptly return any tangible item to the donor, or pay the donor its market value, or, in the case that the tangible item has a market value not in excess of \$100, the employee may destroy the item. An employee who cannot ascertain the actual market value of an item may estimate its market value by reference to the retail cost of similar items of like quality. See § 2635.203(c).

Example 1 to paragraph (a)(1): A Department of Commerce employee received a \$25 T-shirt from a prohibited source after providing training at a conference. Because the gift would not be permissible under an exception to this subpart, the employee must either return or destroy the T-shirt or promptly reimburse the donor \$25. Destruction may be carried out by physical destruction or by permanently discarding the T-shirt by placing it in the trash.

Example 2 to paragraph (a)(1): To avoid public embarrassment to the seminar sponsor, an employee of the National Park Service did not decline a barometer worth \$200 given at the conclusion of his speech on Federal lands policy. To comply with this section, the employee must either promptly return the barometer or pay the donor the market value of the gift. Alternatively, the National Park Service may choose to accept the gift if permitted under specific statutory gift acceptance authority. The employee may not destroy this gift, as the market value is in excess of \$100.

(2) *Gifts of perishable items.* When it is not practical to return a tangible item in accordance with paragraph (a)(1) of this section because the item is perishable, the employee may, at the discretion of the employee's supervisor or the agency designee, give the item to an appropriate charity, share the item within the recipient's office, or destroy the item.

Example 1 to paragraph (a)(2): With approval by the recipient's supervisor, a floral arrangement sent by a disability claimant to a helpful employee of the Social Security Administration may be placed in the office's reception area.

(3) *Gifts of intangibles.* The employee must promptly reimburse the donor the market value for any entertainment, favor, service, benefit or other intangible. Subsequent reciprocation by the employee does not constitute reimbursement.

Example 1 to paragraph (a)(3): A Department of Defense employee wishes to attend a charitable event to which he has

been offered a \$300 ticket by a prohibited source. Although his attendance is not in the interest of the agency under § 2635.204(g), he may attend if he reimburses the donor the \$300 face value of the ticket.

(4) *Gifts from foreign governments or international organizations.* The employee must dispose of gifts from foreign governments or international organizations in accordance with 41 CFR part 102-42.

(b) An agency may authorize disposition or return of gifts at Government expense. Employees may use penalty mail to forward reimbursements required or permitted by this section.

(c) An employee who, on his or her own initiative, promptly complies with the requirements of this section will not be deemed to have improperly accepted an unsolicited gift. An employee who promptly consults his or her agency ethics official to determine whether acceptance of an unsolicited gift is proper and who, upon the advice of the ethics official, returns the gift or otherwise disposes of the gift in accordance with this section, will be considered to have complied with the requirements of this section on the employee's own initiative.

(d) Employees are encouraged to record any actions they have taken to properly dispose of gifts that cannot be accepted under this subpart, such as by sending an electronic mail message to the appropriate agency ethics official or the employee's supervisor.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS 2015-0079]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security/United States Coast Guard-029 Notice of Arrival and Departure System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security is giving concurrent notice of an updated and reissued system of records pursuant to the Privacy Act of 1974 for the "Department of Homeland Security/United States Coast Guard-029 Notice of Arrival and Departure System of Records" and this proposed

rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS 2015-0079, by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-343-4010.

- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this document. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Marilyn Scott-Perez, (202) 475-3515, Privacy Officer, Commandant (CG-61), United States Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Mail Stop 7710, Washington, DC 20593. For privacy questions, please contact: Karen L. Neuman, (202) 343-1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), United States Coast Guard (USCG) is giving notice of a proposed rulemaking that DHS/USCG intends to update its regulations to exempt portions of a system of records from certain provisions of the Privacy Act. Specifically, DHS/USCG proposes to exempt portions of the "DHS/USCG-029 Notice of Arrival and Departure System of Records" from one of more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. DHS/USCG is issuing an updated notice and proposed rule for proposed exemptions for these new categories of records pursuant to 5 U.S.C. 552a(j)(2) and 5 U.S.C. 552 a(k)(2). Furthermore, to the extent certain categories of records are ingested from other systems, the

exemptions applicable to the source systems will remain in effect.

Concurrent with this document, DHS/USCG is updating and reissuing a current DHS system of records titled, “DHS/USCG–029 Notice of Arrival and Departure (NOAD) System of Records.” The collection and maintenance of this information assists DHS/USCG in meeting its statutory obligation to assign priorities while conducting maritime safety and security missions in accordance with international and U.S. regulations. In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) United States Coast Guard (USCG) proposes to update and reissue a current DHS system of records titled, “DHS/USCG–029 Notice of Arrival and Departure (NOAD) System of Records.” The collection and maintenance of this information assists DHS/USCG in meeting its statutory obligation to assign priorities while conducting maritime safety and security missions in accordance with international and U.S. regulations. DHS/USCG is updating this system of records to (1) clarify the authority for the maintenance of the system to align with the recently published *Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System* Final Rule (January 30, 2015, 80 FR 5281); (2) update the security classification; (3) change the system location to clarify that NOAD records may be stored on information technology (IT) systems connected to classified networks; (4) update the purpose(s) to align with the updated authorities for collection, pursuant to the newly issued *Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System* Final Rule and to allow for replication of data for analysis and vetting as part of the DHS Data Framework; (5) update categories of individuals and categories of records to clarify that individuals considered “non-crew” for the purposes of this system may include passenger records, as well as organizations; (6) remove routine use (M) because it is not compatible with the original purpose for collection of the records (7) update the retention period and disposal standards to reflect that records will follow the same retention schedule despite their storage in a classified environment; (8) modify the notification procedures to confirm that regardless of record storage on a classified environment, DHS/USCG will review all replicated records; and (9) update the system manager and mailing address to reflect the new mail stop.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate personally identifiable information. The Privacy Act applies to information that is maintained in a “system of records.” A “system of records” is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

The Privacy Act allows government agencies to exempt certain records from the access and amendment provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is claimed.

DHS is claiming exemptions from certain requirements of the Privacy Act for DHS/USCG–029 Notice of Arrival and Departure System of Records. Some information in DHS/USCG–029 Notice of Arrival and Departure System of Records may be used to support official DHS national security or law enforcement activities. These exemptions are needed to protect information relating to DHS activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required protect information relating to DHS law enforcement investigations from disclosure to subjects of investigations and others who could interfere with investigatory and law enforcement activities. The exemptions are required to preclude subjects of these activities from frustrating the investigative process; to avoid disclosure of investigative techniques; protect the identities and physical safety of confidential informants and of law enforcement personnel; ensure DHS’s and other federal agencies’ ability to obtain information from third parties and other sources; protect the privacy of third parties; and safeguard sensitive information. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

In appropriate circumstances, where compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

DHS will not assert any exemption with respect to information maintained in the system that is collected from a person at the time of arrival or departure, if that person, or his or her agent, seeks access or amendment of such information. The DHS/USCG–029 Notice of Arrival and Departure System of Records Notice is also published in this issue of the **Federal Register**.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS proposes to amend chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

- 1. Revise the authority citation for part 5 to read as follows:

Authority: 6 U.S.C. 101 *et seq.*; Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

- 2. In appendix C to part 5, revise paragraph 34 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

34. The DHS/USCG–029 Notice of Arrival and Departure System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/USCG–029 Notice of Arrival and Departure System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under. The DHS/USCG–029 Notice of Arrival and Departure System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other federal, state, local, tribal, foreign, or international government agencies.

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), exempted this system from the following provisions of the Privacy Act: Sections (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information. Further, DHS has exempted section (c)(3) of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(k)(2) as is necessary and appropriate to protect this information.

Exemptions from these particular subsections are justified, on a case-by-case

basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(c) From subsection (g)(1) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

* * * * *

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015-30304 Filed 11-25-15; 8:45 a.m.]

BILLING CODE 9110-04-P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket No. EERE-2014-BT-TP-0014]

RIN 1904-AD22

Energy Conservation Program: Test Procedures for Portable Air Conditioners

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The U.S. Department of Energy (DOE) proposes to modify the test procedure proposals for portable air conditioners (ACs), initially presented in a notice of proposed rulemaking (NOPR) published on February 25, 2015. Upon further analysis and review of the public comments received in response to the February 2015 NOPR, DOE proposes in this supplemental notice of proposed rulemaking (SNOPR) the following additions and clarifications to its proposed portable AC test procedure: (1) Minor revisions to the indoor and outdoor cooling mode test conditions;

(2) an additional test condition for cooling mode testing; (3) updated infiltration air and capacity calculations to account for the second cooling mode test condition; (4) removal of the measurement of case heat transfer; (5) a clarification of test unit placement within the test chamber; (6) removal of the heating mode test procedure; (7) a revision to the CEER calculation to reflect the two cooling mode test conditions and removal of heating mode testing; and (8) additional technical corrections and clarifications. These proposals are to be combined with the initial NOPR proposals and would be codified in a newly created appendix CC to title 10 of the Code of Federal Regulations (CFR), part 430, subpart B. The test procedures would be used to determine capacities and energy efficiency metrics that would be the basis for any future energy conservation standards for portable ACs.

DATES: DOE will accept comments, data, and information regarding this SNOPR, submitted no later than December 28, 2015. See section V, "Public Participation," for details.

ADDRESSES: Any comments submitted must identify the SNOPR for Test Procedures for Portable Air Conditioners, and provide docket number EERE-2014-BT-TP-0014 and/or regulatory information number (RIN) number 1904-AD22. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

2. *Email:* PortableAC2014TP0014@ee.doe.gov. Include the docket number and/or RIN in the subject line of the message.

3. *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. If possible, please submit all items on a CD. It is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Room 6094, Washington, DC 20024. Telephone: (202) 586-2945. If possible, please submit all items on a CD. It is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section V of this document (Public Participation).

Docket: The docket, which includes **Federal Register** notices, public meeting

attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

A link to the docket Web page can be found at: <http://www.regulations.gov/#!docketDetail;D=EERE-2014-BT-TP-0014>. This Web page will contain a link to the docket for this notice on the www.regulations.gov site. The www.regulations.gov Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See Section V, "Public Participation," for information on how to submit comments through www.regulations.gov.

For further information on how to submit a comment, or review other public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: Brenda.Edwards@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT:

Mr. Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technology Office, EE-5B, 1000 Independence Ave. SW., Washington, DC 20585-0121. Telephone: 202-586-0371. Email: Bryan.Berringer@ee.doe.gov.

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, Mailstop GC-33, 1000 Independence Ave. SW., Washington, DC 20585-0121. Telephone: 202-586-1777; Email: Sarah.Butler@hq.doe.gov.

SUPPLEMENTARY INFORMATION: DOE intends to incorporate by reference the following industry standard into 10 CFR parts 429 and 430: AHAM PAC-1-2015, Portable Air Conditioners. DOE also intends to incorporate by reference the following industry standard into 10 CFR part 430: ANSI/ASHRAE Standard 37-2009, Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment.

Copies of AHAM PAC-1-2015 can be obtained from the Association of Home Appliance Manufacturers 1111 19th Street NW., Suite 402, Washington, DC 20036, 202-872-5955, or by going to <http://www.aham.org/ht/d/ProductDetails/sku/PAC12009/from/714/pid/>.

Copies of ANSI/ASHRAE Standard 37-2009 can be obtained from the American National Standards Institute 25 W. 43rd Street, 4th Floor, New York, NY 10036, 212-642-4980, or by going to

<http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2FASHRAE+Standard+37-2009>.

See section IV.B. for a description of these standards.

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I. Authority and Background

Title III of the Energy Policy and Conservation Act (EPCA), as amended (42 U.S.C. 6291, *et seq.*; “EPCA” or, “the Act”) sets forth various provisions designed to improve energy efficiency. Part A of title III of EPCA (42 U.S.C. 6291–6309) establishes the “Energy Conservation Program for Consumer Products Other Than Automobiles,” which covers consumer products and certain commercial products (hereinafter referred to as “covered products”).¹ EPCA authorizes DOE to establish technologically feasible, economically justified energy conservation standards for covered products or equipment that would be likely to result in significant national energy savings. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII)) In addition to specifying a list of covered consumer and industrial products, EPCA contains

provisions that enable the Secretary of Energy to classify additional types of consumer products as covered products. (42 U.S.C. 6292(a)(20)) For a given product to be classified as a covered product, the Secretary must determine that:

(1) Classifying the product as a covered product is necessary for the purposes of EPCA; and

(2) The average annual per-household energy use by products of each type is likely to exceed 100 kilowatt-hours (kWh) per year. (42 U.S.C. 6292(b)(1))

To prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p) for covered products added pursuant to 42 U.S.C. 6292(b)(1), the Secretary must also determine that:

(1) The average household energy use of the products has exceeded 150 kWh per household for a 12-month period;

(2) The aggregate 12-month energy use of the products has exceeded 4.2 terawatt-hours (TWh);

(3) Substantial improvement in energy efficiency is technologically feasible; and

(4) Application of a labeling rule under 42 U.S.C. 6294 is unlikely to be sufficient to induce manufacturers to produce, and consumers and other persons to purchase, covered products of such type (or class) that achieve the maximum energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(l)(1))

Under EPCA, the energy conservation program consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. The testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA, and (2) making representations about the efficiency of those products. Similarly, DOE must use these test procedures to determine whether the products comply with any relevant standards promulgated under EPCA.

A. General Test Procedure Rulemaking Process

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA provides in relevant part that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results that measure energy efficiency, energy use or estimated annual operating cost of a

covered product during a representative average use cycle or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) In addition, if DOE determines that a test procedure should be prescribed or amended, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2))

B. Test Procedure for Portable Air Conditioners

There are currently no DOE test procedures or energy conservation standards for portable ACs. On July 5, 2013, DOE issued a notice of proposed determination (NOPD) of coverage (hereinafter referred to as the “July 2013 NOPD”), in which DOE announced that it tentatively determined that portable ACs meet the criteria under 42 U.S.C. 6292(b)(1) to be classified as a covered product. 78 FR 40403. DOE estimated that approximately 974,000 portable AC units were shipped in North America in 2012, and projected that approximately 1.74 million units would be shipped in 2018, representing nearly 80-percent growth in 6 years.² *Id.* at 40404. In addition, DOE estimated the average per-household portable AC electricity consumption for those homes with portable ACs to be approximately 650 kWh per year. *Id.*

In response to the July 2013 NOPD, DOE received comments from interested parties on several topics regarding appropriate test procedures for portable ACs that DOE should consider if it issues a final determination classifying portable ACs as a covered product.

1. The May 2014 NODA

On May 9, 2014, DOE published in the **Federal Register** a notice of data availability (NODA) (hereinafter referred to as the “May 2014 NODA”), in which it agreed that a DOE test procedure for portable ACs would provide consistency and clarity for representations of energy use of these products. DOE evaluated available industry test procedures to determine whether such methodologies would be suitable for incorporation in a future DOE test procedure, should DOE determine to classify portable ACs as a covered product. DOE conducted testing on a range of portable ACs to determine typical cooling capacities and cooling energy efficiencies based on the existing industry test methods and other modified approaches for portable ACs. 79 FR 26639, 26640 (May 9, 2014).

² Transparency Media Research, “Air Conditioning Systems Market—Global Scenario, Trends, Industry Analysis, Size, Share and Forecast, 2012–2018,” January 2013.

¹ For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

2. The February 2015 NOPR

On February 25, 2015, DOE published in the **Federal Register** a notice of proposed rulemaking (NOPR) (hereinafter referred to as the “February 2015 NOPR”), in which it proposed test procedures for portable ACs that would provide a means of determining efficiency in various operating modes, including cooling mode, heating mode, off-cycle mode, standby mode, and off mode. 80 FR 10211. For cooling mode and heating mode, DOE proposed test procedures based on the then-current industry-accepted test procedure, Association of Home Appliance Manufacturers (AHAM) PAC–1–2014, “Portable Air Conditioners,” with additional provisions to account for heat transferred to the indoor conditioned space from the case, ducts, and any infiltration air from unconditioned spaces. DOE also proposed various clarifications for cooling mode and heating mode testing, including: (1) Test duct configuration; (2) instructions for condensate collection; (3) control settings for operating mode, fan speed, temperature set point, and louver oscillation; and (4) unit placement within the test chamber. For off-cycle mode, DOE proposed a test procedure that would measure portable AC energy use when the ambient dry-bulb temperature is at or below the setpoint. DOE also identified relevant low-power modes, proposed definitions for inactive mode and off mode, and proposed test procedures to determine representative energy consumption for these modes. *Id.*

In the February 2015 NOPR, DOE proposed to use a combined energy efficiency ratio (CEER) metric for representing the overall energy efficiency of single-duct and dual-duct portable ACs. The CEER metric would represent energy use in all available operating modes. DOE also proposed a cooling mode-specific CEER for units that do not provide a heating function to provide a basis for comparing performance with other cooling products such as room ACs. In addition, DOE proposed separate energy efficiency ratio (EER) metrics for determining energy efficiency in cooling mode and heating mode only. 80 FR 10211, 10234–10235 (Feb. 25, 2015).

DOE also recently initiated a separate rulemaking to consider establishing energy conservation standards for portable ACs. Any new standards would be based on the same efficiency metrics derived from the test procedure that DOE would adopt in a final rule in this rulemaking.

II. Synopsis of the Supplemental Notice of Proposed Rulemaking

Upon further analysis and review of the public comments received in response to the February 2015 NOPR, DOE proposes in this SNOPR the following additions and clarifications to its proposed portable AC test procedure: (1) Minor revisions to the indoor and outdoor cooling mode test conditions; (2) an additional test condition for cooling mode testing; (3) updated infiltration air and capacity calculations to account for the second cooling mode test condition; (4) removal of the measurement of case heat transfer; (5) a clarification of test unit placement within the test chamber; (6) removal of the heating mode test procedure; (7) a revision to the CEER calculation to reflect the two cooling mode test conditions and removal of heating mode testing; and (8) additional technical corrections and clarifications.

Other than the specific amendments newly proposed in this SNOPR, DOE continues to propose the test procedure originally included in the February 2015 NOPR. For the reader’s convenience, DOE has reproduced in this SNOPR the entire body of proposed regulatory text from the February 2015 NOPR, amended as appropriate according to these proposals. DOE’s supporting analysis and discussion for the portions of the proposed regulatory text not affected by this SNOPR may be found in the February 2015 NOPR. 80 FR 10211 (Feb. 25, 2015).

III. Discussion

A. Active Mode

In the February 2015 NOPR, DOE proposed to define active mode, for purposes of the portable AC test procedure, as a mode in which the portable AC is connected to a mains power source, has been activated, and is performing the main functions of cooling or heating the conditioned space, circulating air through activation of its fan or blower without activation of the refrigeration system, or defrosting the refrigerant coil. 80 FR 10211, 10216 (Feb. 25, 2015). DOE has determined that the existing statutory definition of “active mode” is sufficient for purposes of this test procedure and therefore is no longer proposing a separate definition of “active mode” for portable ACs.

B. Cooling Mode

In the February 2015 NOPR, DOE proposed that cooling mode is a mode in which a portable AC has activated the main cooling function according to the thermostat or temperature sensor signal, including activating the refrigeration

system or the fan or blower without activation of the refrigeration system. 80 FR 10211, 10217 (Feb. 25, 2015). DOE determined that the existing industry standards used to measure portable AC cooling capacity and EER, which are based on air enthalpy methods, may not represent true portable AC performance. Additionally, DOE is aware that manufacturers may test according to different industry standards, causing confusion and variation in the reported cooling capacities and EERs for units currently on the market. DOE further concluded that varying infiltration air flow rates and heat losses would preclude a fixed translation factor that could be applied to the results of an air enthalpy measurement to account for the impact of these effects. Therefore, although DOE generally proposed a test procedure for portable ACs based on AHAM PAC–1–2014, the industry-accepted standard for testing portable ACs (which is based on an air enthalpy approach), the proposed test procedure incorporated infiltration air effects and heat losses to more accurately measure performance representative of typical operation and provide a clear and consistent basis for comparison of portable AC capacity and energy use. 80 FR 10211, 10222–10223 (Feb. 25, 2015).

The Appliance Standards Awareness Project (ASAP), Alliance to Save Energy (ASE), American Council for an Energy-Efficient Economy (ACEEE), National Consumer Law Center (NCLC), Natural Resources Defense Council (NRDC), and Northwest Energy Efficiency Alliance (NEEA) (hereinafter the “Joint Commenters”) and the Pacific Gas and Electric Company (PG&E), Southern California Gas Company (SCGC), Southern California Edison (SCE), and San Diego Gas and Electric Company (SDG&E) (hereinafter the “California IOUs”) supported DOE’s proposal to adopt AHAM PAC–1–2014 with modifications to account for the impacts of infiltration air and heat transfer from the duct(s) and case, as this would better reflect real-world performance of both single-duct and dual-duct portable ACs. (Joint Commenters, No. 19 at p. 1; California IOUs, No. 20 at p. 1)³ The Joint Commenters further noted that in

³ A notation in the form “Joint Commenters, No. 19 at p. 1” identifies a written comment: (1) Made by the Appliance Standards Awareness Project, Alliance to Save Energy, American Council for an Energy-Efficient Economy, National Consumer Law Center, Natural Resources Defense Council, and Northwest Energy Efficiency Alliance (the “Joint Commenters”); (2) recorded in document number 19 that is filed in the docket of this test procedure rulemaking (Docket No. EERE–2014–BT–TP–0014) and available for review at www.regulations.gov; and (3) which appears on page 1 of document number 19.

response to the NODA, they had encouraged DOE to adopt a test procedure based on the calorimeter approach. In light of the data presented in the February 2015 NOPR, the Joint Commenters now support the proposal to base a DOE portable AC test procedure on AHAM PAC–1–2014 as there is a good correlation with the calorimeter test results when the proposed adjustments that account for the impact of infiltration air and duct and case heat transfer are applied. (Joint Commenters, No. 19 at p. 2)

China WTO/TBT National Notification & Enquiry Center (China) noted that, compared to the industry-accepted and commonly used American National Standards Institute (ANSI)/American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 128–2001, “Method of Rating Unitary Spot Air Conditioners,” AHAM PAC–1–2014 is significantly more complex, increases the cost of testing, and would require laboratories to purchase new instrumentation and update or reconstruct their chambers. Further, China stated that DOE did not provide a comparison between AHAM PAC–1–2014 and ANSI/ASHRAE 128–2001 based on test data. Without a comparison of the results, China does not believe that DOE can conclude there is a marked difference between the two, and cannot determine that testing according to AHAM PAC–1–2014 is necessary. China requested that DOE provide comparative data between the two test procedures. (China, No. 15 at pp. 3–4)

De’ Longhi Appliances s.r.l. (De’ Longhi) claimed that in the United States, most manufacturers are using the standard ANSI/ASHRAE 128–2001 to rate the performance of single-duct

portable ACs. De’ Longhi stated, however, that testing a single-duct portable AC according to AHAM PAC–1–2014 results in a cooling capacity about 25 percent lower than the rating obtained with ANSI/ASHRAE 128–2001. Despite this rated cooling capacity reduction, De’ Longhi supports the use of AHAM PAC–1–2014 because it ensures more reliable and repeatable testing data. (De’ Longhi, No. 16 at pp. 1–2)

AHAM and De’ Longhi support the use of AHAM PAC–1–2014 as the basis for a DOE test procedure for portable ACs, albeit without the addition of certain test procedure provisions that DOE has proposed. (Public Meeting Transcript, AHAM, No. 13 at p. 31; Public Meeting Transcript, De’ Longhi, No. 13 at pp. 13, 33; AHAM, No. 18 at p. 2; De’ Longhi, No. 16 at p. 2)⁴

DOE agrees that certain portable ACs may be currently tested according to ANSI/ASHRAE 128–2001, but believes this is largely due to California’s regulations for certifying spot coolers sold in that State. As discussed in the February 2015 NOPR, DOE is not proposing testing procedures for spot coolers at this time. 80 FR 10212, 10214–15 (Feb. 25, 2015). In addition, ANSI/ASHRAE 128–2001 is an obsolete version of that test standard, and DOE expects that manufacturers conducting testing of their portable ACs for reasons other than certification in California may be using a current, industry-accepted test standard such as AHAM PAC–1–2014 or ANSI/ASHRAE 128–2011, both of which were discussed and analyzed in the May 2014 NODA and February 2015 NOPR. For these reasons, and with the general support of interested parties, DOE continues to propose a test procedure for portable ACs that is based on the current version

of AHAM PAC–1. DOE notes that AHAM issued a new version of PAC–1 in 2015, with no changes in language from the 2014 version. Therefore, although DOE previously proposed to adopt a test procedure for portable ACs that is based on AHAM PAC–1–2014, DOE now proposes in this SNOPR to reference the identical updated version, AHAM PAC–1–2015, in the proposed DOE portable AC test procedure. Accordingly, DOE refers to AHAM PAC–1–2015 for the remainder of this SNOPR when discussing its current proposals.

Additionally, this notice discusses other modifications to the test procedure proposed in the February 2015 NOPR to address commenters’ concerns, improve repeatability, minimize test burden, and ensure the test procedure is representative of typical consumer usage.

1. Test Chamber and Infiltration Air Conditions

DOE proposed in the February 2015 NOPR to utilize the following ambient conditions presented in Table III.1 below, based on those test conditions specified in Table 3, “Standard Rating Conditions,” of AHAM PAC–1–2014. DOE also proposed to determine test configurations according to Table 2 of AHAM PAC–1–2014, with Test Configuration 3 applicable to dual-duct portable ACs and Test Configuration 5 applicable to single-duct portable ACs. 80 FR 10211, 10226 (Feb. 25, 2015). For single-duct units, the condenser inlet conditions are the same as the evaporator inlet. For dual-duct units, the condenser inlet air conditions are monitored at the interface between the condenser inlet duct and outdoor test room.

TABLE III.1—STANDARD RATING CONDITIONS—COOLING MODE—NOPR PROPOSAL

Test configuration	Evaporator inlet air, °F (°C)		Condenser inlet air, °F (°C)	
	Dry bulb	Wet bulb	Dry bulb	Wet bulb
3	80.6 (27)	66.2 (19)	95.0 (35)	75.2 (24)
5	80.6 (27)	66.2 (19)	80.6 (27)	66.2 (19)

⁴ A notation in the form “AHAM, Public Meeting Transcript, No. 13 at p. 31” identifies an oral comment that DOE received on March 18, 2015 during the NOPR public meeting, was recorded in the public meeting transcript in the docket for this test procedure rulemaking (Docket No. EERE–2014–BT–TP–0014). This particular notation refers to a comment (1) made by the Association of Home Appliance Manufacturers during the public

meeting; (2) recorded in document number 13, which is the public meeting transcript that is filed in the docket of this test procedure rulemaking; and (3) which appears on page 31 of document number 13.

a. Test Chamber Conditions

In the February 2015 NOPR, DOE noted that the AHAM PAC–1–2014 test conditions are slightly different from the AHAM PAC–1–2009 test conditions, which AHAM revised to harmonize with the temperatures specified in Canadian Standards Association (CSA) C370–2013, “Cooling Performance of Portable Air Conditioners” and ANSI/ASHRAE Standard 128–2011, “Method of Rating Portable Air Conditioners.” DOE’s analysis and testing was conducted in accordance with AHAM PAC–1–2009, as the next version of the standard, AHAM PAC–1–2014, had not yet been finalized. DOE tentatively determined that the test condition differences between the 2009 and 2014 versions of AHAM PAC–1 would not substantively impact test results. Therefore, DOE proposed to use the updated test conditions from AHAM PAC–1–2014. DOE also noted in the February 2015 NOPR that these conditions are close, but not identical, to those required by the DOE room AC test procedure (80 degrees Fahrenheit (°F) dry-bulb temperature and 67 °F wet-bulb temperature on the indoor side, and 95 °F dry-bulb temperature and 75 °F wet-bulb temperature on the outdoor side, consistent with the AHAM PAC–1–2009 conditions). 80 FR 10211, 10226 (Feb. 25, 2015).

AHAM agreed that there are no major differences between the 2009 and 2014 versions, and that the main changes were editorial in nature to harmonize with the Canadian test procedure. AHAM stated that it is important that the North American and Canadian methods are harmonized. (Public Meeting Transcript, AHAM, No. 13 at pp. 31–32)

DENSO Products and Services Americas, Inc. (DENSO) commented that the room AC indoor test conditions

in the DOE test procedure for those products correspond to about 50-percent relative humidity, whereas the AHAM PAC–1–2014 indoor test conditions are closer to 40-percent relative humidity. According to DENSO, this is a significant difference in test conditions and thus the AHAM PAC–1–2014 test conditions are not comparable to those for room ACs or other air conditioning products. DENSO also commented that the test conditions should be expressed in whole degrees instead of three-digit dry-bulb and wet-bulb temperatures in °F that are equivalent to whole degrees Celsius in other standards. (Public Meeting Transcript, DENSO, No. 13 at pp. 47–48, 69–70; DENSO, No. 14 at p. 2)

In response to the comments received regarding the chamber test conditions, DOE examined the relative impact of the varying latent heat differential between the indoor and outdoor conditions in the February 2015 NOPR proposal and in AHAM PAC–1–2009. The latent heat differential impacts cooling capacity primarily through the effects of infiltration air. Based on the average dry air mass flowrate for the single-duct and dual-duct units in DOE’s test sample, DOE estimated that the change in test conditions from the 2009 to either the 2014 or 2015 version of AHAM PAC–1 would decrease cooling capacity by increasing the heating effect due to infiltration air by an average of 755 Btu/h and 330 Btu/h for the two configurations, respectively. With an average PAC–1–2009 cooling capacity (without accounting for infiltration air, case, or duct heat effects) of 7,650 Btu/h for single-duct units and 6,800 Btu/h for dual-duct units, adjusting the test conditions from the 2009 to 2015 version of AHAM PAC–1 would decrease cooling capacity by 5–10 percent, an amount which DOE

considers to be significant. Therefore, DOE no longer concludes that the test condition differences between the 2009 and 2014 (and, thus, 2015) versions of AHAM PAC–1 would not substantively impact test results.

DOE further notes that the test conditions in AHAM PAC–1–2015, although harmonized with those in CSA C370–2013 and ANSI/ASHRAE Standard 128–2011, do not align with the test conditions in the DOE test procedures for other cooling products, particularly room ACs and central ACs. As noted earlier in this section, the AHAM PAC–1–2015 test approach is generally appropriate for portable ACs. However, DOE believes that the test conditions in AHAM PAC–1–2009, which align with the conditions used for testing other DOE covered products, are more appropriate for testing portable AC performance than those in AHAM PAC–1–2015. The temperatures specified in AHAM PAC–1–2015 were rounded to produce whole degrees Celsius, which results in a relative humidity on the indoor side (47.0 percent) that differs significantly from the relative humidity that DOE has previously determined for room ACs and central ACs is representative of a residential air-conditioned space (51.1 percent). To maintain consistency among products with similar functions, DOE proposes in this SNOPR to revise the test conditions proposed in the February 2015 NOPR to those presented in Table III.2 below, which would replace the test conditions specified in Table 3, “Standard Rating Conditions,” of AHAM PAC–1–2015. As discussed in the next section, however, these revisions do not comprise the only changes that DOE is proposing in this SNOPR to the rating conditions for portable ACs.

TABLE III.2—REVISED STANDARD RATING CONDITIONS—COOLING MODE

Test configuration	Evaporator inlet air, °F (°C)		Condenser inlet air, °F (°C)	
	Dry bulb	Wet bulb	Dry bulb	Wet bulb
3	80 (26.7)	67 (19.4)	95 (35)	75 (23.9)
5	80 (26.7)	67 (19.4)	80 (26.7)	67 (19.4)

b. Infiltration Air Conditions

In the February 2015 NOPR, DOE noted that infiltration from outside the conditioned space occurs due to the negative pressure induced as condenser air is exhausted to the outdoor space. Although this effect is most pronounced for single-duct units, which draw all of their condenser air from within the

conditioned space, dual-duct units also draw a portion of their condenser air from the conditioned space. DOE proposed calculating the infiltration air flow rate as the condenser exhaust flow rate to the outdoor chamber minus any condenser intake flow rate from the outdoor chamber. DOE proposed that the infiltration air conditions be 95 °F dry-bulb temperature and 75.2 °F wet-

bulb temperature, consistent with the outdoor conditions specified in AHAM PAC–1–2014. 80 FR 10211, 10224–10225 (Feb. 25, 2015).

The Joint Commenters supported the proposal to use 95 °F dry-bulb temperature and 75 °F wet-bulb temperature outdoor air. (Public Meeting Transcript, ASAP, No. 13 at p. 44; Joint Commenters, No. 19 at p. 2)

The Joint Commenters further stated that because AHAM PAC-1-2014 is conducted using these outdoor air conditions, it is important that the same conditions be used for the infiltration air to reflect the real-world performance of portable ACs under these outdoor air conditions. The Joint Commenters noted that all infiltration air is ultimately coming from the outdoors and adding heat to the home where the portable AC is installed. The Joint Commenters suspect that, in many cases, the bulk of the infiltration air will be coming directly from the outdoors due to imperfect installations, resulting in leaks through the window where the portable AC is installed. The Joint Commenters also suspect that over time, a greater portion of the infiltration air will come directly through the window where the portable AC is installed due to deterioration of the installation as the unit is repeatedly removed and re-installed. (Joint Commenters, No. 19 at p. 2)

De' Longhi did not agree with DOE's proposed approach to address infiltration air, stating that it would improperly represent the performance of single-duct products because the proposed infiltration air conditions of 95 °F dry-bulb temperature and 75.2 °F wet-bulb temperature represent worst-case outdoor conditions which occur for a negligible period of time during the cooling season. De' Longhi noted that according to ANSI/Air-Conditioning, Heating, and Refrigeration Institute (AHRI) 210/240, "Performance Rating of Unitary Air-Conditioning and Air-Source Heat Pump Equipment", outdoor temperatures ranging from 95 to 104 °F represent just 2.2 percent of the season while outdoor temperatures range from 65 to 80 °F during 66.1 percent of the season. De' Longhi stated that selection of an appropriate outdoor temperature for rating testing is critical for single-duct portable ACs. As a consequence, De' Longhi commented that DOE's proposed procedure overstates the impacts of infiltration air. (Public Meeting Transcript, De' Longhi, No. 13 at pp. 39-40; De' Longhi, No. 16 at p. 3)

The National Association of Manufacturers (NAM) stated that if the test procedure includes an infiltration air adjustment, the temperature must be representative and based on data. In NAM's view, given the uniqueness of homes, the proposed infiltration air temperatures are not practical, nor are they shown to be based on available data. (NAM, No. 17 at p. 2)

AHAM commented that portable ACs are not used just on the hottest summer days, but also during the transition

periods before and after summer to cool only a certain room or rooms before central air conditioning or heating is turned on. According to AHAM, this use pattern suggests that an outdoor temperature representing the hottest days of summer is not representative of consumer use. AHAM commented that even if consumers use portable ACs only in the summer and only the outdoor air temperature is considered, a 95 °F infiltration air temperature would still be too high. (AHAM, No. 18 at p. 4)

De' Longhi and AHAM suggested that, should DOE include a numerical adjustment for infiltration air to the results of testing with AHAM PAC-1-2014, the proper temperature for the infiltration air would be 70 °F, based on available data. They noted that 70 °F is the representative average cooling season temperature that DOE found for the United States as a whole. They also claimed that according to ANSI/AHRI 210/240-2008, an outdoor temperature of 70 °F represents 50 percent of the total cooling season hours. (Public Meeting Transcript, De' Longhi, No. 13 at p. 41; De' Longhi, No. 16 at p. 3; AHAM, No. 18 at p. 4) De' Longhi further stated that if DOE decides not to use 70 °F as the outdoor air temperature, this test condition should be no greater than 80.6 °F dry-bulb, the standard rating condition for single-duct portable ACs in AHAM PAC-1-2014 for both indoor and outdoor conditions. In order to compare single-duct and dual-duct portable ACs under the same conditions, De' Longhi would also accept 80.6 °F as the outdoor conditions for dual-duct units as well. (Public Meeting Transcript, De' Longhi, No. 13 at pp. 43-44; De' Longhi, No. 16 at p. 4)

Friedrich commented that 70 °F is low for an outdoor temperature that would necessitate AC use, and suggested DOE consider 80 °F as the outdoor condition. (Public Meeting Transcript, Friedrich, No. 13 at pp. 84-85)

In addition to the proposed temperatures for infiltration air, DOE received comments regarding the likely origin of the infiltration air to help inform the appropriate infiltration air conditions. De' Longhi noted that it is possible that some or all of the replacement air is drawn from a location other than the outdoors directly, such as a basement, attic, garage, or a space that is conditioned by other equipment. Thus, De' Longhi stated that DOE's proposed approach is unrealistic, as the building spaces from which infiltration air may be drawn and other inside air that may be cooled by central cooling

systems must be taken into account. De' Longhi also commented that DOE's approach did not account for any internal heating loads, solar radiation, or thermal lag of the building itself. (Public Meeting Transcript, De' Longhi, No. 13 at pp. 41-43; De' Longhi, No. 16 at pp. 3-4)

AHAM agreed with De' Longhi, and noted that even if all air in a home originates from outdoors, the infiltration air may be cooled once indoors. Moreover, AHAM noted that the infiltration air could be at different temperatures for a portable AC that is moved from room to room—for example, the air in a garage is not likely the same temperature as the air in an attic or basement. AHAM commented that if DOE accounts for the effects of infiltration air, DOE must ensure that the temperature is representative and based on data. In AHAM's view, given the uniqueness of homes, that is not practical to do. (AHAM, No. 18 at pp. 3-4)

AHAM, NAM, and DENSO stated that should DOE nevertheless move forward with its proposal, it must ensure it selects a representative test temperature for that infiltration air. They commented that DOE's current proposal is not representative and should be revised. (AHAM, No. 18 at p. 1; NAM, No. 17 at p. 3; DENSO, No. 14 at p. 3)

In response to comments received on the February 2015 NOPR, DOE conducted additional analysis to ensure the DOE test procedure for portable ACs is representative of typical cooling product operation and consumer usage. On the matter of the source of infiltration air, DOE reviewed information developed on infiltration air flow rates and sources for room ACs, which encounter issues for sealing in windows similar to portable ACs. In a study conducted by the National Renewable Energy Laboratory (NREL),⁵ infiltration air flow rates around the louvers on either side of three room AC test units and the air flow rates through the units themselves were measured when the units were installed in a test chamber outfitted with two residential single-hung windows. The units, including the side louvers, were installed per manufacturer instructions (*i.e.*, no additional sealing around the louvers was provided). A variable-speed blower was used to vary the differential pressure between the test chamber and ambient (outdoor condition) from 0 to 50 Pascals (Pa). NREL found that at 50

⁵ Winkler, J., *et al.*, 2013. "Laboratory Performance Testing of Residential Window Air Conditioners," National Renewable Energy Laboratory, Technical Report NREL/TP-5500-57617, March 2013.

Pa, the infiltration air flow rates around the louvers ranged from approximately 50 to 90 standard cubic feet per minute (SCFM) among the three test units. These infiltration air flow rates represented as much as two thirds of the rated evaporator air flow rates at high fan speed, and similarly would also represent a substantial percentage of the infiltration air for a single-duct portable AC. NREL estimated that the infiltration air leakage path around the louvers was the equivalent of a 27 to 42 square-inch hole in the wall. Because DOE observed that the window brackets for mounting the portable AC duct(s) in its test sample typically did not include any gasket, tape, or other sealing material, it concludes that outdoor air leaking through the portable AC's window bracket likely also represents the source of a substantial percentage of the infiltration air for portable ACs. Additionally, because portable ACs that do not draw all of the condenser air from outside the conditioned space create net negative pressure within the conditioned space, infiltration air flow is likely greater than for room ACs. Therefore, DOE continues to conclude that infiltration air temperature is best represented as the outdoor test condition.

DOE also notes that the temperature of infiltration air from sources other than the window bracket cannot be definitively characterized because the air temperature in the other locations may be greater than (e.g., an attic) or less than (e.g., a basement) the outdoor temperature. In addition, infiltration air that is drawn from other conditioned

space initially originated from locations that could also be direct sources of infiltration air for a portable AC, and thus DOE believes that the portable AC should not derive a *de facto* benefit by being rated at a lower infiltration air temperature achieved via the energy consumption of other conditioning equipment.

DOE next considered commenters' suggestion that the outdoor test condition in the current version of AHAM PAC-1 may not be representative of a significant portion of portable AC operation. DOE revisited its climate analysis from the February 2015 NOPR to determine the overall average dry-bulb temperature and relative humidity during hours allotted for cooling mode operation, in locations where portable ACs are likely to be used. DOE again performed this climate analysis using 2012 hourly ambient temperature data from the National Climatic Data Center (NCDC) of the National Oceanic and Atmospheric Administration (NOAA), collected at weather stations in 44 representative states. DOE determined the average temperature and humidity associated with the hottest 750 hours for each state for which there was data available. DOE then reviewed data from the 2009 *Residential Energy Consumption Survey (RECS)*⁶ to identify room AC ownership in the different geographic regions because no portable AC-specific usage data were available. Based on the *RECS* ownership data, DOE used a weighted-average approach to combine the average temperature and humidity for each individual state into sub-regional,

regional, and finally, the representative national average temperature and humidity for the hottest 750 hours in each state.⁷ DOE found that the national average dry-bulb temperature and relative humidity associated with the hottest 750 hours are 83 °F and 45 percent, respectively.

To maintain harmonization with other cooling products and the AHAM PAC-1-2009 test conditions, as discussed previously, and to continue to consider cooling performance under a rating condition at which product performance is most important to consumers, DOE proposes to specify the outdoor test conditions and associated infiltration air conditions of 95 °F dry-bulb and 75 °F wet-bulb temperature. However, DOE also proposes in this SNOPR that a second cooling mode test be conducted for dual-duct units (Test Configuration 3) at outdoor test conditions that reflect the weighted-average temperature and humidity observed during the hottest 750 hours (the hours during which DOE expects portable ACs to operate in cooling mode): 83 °F dry-bulb temperature and 67.5 °F wet-bulb temperature. For single-duct units (Test Configuration 5), DOE would specify a second set of numerical calculations for cooling capacity and CEER based on adjustments for infiltration air at these same conditions, rather than providing for an additional test at the weighted-average outdoor temperature and humidity. In sum, Table III.3 shows the complete set of cooling mode rating conditions that DOE proposes for portable ACs in this SNOPR.

TABLE III.3—STANDARD RATING CONDITIONS—COOLING MODE—SNOPR PROPOSAL

Test configuration	Evaporator inlet air, °F (°C)		Condenser inlet air, °F (°C)	
	Dry bulb	Wet bulb	Dry bulb	Wet bulb
3 (Condition A)	80 (26.7)	67 (19.4)	95 (35)	75 (23.9)
3 (Condition B)	80 (26.7)	67 (19.4)	83 (28.3)	67.5 (19.7)
5	80 (26.7)	67 (19.4)	80 (26.7)	67 (19.4)

c. Infiltration Air Calculations

In the February 2015 NOPR, DOE proposed that the sensible and latent components of infiltration air heat transfer be calculated using the evaporator inlet conditions, to be representative of the indoor room's ambient conditions. As discussed above, DOE proposed that the nominal indoor test chamber conditions for portable AC testing would be 80 °F dry-bulb

temperature and 67 °F wet-bulb temperature, resulting in a humidity ratio of 0.0112 pounds of water per pounds of dry air (lb_w/lb_{da}). DOE further proposed in the February 2015 NOPR that the indoor test chamber dry-bulb and wet-bulb temperature conditions be maintained within a range of 1.0 °F, with an average difference of 0.3 °F. 80 FR 10211, 10224, 10226 (Feb. 25, 2015).

DOE notes that the allowable tolerances for the indoor evaporator

inlet conditions would permit variations in the humidity ratio of up to 8.6 percent. DOE reviewed its test data and found that the maximum variation between the measured and proposed humidity ratio was 4.5 percent. DOE believes that the proposal to use the measured evaporator inlet conditions (dry-bulb and wet-bulb temperatures and the resulting humidity ratio) when calculating the impacts of infiltration air

⁶ RECS data are available online at: <http://www.eia.gov/consumption/residential/data/2009/> www.eia.gov/consumption/residential/data/2009/.

⁷ For more information on the weighted-average approach that DOE conducted for this analyses, see

the February 2015 NOPR. 80 FR 10211, 10235-27 (Feb. 25, 2015).

heat transfer may introduce variability in the test results due to the sensitivity of infiltration air to the allowable evaporator inlet conditions variability and the resulting impact on overall cooling capacity. Therefore, DOE proposes in this SNOPR to calculate the sensible and latent heat contributions of infiltration air using the nominal test chamber temperatures and subsequent humidity ratio to reduce test variability.

DOE further notes that there was an error in the equations proposed in the February 2015 NOPR that divided the quantity of heat, in Btu/min, by 60 instead of multiplying by 60 to convert to Btu/h. 80 FR 10211, 10224 (Feb. 25, 2015). This SNOPR corrects the calculation error in DOE's proposal.

Based on these changes, DOE proposes in this SNOPR to calculate the sensible and latent heat components of infiltration air, using the nominal test chamber temperatures and subsequent humidity ratio, as follows:

$$Q_s = \dot{m} \times 60 \times [(c_{p_da} \times (T_{ia} - T_{indoor})) + c_{p_wv} \times (\omega_{ia} \times T_{ia} - \omega_{indoor} \times T_{indoor})]$$

Where:

Q_s is the sensible heat added to the room by infiltration air, in Btu/h;

\dot{m} is the dry air mass flow rate of infiltration air for a single-duct or dual-duct unit, in lb/m;

c_{p_da} is the specific heat of dry air, 0.24 Btu/lb_m-°F.

c_{p_wv} is the specific heat of water vapor, 0.444 Btu/lb_m-°F.

T_{indoor} is the indoor chamber dry-bulb temperature, 80 °F.

T_{ia} is the infiltration air dry-bulb temperature, 95 °F.

ω_{ia} is the humidity ratio of the infiltration air, 0.0141 lb_w/lb_{da}.

ω_{indoor} is the humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 is the conversion factor from minutes to hours.

$$Q_l = \dot{m} \times 60 \times H_{fg} \times (\omega_{ia} - \omega_{indoor})$$

Where:

Q_l is the latent heat added to the room by infiltration air, in Btu/h.

\dot{m} is the mass flow rate of infiltration air for a single-duct or dual-duct unit, in lb/m.

H_{fg} is the latent heat of vaporization for water vapor, 1061 Btu/lb_m.

ω_{ia} is the humidity ratio of the infiltration air, 0.0141 lb_w/lb_{da}.

ω_{indoor} is the humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 is the conversion factor from minutes to hours.

2. Test Duration

AHAM PAC-1-2015 specifies testing in accordance with certain sections of ANSI/ASHRAE Standard 37-2009, "Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment" (ASHRAE 37-2009), but

does not explicitly specify the test duration required when conducting portable AC active mode testing. Therefore, DOE proposes in this SNOPR that the active mode test duration shall be determined in accordance with section 8.7 of ASHRAE 37-2009.

3. Seasonally Adjusted Cooling Capacity

In the February 2015 NOPR, DOE proposed a calculation for adjusted cooling capacity, ACC, defined as the measured cooling capacity adjusted for case, duct, and infiltration air heat transfer impacts. 80 FR 10211, 10225 (Feb. 25, 2015).

With the proposal to add a second cooling mode test condition for dual-duct portable ACs and, similarly, a second numerically applied infiltration air condition for single-duct portable ACs, DOE proposes that the adjusted cooling capacities for both sets of conditions be combined to create a seasonally adjusted cooling capacity, SACC. The higher outdoor temperature condition is consistent with that used for testing other air conditioning equipment and ensures that products can operate when they are most needed, while the cooler condition represents the typical outdoor temperatures encountered during use. Because the performance of a portable AC is important under each of these scenarios, DOE proposes in this SNOPR to weight the adjusted cooling capacities obtained under the two cooling mode conditions to calculate the SACC as follows.

Using an analytical approach based on climate and RECS data that was similar to the method used to determine representative rating conditions, DOE estimated the percentage of portable AC operating hours that would be associated with each rating condition. From the climate data, DOE allocated the number of annual hours with temperatures that ranged from 80 °F (the indoor test condition) to 89 °F (a temperature mid-way between the two rating conditions) to the 83 °F rating condition. The hours in which the ambient temperature was greater than 89 °F were assigned to the 95 °F rating condition. DOE then performed the geographical weighted averaging using the RECS data as discussed in section III.1.b to determine weighting factors of 19.7 percent and 80.3 percent, respectively, for the 95 °F and 83 °F rating conditions. A similar approach was adopted for central ACs, where DOE specifies eight test conditions and corresponding weighting factors that are based on the distribution of fractional hours for representative temperature

bins.⁸ For portable ACs, DOE estimated hours per temperature bin from the climate data analysis, and proposes in this SNOPR to apply weighting factors of 20 percent and 80 percent to the results of its testing at 95 °F and 83 °F, respectively. DOE welcomes input on whether different weighting factors would be appropriate.

Therefore, DOE proposes to calculate SACC according to the following equation.

$$SACC = (ACC_{95} \times 0.2) + (ACC_{83} \times 0.8)$$

Where:

SACC is the seasonally adjusted cooling capacity, in Btu/h.

ACC_{95} and ACC_{83} are the adjusted cooling capacities calculated at the 95 °F and 83 °F dry-bulb outdoor conditions, in Btu/h, respectively.

0.2 is the weighting factor for ACC_{95} .

0.8 is the weighting factor for ACC_{83} .

4. Duct Heat Transfer and Leakage

In the February 2015 NOPR, DOE presented its determination that duct heat losses and air leakage are non-negligible effects, and therefore proposed to account for heat transferred from the duct surface to the conditioned space in the portable AC test procedure. DOE proposed that four equally spaced thermocouples be adhered to the side of the entire length of the condenser exhaust duct for single-duct units and the condenser inlet and exhaust ducts for dual-duct units. DOE proposed to determine the duct heat transfer for each duct from the average duct surface temperature as measured by the four thermocouples, a convection heat transfer coefficient of 4 Btu/h per square foot per °F (Btu/h-ft²-°F), and the calculated duct surface area based on the test setup. 80 FR 10211, 10227 (Feb. 25, 2015).

a. Duct Heat Transfer Impacts

ASAP supported incorporating the duct heat transfer effects into the measurement of cooling capacity, and noted that there was a reasonably good correlation between the results using the calorimeter method and the modified AHAM method, as presented in the February 2015 NOPR. (Public Meeting Transcript, ASAP, No. 13 at p. 56)

AHAM and De' Longhi stated that DOE's proposed test for duct heat transfer and leakage unnecessarily complicates the test procedure without a corresponding benefit. They also stated that the methodology for the temperature sensor placement and determination of overall heat losses may be interpreted differently. AHAM

⁸ The DOE test procedure for central ACs is codified at 10 CFR part 430, subpart B, appendix M.

further commented that should DOE decide to include provisions for duct heat transfer and leakage, DOE should evaluate the impact of these effects on test procedure repeatability and reproducibility, preferably through a round robin test including manufacturers and third-party laboratories. (AHAM, No. 18 at p. 5; De' Longhi, No. 16 at p. 4)

China commented that DOE did not present the percent of the total cooling capacity associated with the duct and case heat transfer, and that it would be necessary to consider such data before adopting an approach that accounts for these heat transfer effects. (China, No. 15 at p. 3)

In response to these comments, DOE conducted further analysis to quantify the impacts of duct heat transfer. Figure

III.1 shows the impact of duct heat transfer as a percentage of the AHAM PAC-1-2009 cooling capacity measured in the February 2015 NOPR for each unit in DOE's test sample. Exhaust duct heat transfer is presented for each single-duct unit, while a pair of values for inlet duct heat transfer and exhaust duct heat transfer are presented for each dual-duct unit.

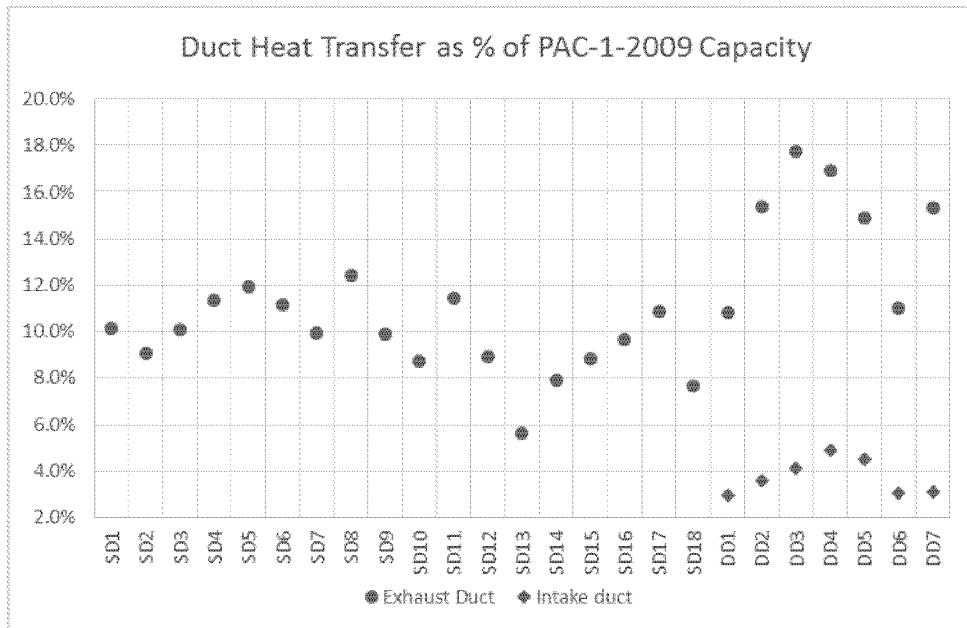


Figure III.1 Duct Heat Transfer as a Percentage of AHAM PAC-1-2009 Cooling Capacity for each Test Unit in the February 2015 NOPR

As shown in Figure III.1, the exhaust duct heat transfer determined according to the proposed methodology ranged from just below 6 percent to almost 18 percent of the AHAM PAC-1-2009 cooling capacity, with an average value of 11.1 percent. The intake duct heat transfer effect was lower than that of the exhaust duct due to the lower air temperature at the inlet, with values ranging from about 3 percent to almost 5 percent of the unadjusted cooling capacity and an average of 3.7 percent. DOE finds the exhaust and intake duct heat transfer impacts sufficiently significant to warrant the added test burdens associated with determining duct heat transfer. Therefore, DOE maintains the proposal from the February 2015 NOPR to measure and incorporate the duct heat transfer impacts into the overall seasonally adjusted cooling capacity.

b. Convection Coefficient

DENSO considered the 4 Btu/h-ft² °F convection coefficient

proposed for the duct heat transfer calculation to be arbitrary, and recommended measuring the conditions of the air at the inlet and outlet of each duct to substantiate that factor. (Public Meeting Transcript, DENSO, No. 13 at p. 53; DENSO, No. 14 at p. 2) DOE recognizes that different test setups may have somewhat different convective heat transfer coefficients. However, when developing test procedures, DOE must consider the test burden and impact on manufacturers and test laboratories. Taking that into consideration, DOE proposed an approach in the February 2015 NOPR that would minimize burden while capturing the impact of heat transfer from ducts, which DOE determined to have a significant impact on overall net cooling capacity. DOE also notes that the approach proposed by DENSO to characterize heat loss to the conditioned space would significantly increase test burden, requiring additional thermocouples and modification of the test setup on the unit-side of the duct.

Further, DOE notes that the convection heat transfer coefficient may vary among different laboratories and even for different chambers and test setups within each test laboratory. This would introduce variability from test to test, as the heat transfer coefficient may be highly sensitive to the specific test setup. To minimize the test burden and limit variability, DOE proposed one convection heat transfer coefficient for all units to provide a consistent estimate of the duct heat transfer.

In the February 2015 NOPR, DOE estimated the convection heat transfer coefficient to be 4 Btu/h-ft² °F based on a midpoint of values associated with free convection and forced convection, as recommended by the test laboratory that conducted testing for the NOPR. 80 FR 10211, 10219 (Feb. 25, 2015). The convection coefficient was based on values derived from coefficients listed in the 2013 *ASHRAE Handbook*—

*Fundamentals*⁹ for various types of assemblies in buildings. Depending on the orientation of the surface, direction of heat flow, and emissivity of the heat transfer surface, the typical coefficients for indoor assemblies, which DOE deduced would be subject primarily to free convection, ranged from 0.22 to 1.63 Btu/h-ft² °F. ASHRAE also provided coefficients for assemblies located outside and subject to wind speeds of 7.5 and 15 miles per hour (5.1 and 10.2 feet per second, respectively), which were 4.00 and 6.00 Btu/h-ft² °F, respectively. Because these speeds potentially correspond to air flow speeds over the portable AC duct(s) due to circulation of the conditioned air in the space, for example by the portable AC blower and infiltration air, DOE used these values as proxies for convective heat transfer coefficients for the duct surfaces. Therefore, DOE proposed in the February 2015 NOPR that the overall heat transfer coefficient for calculating duct heat losses would be 4 Btu/h-ft² °F, an approximate midpoint of the values described.

To further validate the proposed convection heat transfer coefficient for this notice, DOE re-examined the data it obtained from testing a sample of four single-duct and two dual-duct portables ACs with and without duct insulation for the May 2014 NODA. These tests were conducted using the calorimeter approach described in the May 2014 NODA, such that duct heat losses could be measured by subtracting the measured cooling capacity without insulation from the cooling capacity with insulation. Using the duct heat losses, duct surface area, and the differential between the indoor side ambient temperature and the average of the duct surface temperatures, an average duct heat transfer coefficient could be empirically determined for units in DOE's test sample. The results of this calculation are shown in Table III.4 below.

TABLE III.4—MEASURED DUCT CONVECTION HEAT TRANSFER COEFFICIENTS

Test unit	Duct convection heat transfer coefficient (Btu/h-ft ² °F)
SD1	2.74
SD2	3.08
SD3	1.70
SD4	5.26

⁹ ASHRAE Handbook—Fundamentals. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Atlanta, GA. 2013.

TABLE III.4—MEASURED DUCT CONVECTION HEAT TRANSFER COEFFICIENTS—Continued

Test unit	Duct convection heat transfer coefficient (Btu/h-ft ² °F)
DD1 (Test 1)	4.10
DD1 (Test 2)	3.76
DD2 (Test 1)	2.11
DD2 (Test 2)	2.27
Average	3.13

SD = Single-duct.
DD = Dual-duct.

Although the average heat transfer coefficient calculated from DOE's test results was slightly lower than the value proposed in the February 2015 NOPR, DOE notes that there is variation in individual results that is likely due to different duct types, installation configurations, forced convection air flow patterns, and other factors. Therefore, DOE proposes to maintain the original duct heat transfer proposal from the February 2015 NOPR, including the convection heat transfer coefficient of 4 Btu/h-ft² °F.

c. Duct Surface Area Measurements

In the February 2015 NOPR, DOE proposed that the duct surface area be calculated using the outer duct diameter and extended length of the duct while under test. 80 FR 10211, 10227 (Feb. 25, 2015).

De' Longhi and AHAM commented that ducts often have a corrugated surface, so that the measure of the duct(s) surface area will have high uncertainty. (De' Longhi, No. 16 at p. 4; AHAM, No. 18 at p. 5) DOE further examined the surface area of the ducts in its test sample. DOE calculated the surface area in two ways, one with the ducts fully extended and the other with the duct setup as required in AHAM PAC-1-2015. DOE found that the average difference in surface area calculated using the fully extended duct versus using the test setup was 7.5 percent. With the average duct impact on cooling capacity of 11.1 percent and 3.7 percent for single-duct and dual-duct units, respectively, the overall variability that differences in duct surface area determinations would introduce into the cooling capacity would be no greater than 1 percent. Therefore, DOE concludes that any uncertainty in duct surface area measurements would not have a significant impact on test repeatability and reproducibility and maintains the surface area measurement as proposed in the February 2015 NOPR.

5. Case Heat Transfer

In the February 2015 NOPR, DOE proposed that case heat transfer be determined using a method similar to the approach proposed for duct heat transfer. DOE proposed that the surface area and average temperature of each side of the case be measured to determine the overall case heat transfer, which would be used to adjust the cooling capacity and efficiency. DOE noted that the case heat transfer methodology would impose additional test burden, but determined that the burdens were likely outweighed by the benefit of addressing the heat transfer effects of all internal heating components. 80 FR 10211, 10227-10229 (Feb. 25, 2015).

DENSO commented that DOE should incorporate the effects of evaporator fan heat rather than case heat transfer effects, because all of the fan motor power ends up in the evaporator exhaust air stream. DENSO also stated that heat transfer mechanics for all surfaces of the case are not the same. (DENSO, No. 14 at p. 2)

Friedrich believes that there is no need to measure heat loss from the electrical components inside the case because the end result of the test would be the total cooling capacity coming from the portable AC and the total measure of energy consumption. (Public Meeting Transcript, Friedrich, No. 13 at p. 34)

De' Longhi noted that because there is a wide range in unit design, each portable AC may have uniquely shaped faces on the case, and it would be very difficult or impossible to identify the front, back, right, left, top, and bottom of the case. De' Longhi stated that laboratories may measure the surface temperature differently, and therefore, the proposal in the February 2015 NOPR may lead to inconsistencies among different laboratories. De' Longhi further suggested that the convection coefficient should be different for each side of the case due to the different orientation of each surface, and commented that a small variation in the position of the temperature sensors can cause significant differences in the average temperatures of each case. (Public Meeting Transcript, De' Longhi, No. 13 at pp. 55-56; De' Longhi, No. 16 at p. 4)

AHAM stated that the proposed methodology for determining case heat transfer unnecessarily complicates the test procedure and will likely lead to variation. AHAM believes the impact of case heat transfer is negligible and does not justify the added burden and variation. According to AHAM, if DOE

continues to consider case heat transfer, DOE should characterize the proposed test procedure's repeatability and reproducibility, preferably through a round robin test including manufacturers and third-party

laboratories. (AHAM, No. 18 at pp. 5–6)

In response to these comments, DOE further investigated the effects of case heat transfer as a percentage of the overall cooling capacity by analyzing the data determined in accordance with

AHAM PAC–1–2009 for the February 2015 NOPR. Figure III.2 shows, for each portable AC in its test sample, the heat transfer determined for each case side and the sum of all case sides as a percentage of the AHAM PAC–1–2009 cooling capacity.

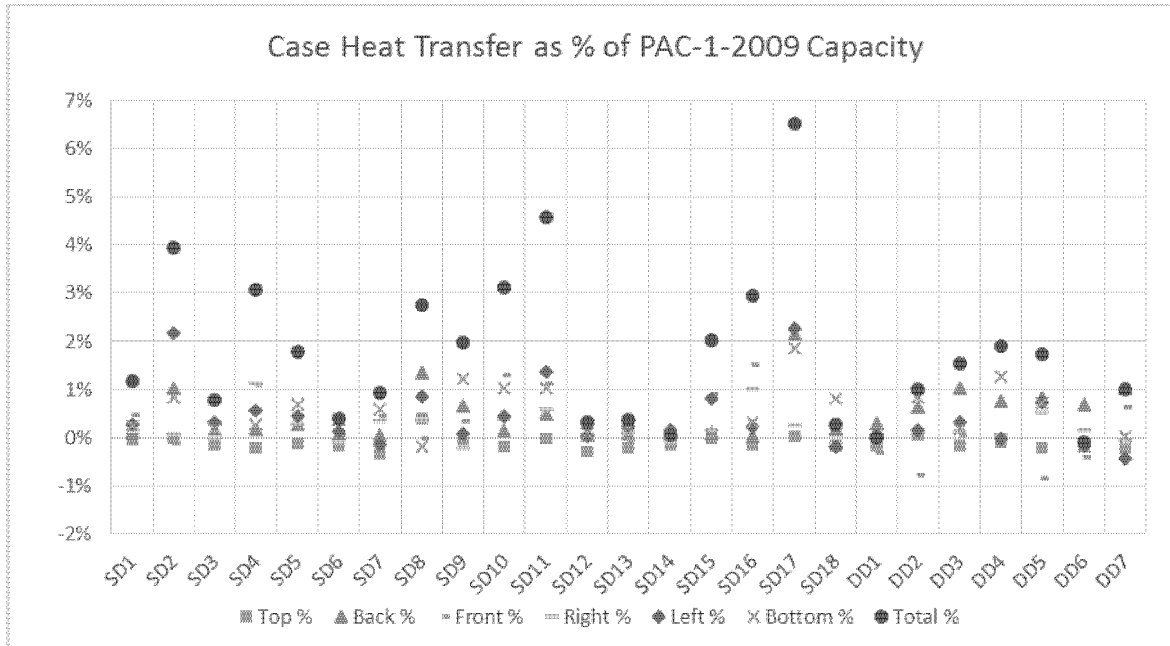


Figure III.2 Case Heat Transfer as a Percentage of AHAM PAC-1-2009 Cooling Capacity for Each Test Unit in the February 2015 NOPR

From the data in Figure III.2, DOE calculated that the average heat transfer for individual case sides was 0.29 percent of the AHAM PAC–1–2009 cooling capacity, and the maximum heat transfer observed for a single side was 2.27 percent. The total case heat transfer impact was, on average, 1.76 percent of the AHAM PAC–1–2009 cooling capacity, with a maximum of 6.53 percent. Because the total case heat transfer impact is, on average, less than 2 percent of the cooling capacity without adjustments for infiltration air and heat transfer effects, DOE proposes to remove the provisions for determining case heat transfer from the proposed portable AC test procedure.

6. Test Unit Placement

In the February 2015 NOPR, DOE proposed that for all portable AC configurations, there must be no less than 6 feet between the evaporator inlet and any chamber wall surface, and for single-duct units, there must be no less than 6 feet between the condenser inlet surface and any other wall surface. Additionally, DOE proposed that there be no less than 3 feet between the other

surfaces of the portable AC with no air inlet or exhaust (other than the bottom of the unit) and any wall surfaces. 80 FR 10211, 10229–10230 (Feb. 25, 2015).

According to DENSO, the 6-foot minimum spacing would cause an unreasonable performance penalty when duct losses are incorporated into the efficiency rating. DENSO further noted that the ducted side of a portable AC is often located relatively close to the wall where the duct is mounted. (DENSO, No. 14 at p. 3)

AHAM objected to the proposed test unit placement, commenting that, due to duct length, it may not be feasible to maintain the proposed distances from the partition wall. AHAM stated that this particular distance is variable and unit-dependent, and should not be applicable for single-duct or dual-duct units. (AHAM, No. 18 at pp. 6–7)

De' Longhi requested clarification as to whether the back of the unit, or side with the duct attachments, is considered a side that must be placed at the minimum distance from the chamber or partition walls. If so, De' Longhi commented that the unit should be placed at least 6 feet from the partition wall and the ducts would likely not

reach. (Public Meeting Transcript, De' Longhi, No. 13 at pp. 59–60; De' Longhi, No. 16 at p. 4)

DOE recognizes that the length of the duct and duct setup as outlined in AHAM PAC–1–2015 dictate the distance of the portable AC from the partition wall. Therefore, DOE proposes to adjust the February 2015 NOPR proposals for unit placement that would have required no less than 6 feet between the evaporator inlet and any chamber wall surfaces, and for single-duct units, no less than 6 feet between the condenser inlet surface and any other wall surface. Because AHAM PAC–1–2015 specifies the distance between the test unit and the partition wall, DOE proposes that the test unit be placed in such a way that there is no less than 3 feet between any test chamber wall and any surface on the portable AC, except the surface or surfaces that have a duct attachment, as prescribed by the AHAM PAC–1–2015 test setup requirements. DOE notes that this test unit placement would provide manufacturers and test laboratories more flexibility in the use of their test chambers than that proposed in the

February 2015 NOPR, and would still provide sufficient space around the test unit to ensure free air flow with no air constriction.

C. Heating Mode

As discussed in the February 2015 NOPR, certain portable ACs, including some of the units in DOE's test sample, incorporate a heating function in addition to cooling mode. DOE proposed to define heating mode as an active mode in which a portable AC has activated the main heating function according to the thermostat or temperature sensor signal, including activating a resistance heater, the refrigeration system with a reverse refrigerant flow valve, or the fan or blower without activation of the resistance heater or refrigeration system. 80 FR 10211, 10217 (Feb. 25, 2015). In the February 2015 NOPR, DOE concluded that a heating mode test to measure heating mode performance was feasible, and proposed a heating mode test procedure that utilized AHAM PAC-1-2014 at lower temperature ambient conditions and with comparable adjustments as were considered for cooling mode. 80 FR 10211, 10230-10231 (Feb. 25, 2015).

AHAM and De' Longhi opposed DOE's proposal to require testing in heating mode. They noted that heating mode is not the main consumer utility offered by portable ACs, and commented that it was not clear how often consumers use the heating feature and whether the burden of including this mode in the test procedure would be justified. AHAM, NAM, and De' Longhi commented that there are not sufficient heating mode data upon which to determine whether to include measurement of or assign annual operating hours to heating mode. AHAM and NAM further noted that in the heating analysis, DOE assumed that the consumer will use a portable AC in heating mode when the temperature has fallen below 45 °F, but presented no consumer data to support that assumption. According to AHAM, consumer usage of portable ACs in heating mode is extremely limited due to the seasonality of the product. AHAM, NAM, and De' Longhi commented that DOE should be consistent with its other analyses when considering heating mode. For example, they stated that DOE did not propose testing in fan-only mode because it would be impractical, nor did it propose testing in dehumidification mode because it is not the primary mode of operation for portable ACs. These commenters considered heating mode to be no different, and therefore concluded

that DOE should not require it to be tested. (Public Meeting Transcript, AHAM, No. 13 at p. 64; AHAM, No. 18 at pp. 7, 10; De' Longhi, No. 16 at p. 5; NAM, No. 17 at p. 2)

AHAM noted that many of the comments submitted regarding cooling mode would also apply to heating mode where applicable. Specifically, should DOE require measurement of heating mode, AHAM would not object to DOE's proposal to use the unit and duct setup requirements and control settings of AHAM PAC-1-2014, as well as the test configurations referenced in Table 2 of AHAM PAC-1-2014. AHAM opposed the inclusion of infiltration air, duct heat transfer, case transfer, and test unit placement for heating mode as discussed for cooling mode. (AHAM, No. 18 at pp. 7-8)

DENSO stated that its cooling mode comments are generally applicable for heating mode as well. (DENSO, No. 14 at p. 3)

After considering stakeholder comments opposing the test procedure for heating mode and in light of the test burden that the heating mode test would impose, DOE proposes to remove the heating mode test provisions from the proposed DOE portable AC test procedure, including the definition of heating mode and calculations for EER_{nm} and total combined energy efficiency ratio. Accordingly, the cooling-specific energy efficiency ratio, EER_{cm} , is no longer necessary, as the combined efficiency ratio, CEER, would appropriately represent energy efficiency in all modes under consideration. DOE expects that measuring performance in cooling mode, off-cycle mode, standby mode, and off mode would capture representative performance of portable ACs during the cooling season. DOE may reconsider including a test for heating mode in a future test procedure rulemaking.

D. Combined Energy Efficiency Ratio

In the February 2015 NOPR, DOE proposed a single energy conservation standard metric for portable ACs, in accordance with the requirements of EPCA. (42 U.S.C. 6295(gg)(3)(A)) The single integrated efficiency metric, CEER, weights the average power in each operating mode, as measured by the proposed test procedure, with estimated annual operating hours for each mode. The modes considered in the February 2015 NOPR procedure were cooling mode, heating mode, off-cycle mode (with and without fan operation), inactive mode (including bucket-full mode), and off mode. 80 FR 10211, 10234-10235 (Feb. 25, 2015).

1. Annual Operating Mode Hours

As presented in the February 2015 NOPR, DOE developed several estimates of portable AC annual operating mode hours for cooling, heating, off-cycle, and inactive or off modes. However, the three estimates that addressed units with both cooling and heating mode operating hours are no longer applicable with the removal of the heating mode test procedure. Therefore, for this revised analysis, DOE considered the annual operating mode hours for all portable ACs to be those from the "Cooling Only" scenario presented in the February 2015 NOPR as follows:

TABLE III.5—PROPOSED ANNUAL OPERATING HOURS BY MODE

Modes	Operating hours
Cooling Mode	750
Off-Cycle Mode	880
Off/Inactive Mode	1,355

More information on the development of these annual hours for each operating mode can be found in the February 2015 NOPR. 80 FR 10211, 10235-10237 (Feb. 25, 2015).

Friedrich noted that it rates its portable AC energy consumption based on 750 hours, the same cooling mode operating hours as room ACs. Friedrich suggested that DOE maintain the proposal of 750 annual cooling mode operating hours for portable ACs to maintain harmonization with room ACs and properly reflect unit annual energy consumption. (Public Meeting Transcript, Friedrich, No. 13 at p. 84)

AHAM and NAM disagreed with DOE's proposals, stating that the majority of the analysis was based on outdated room AC data. They asserted that although portable ACs and room ACs are similar in some ways, the usage profiles and installation locations of the two products differ. AHAM and NAM urged DOE to obtain data on consumer usage of portable ACs or demonstrate that consumer use of portable ACs and room ACs are sufficiently comparable. (Public Meeting Transcript, AHAM, No. 13 at pp. 81-83; AHAM, No. 18 at p. 10; NAM, No. 17 at pp. 1-2)

AHAM and NAM also objected to DOE basing the proposed unplugged hours on assumptions, without any consumer study or supporting data. These commenters stated that DOE should obtain consumer use data in order to inform its proposal on the number of unplugged hours. (Public Meeting Transcript, AHAM, No. 13 at p. 81; AHAM, No. 18 at p. 10; NAM, No. 17 at p. 2)

AHAM further commented that it is not aware of consumer usage data for portable ACs, but would attempt to request that information from its members. AHAM urged DOE not to proceed in the absence of such consumer use data. (Public Meeting Transcript, AHAM, No. 13 at pp. 83–84)

Neither AHAM nor manufacturers provided additional consumer usage data, and no further data were available from RECS or other sources. Therefore, DOE continues to utilize the most relevant consumer use data available and proposes the annual operating hours in Table III.5, maintaining the

analysis and approach described in the February 2015 NOPR. DOE welcomes any additional information and data regarding consumer use to further inform the proposed annual mode operating hours.

2. CEER Calculation

In addition to the CEER metric that incorporated energy consumption in all operating modes, including heating mode, DOE proposed a simplified CEER metric in the February 2015 NOPR for portable ACs that do not include a heating mode (CEER_{cm}). The CEER calculation in the February 2015 NOPR

would equal CEER_{cm} for units without heating mode. With the newly proposed removal of heating mode from the test procedure and addition of a second set of testing conditions for dual-duct units, DOE also proposes in this SNOPR to eliminate the CEER_{cm} calculation and to revise the CEER metric calculation as follows, using the same weighting factors as were developed for SACC. The revised calculations also correctly divide energy consumption by annual cooling mode hours rather than total annual hours, as was initially proposed in the February 2015 NOPR.

$$CEER_{SD} = \left[\frac{(ACC_{95} \times 0.2 + ACC_{83} \times 0.8)}{\left(\frac{AEC_{SD} + AEC_T}{k \times t} \right)} \right]$$

$$CEER_{DD} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{k \times t} \right)} \right] \times 0.2 + \left[\frac{ACC_{83}}{\left(\frac{AEC_{83} + AEC_T}{k \times t} \right)} \right] \times 0.8$$

Where:

CEER_{SD} and CEER_{DD} are the combined energy efficiency ratios for single-duct and dual duct units, respectively, in Btu/Wh.

ACC₉₅ and ACC₈₃ are the adjusted cooling capacities, tested at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively, in Btu/h.

AEC_{SD} is the annual energy consumption in cooling mode for single-duct units, in kWh/year.

AEC₉₅ is the annual energy consumption in cooling mode for dual-duct units, assuming all cooling mode hours would be at the 95 °F dry-bulb outdoor conditions, in kWh/year.

AEC₈₃ is the annual energy consumption in cooling mode for dual-duct units, assuming all cooling mode hours would be at the 83 °F dry-bulb outdoor conditions, in kWh/year.

AEC_T is the total annual energy consumption attributed to all modes except cooling, in kWh/year.

t is the number of cooling mode hours per year, 750.

k is 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

0.2 is the weighting factor for the 95 °F dry-bulb outdoor condition test.

0.8 is the weighting factor for the 83 °F dry-bulb outdoor condition test.

The February 2015 NOPR included incorrect text stating that the representative CEER would be the mean of the test unit efficiencies. DOE proposes in this SNOPR to clarify that the representative CEER for a basic model is calculated based on the sampling plan instructions proposed in

10 CFR 429.62. DOE further maintains its proposal that the CEER would be rounded to the nearest 0.1 Btu/Wh.

E. Compliance With Other Energy Policy and Conservation Act Requirements

1. Test Burden

EPCA requires that any test procedures prescribed or amended shall be reasonably designed to produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use, and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) In the February 2015 NOPR, DOE concluded that establishing a test procedure to measure the energy consumption of portable ACs in active mode, standby mode, and off mode would produce the required test results and would not be unduly burdensome to conduct. This determination was driven by the many similarities between the necessary testing equipment and facilities for portable ACs and other products, whose performance is currently certified through a DOE test procedure. Therefore, DOE concluded that manufacturers would not be required to make significant investment in test facilities and new equipment.

DOE notes that the modifications to the portable AC test procedures introduced in this notice, mainly the additional test condition in cooling mode for dual-duct units and the

removal of heating mode testing and case heat transfer considerations, would not significantly increase the overall test burden compared to the test procedure proposed in the February 2015 NOPR. Further, because the added cooling mode test conditions are closer to those of the originally proposed cooling mode test than the test conditions for the heating mode test, DOE estimates that less time would be required to achieve and maintain the chamber conditions for the second cooling mode test than for a heating mode test, decreasing the test burden for dual-duct units with a heating mode. In addition, the outdoor test chamber would not be required to reach the low temperatures required for the proposed heating mode test, which may have presented difficulties for some manufacturers and test laboratories to achieve.

For dual-duct units without a heating mode, the proposals in this notice would introduce test burden by requiring a second cooling mode test. However, the removal of case surface temperature measurements would likely mitigate the increased burden associated with this second cooling mode test, resulting in similar overall test burden as for the test procedure proposed in the February 2015 NOPR.

DOE concludes that although this SNOPR introduces modifications to the test procedures proposed in the February 2015 NOPR, it does not significantly increase the test burden,

and may instead reduce the overall test burden. Therefore, the determination in the February 2015 NOPR that the proposed portable AC test procedure would produce test results that measure energy consumption during representative use and that the test procedure would not be unduly burdensome to conduct still applies.

IV. Procedural Issues and Regulatory Review

DOE has concluded that the determinations made pursuant to the various procedural requirements applicable to the February 2015 NOPR, set forth at 80 FR 10212, 10238–10241, remain unchanged for this SNOPR, except for the following additional analysis and determination DOE conducted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

A. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel’s Web site: <http://energy.gov/gc/office-general-counsel>.

DOE reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE’s IRFA is set forth in the February 2015 NOPR, with additional analysis below based on the proposals in this SNOPR. DOE seeks comment on its analysis and the economic impacts of the rule on small manufacturers. In the February 2015 NOPR, DOE estimated that there is one small business that manufactures portable ACs. Since the February 2015 NOPR, DOE has determined that this small business no longer produces portable ACs and, therefore, DOE is unable to identify any small businesses that currently manufacture portable ACs. For this reason, DOE tentatively concludes and certifies that the proposed rule would

not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration (SBA) for review under 5 U.S.C. 605(b).

In the alternative, should any small business manufacturers of portable ACs be identified, DOE evaluated the modifications proposed in this SNOPR to determine if these modification would have a significant economic impact on small businesses as compared to the proposals in the February 2015 NOPR. DOE believes that these modifications are likely to reduce overall test burden with respect to the proposals in the February 2015 NOPR, and therefore would not have a significant economic impact on small businesses, should any be identified.

In this SNOPR, DOE proposes to increase the number of cooling mode tests for dual-duct portable ACs from one test to two tests at different outdoor test conditions. Although this increase requires running the cooling mode test a second time, DOE notes that the test setup would not need to be modified between testing and as such would not significantly increase the test burden beyond that for a single cooling mode test. The remaining changes associated with the additional outdoor test condition impact the post-testing calculations and therefore do not increase test burden.

DOE further proposes in this SNOPR to remove the measurement of case heat transfer and the heating mode testing requirements that were originally proposed in the February 2015 NOPR. The removal of the case heat transfer measurement eliminates the added burden of determining surface area of each case surface and measuring the average temperature of each surface. In addition, the removal of the heating mode test significantly reduces test burden for dual-duct units with a heating mode, in that a substantial stabilization period is avoided that would require reducing the outdoor chamber conditions well below those for the cooling mode test.

In the February 2015 NOPR, DOE concluded that the costs associated with the February 2015 NOPR proposals were small compared to the overall financial investment needed to undertake the business enterprise of developing and testing consumer products. 80 FR 10211, 10239. Compared to the proposals in the February 2015 NOPR, there is no net change in the number of

tests or power metering instrumentation required. In addition, the elimination of the case heat transfer requirement would avoid the potential need for setting up and purchasing additional temperature sensors, estimated to cost less than \$500 for both equipment and labor.

On the basis of this analysis, DOE tentatively concludes that the proposed rule would not have a significant economic impact on a substantial number of small entities, should any small business manufacturers of portable ACs be identified.

DOE seeks comment on the determinations in this section and information on whether any small businesses manufacture portable ACs.

B. Description of Materials Incorporated by Reference

In this SNOPR, DOE proposes to incorporate by reference the test standard published by AHAM, titled “Portable Air Conditioners,” AHAM PAC–1–2015. AHAM PAC–1–2015 is an industry accepted test procedure that measures portable AC performance in cooling mode and is applicable to products sold in North America. AHAM PAC–1–2015 specifies testing conducted in accordance with other industry accepted test procedures (already incorporated by reference) and determines energy efficiency metrics for various portable AC configurations. The test procedure proposed in this SNOPR references various sections of AHAM PAC–1–2015 that address test setup, instrumentation, test conduct, calculations, and rounding. AHAM PAC–1–2015 is readily available on AHAM’s Web site at <http://www.aham.org/ht/d/ProductDetails/sku/PAC12009/from/714/pid/>.

In this SNOPR, DOE also proposes to incorporate by reference the test standard ASHRAE Standard 37–2009, titled “Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment,” (ANSI Approved). ANSI/ASHRAE Standard 37–2009 is an industry-accepted test standard referenced by AHAM PAC–1–2015 that defines various uniform methods for measuring performance of air conditioning and heat pump equipment. Although AHAM PAC–1–2015 references a number of sections in ANSI/ASHRAE Standards 37–2009, the test procedure proposed in this SNOPR additionally references one section in ANSI/ASHRAE Standards 37–2009 that addresses test duration. ANSI/ASHRAE Standards 37–2009 is readily available on ANSI’s Web site at <http://webstore>.

ansi.org/RecordDetail.aspx?sku=ANSI%2FASHRAE+Standard+37-2009.

V. Public Participation

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

Submitting comments via www.regulations.gov. The www.regulations.gov Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through [regulations.gov](http://www.regulations.gov) cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through [regulations.gov](http://www.regulations.gov) before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that [regulations.gov](http://www.regulations.gov) provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to [regulations.gov](http://www.regulations.gov). If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is

generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this supplemental notice of proposed rulemaking.

List of Subjects

10 CFR Part 429

Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on November 17, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE proposes to amend parts 429 and 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.4 is amended by adding paragraph (b)(3) to read as follows:

§ 429.4 Materials incorporated by reference.

* * * * *

(b) * * *

(3) AHAM PAC-1-2015, Portable Air Conditioners, 2015, IBR approved for § 429.62.

* * * * *

■ 3. Add § 429.62 to read as follows:

§ 429.62 Portable air conditioners.

(a) *Sampling plan for selection of units for testing.* (1) The requirements of § 429.11 are applicable to portable air conditioners; and

(2) For each basic model of portable air conditioner, a sample of sufficient size shall be randomly selected and tested to ensure that—

(i) Any represented value of energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be greater than or equal to the higher of:

(A) The mean of the sample:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

Where:

\bar{x} is the sample mean;
 x_i is the i^{th} sample; and
 n is the number of units in the test sample.

Or,

(B) The upper 95 percent confidence limit (UCL) of the true mean divided by 1.10:

$$UCL = \bar{x} + t_{0.95} \left(\frac{s}{\sqrt{n}} \right)$$

Where:

\bar{x} is the sample mean;
 s is the sample standard deviation;
 n is the number of units in the test sample; and
 $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with $n-1$ degrees of freedom.

And,

(ii) Any represented value of the combined energy efficiency ratio or other measure of energy consumption of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

(A) The mean of the sample:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

Where:

\bar{x} is the sample mean;
 x_i is the i^{th} sample; and
 n is the number of units in the test sample.

Or,

(B) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.90:

$$LCL = \bar{x} - t_{0.95} \left(\frac{s}{\sqrt{n}} \right)$$

Where:

\bar{x} is the sample mean;
 s is the sample standard deviation;
 n is the number of units in the test sample; and
 $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with $n-1$ degrees of freedom.

And,

(3) The value of seasonally adjusted cooling capacity of a basic model shall be the mean of the seasonally adjusted cooling capacities for each tested unit of the basic model. Round the mean capacity value to the nearest 50, 100, 200, or 500 Btu/h, depending on the value being rounded, in accordance with Table 1 of AHAM PAC-1-2015, (incorporated by reference, see § 429.4), “Multiples for reporting Dual Duct Cooling Capacity, Single Duct Cooling Capacity, Spot Cooling Capacity, Water Cooled Condenser Capacity and Power Input Ratings.”

(4) Round the value of combined energy efficiency ratio of a basic model to the nearest 0.1 Btu/Wh.

(b) *Certification reports.* [Reserved]

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 4. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291-6309; 28 U.S.C. 2461 note.

■ 5. Section 430.2 is amended by adding the definition of “portable air conditioner” in alphabetical order to read as follows:

§ 430.2 Definitions.

* * * * *

Portable air conditioner means an enclosed assembly, other than a “packaged terminal air conditioner,” “room air conditioner,” or “dehumidifier,” designed as a portable unit for delivering cooled, conditioned air to an enclosed space, that is powered by single-phase electric current, and which may rest on the floor or other elevated surface. It includes a source of refrigeration and may include additional means for air circulation and heating.

* * * * *

■ 6. Section 430.3 is amended by:

- a. Revising paragraph (g)(4);
- b. Redesignating paragraph (i)(8) as (i)(9), and adding a new paragraph (i)(8); and

■ c. Revising paragraph (p)(4).

The revisions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(g) * * *

(4) ANSI/ASHRAE Standard 37-2009, (“ASHRAE 37-2009”), Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment, ANSI approved June 25, 2009, IBR approved for appendix AA and CC to subpart B.

* * * * *

(i) * * *

(8) AHAM PAC-1-2015, Portable Air Conditioners, 2015, IBR approved for appendix CC to subpart B.

* * * * *

(p) * * *

(4) IEC 62301 (“IEC 62301”), Household electrical appliances— Measurement of standby power, (Edition 2.0, 2011-01), IBR approved for appendices C1, D1, D2, G, H, I, J2, N, O, P, X, X1, Z and CC to subpart B.

* * * * *

■ 7. Section 430.23 is amended by adding paragraph (dd) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(dd) *Portable air conditioners.* (1) For portable air conditioners, measure the seasonally adjusted cooling capacity, expressed in British thermal units per hour (Btu/h), and the combined energy efficiency ratio, expressed in British thermal units per watt-hour (Btu/Wh) in accordance with section 5 of appendix CC of this subpart.

(2) Determine the estimated annual operating cost for portable air conditioners, expressed in dollars per year, by multiplying the following two factors:

(i) For dual-duct portable air conditioners, the sum of AEC_{05} multiplied by 0.2, AEC_{83} multiplied by 0.8, and AEC_T as measured in accordance with section 5.3 of appendix CC of this subpart; or for single-duct portable air conditioners, the sum of AEC_{SD} and AEC_T as measured in accordance with section 5.3 of appendix CC of this subpart; and

(ii) A representative average unit cost of electrical energy in dollars per kilowatt-hour as provided by the Secretary.

(iii) Round the resulting product to the nearest dollar per year.

■ 7. Add appendix CC to subpart B of part 430 to read as follows:

Appendix CC to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Portable Air Conditioners

1. Scope

This appendix covers the test requirements used to measure the energy performance of single-duct and dual-duct portable air conditioners. It does not contain testing provisions for measuring the energy performance of spot coolers at this time.

2. Definitions

2.1 *AHAM PAC-1* means the test standard published by the Association of Home Appliance Manufacturers, titled “Portable Air Conditioners,” AHAM PAC-1-2015 (incorporated by reference; see § 430.3).

2.2 *Combined energy efficiency ratio* is the energy efficiency of a portable air conditioner as measured in accordance with this test procedure in Btu per watt-hours (Btu/Wh) and determined in section 5.4.

2.3 *Cooling mode* means a mode in which a portable air conditioner has activated the main cooling function according to the thermostat or temperature sensor signal, including activating the refrigeration system or the fan or blower without activation of the refrigeration system.

2.4 *Dual-duct portable air conditioner* means a portable air conditioner that draws some or all of the condenser inlet air from outside the conditioned space through a duct, and may draw additional condenser inlet air from the conditioned space. The condenser outlet air is discharged outside the conditioned space by means of a separate duct. 2.6 *IEC 62301* means the test standard published by the International Electrotechnical Commission, titled “Household electrical appliances—Measurement of standby power,” Publication 62301 (Edition 2.0 2011-01) (incorporated by reference; see § 430.3).

2.5 *Inactive mode* means a standby mode that facilitates the activation of an active mode or off-cycle mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display.

2.6 *Off-cycle mode* means a mode in which a portable air conditioner:

(1) Has cycled off its main cooling or heating function by thermostat or temperature sensor signal;

(2) May or may not operate its fan or blower; and

(3) Will reactivate the main function according to the thermostat or temperature sensor signal.

2.7 *Off mode* means a mode in which a portable air conditioner is connected to a mains power source and is not providing any active mode, off-cycle mode, or standby mode function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the portable air conditioner is in the off position is included within the classification of an off mode.

2.8 *Seasonally adjusted cooling capacity* means a measure of the cooling, measured in Btu/h, provided to the indoor conditioned space, measured under the specified ambient conditions.

2.9 *Single-duct portable air conditioner* means a portable air conditioner that draws all of the condenser inlet air from the conditioned space without the means of a duct, and discharges the condenser outlet air outside the conditioned space through a single duct.

2.10 *Spot cooler* means a portable air conditioner that draws condenser inlet air from and discharges condenser outlet air to the conditioned space, and draws evaporator inlet air from and discharges evaporator outlet air to a localized zone within the conditioned space.

2.11 *Standby mode* means any mode where a portable air conditioner is connected to a mains power source and offers one or more of the following user-oriented or protective functions which may persist for an indefinite time:

(1) To facilitate the activation of other modes (including activation or deactivation of cooling mode) by remote switch (including remote control), internal sensor, or timer; or

(2) Continuous functions, including information or status displays (including clocks) or sensor-based functions. A timer is a continuous clock function (which may or may not be associated with a display) that provides regular scheduled tasks (e.g., switching) and that operates on a continuous basis.

3. Test Apparatus and General Instructions

3.1 Active mode.

3.1.1 *Test conduct.* The test apparatus and instructions for testing portable air conditioners in cooling mode and off-cycle mode shall conform to the requirements specified in Section 4, “Definitions” and Section 7, “Tests,” of AHAM PAC-1-2015 (incorporated by reference; see § 430.3), except as otherwise specified in this appendix. Where applicable, measure duct heat transfer and infiltration air heat transfer according to section 4.1.1.1 and section 4.1.1.2 of this appendix, respectively.

3.1.1.1 *Duct setup.* Use ducting components provided by the manufacturer, including, where provided by the manufacturer, ducts, connectors for attaching the duct(s) to the test unit, and window mounting fixtures. Do not apply additional sealing or insulation.

3.1.1.2 *Single-duct evaporator inlet test conditions.* When testing single-duct portable air conditioners, maintain the evaporator inlet dry-bulb temperature within a range of 1.0 °F with an average difference within 0.3 °F.

3.1.1.3 *Condensate Removal.* Setup the test unit in accordance with manufacturer instructions. If the unit has an auto-evaporative feature, keep any provided drain plug installed as shipped and do not provide other means of condensate removal. If the internal condensate collection bucket fills during the test, halt the test, remove the drain plug, install a gravity drain line, and start the test from the beginning. If no auto-evaporative feature is available, remove the drain plug and install a gravity drain line. If no auto-evaporative feature or gravity drain is available and a condensate pump is included, or if the manufacturer specifies the use of an included condensate pump during

cooling mode operation, then test the portable air conditioner with the condensate pump enabled. For units tested with a condensate pump, apply the provisions in Section 7.1.2 of AHAM PAC-1-2015 (incorporated by reference; see § 430.3) if the pump cycles on and off.

3.1.1.4 *Unit Placement.* There shall be no less than 3 feet between any test chamber wall surface and any surface on the portable air conditioner, except the surface or surfaces of the portable air conditioner that include a duct attachment. The distance between the test chamber wall and a surface with one or more duct attachments is prescribed by the test setup requirements in Section 7.3.7 of AHAM PAC-1-2015 (incorporated by reference; see § 430.3).

3.1.1.5 *Electrical supply.* Maintain the input standard voltage at 115 V ±1 percent. Test at the rated frequency, maintained within ±1 percent.

3.1.1.6 *Duct temperature measurements.* Measure the surface temperatures of each duct using four equally spaced thermocouples per duct, adhered to the outer surface of the entire length of the duct. Temperature measurements must have an error no greater than ±0.5 °F over the range being measured.

3.1.2 *Control settings.* Set the controls to the lowest available temperature setpoint for cooling mode. If the portable air conditioner has a user-adjustable fan speed, select the maximum fan speed setting. If the portable air conditioner has an automatic louver oscillation feature, disable that feature throughout testing. If the louver oscillation feature is included but there is no option to disable it, testing shall proceed with the louver oscillation enabled. If the portable air conditioner has adjustable louvers, position the louvers parallel with the airflow to maximize air flow and minimize static pressure loss.

3.1.3 *Measurement resolution and rounding.* Record measurements at the resolution of the test instrumentation. Round the seasonally adjusted cooling capacity value in accordance with Table 1 of AHAM PAC-1-2015 (incorporated by reference; see § 430.3). Round CEER as calculated in section 5 of this appendix, to the nearest 0.1 Btu/Wh.

3.2 Standby mode and off mode.

3.2.1 *Installation requirements.* For the standby mode and off mode testing, install the portable air conditioner in accordance with Section 5, Paragraph 5.2 of IEC 62301 (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes.

3.2.2 Electrical energy supply.

3.2.2.1 *Electrical supply.* For the standby mode and off mode testing, maintain the input standard voltage at 115 V ±1 percent. Maintain the electrical supply at the rated frequency ±1 percent.

3.2.2.2 *Supply voltage waveform.* For the standby mode and off mode testing, maintain the electrical supply voltage waveform indicated in Section 4, Paragraph 4.3.2 of IEC 62301 (incorporated by reference; see § 430.3).

3.2.3 *Standby mode and off mode wattmeter.* The wattmeter used to measure

standby mode and off mode power consumption must meet the requirements specified in Section 4, Paragraph 4.4 of IEC 62301 (incorporated by reference; see § 430.3).

3.2.4 *Standby mode and off mode ambient temperature.* For standby mode and off mode testing, maintain room ambient air temperature conditions as specified in Section 4, Paragraph 4.2 of IEC 62301 (incorporated by reference; see § 430.3).

4. Test Measurement

4.1 *Cooling mode.* Measure the indoor room cooling capacity and overall power input in cooling mode in accordance with Section 7.1.b and 7.1.c of AHAM PAC-1-2015 (incorporated by reference; see § 430.3), respectively. The test duration shall be determined in accordance with Section 8.7 of ASHRAE 37-2009 (incorporated by reference; § 430.3). Substitute the test conditions in Table 3 of AHAM PAC-1-2015 with the test conditions for single-duct and dual-duct portable air conditioners presented

in Table 1 of this appendix. For single-duct units, measure the indoor room cooling capacity, Capacity_{SD}, and overall power input in cooling mode, P_{SD}, in accordance with the ambient conditions for test configuration 5, presented in Table 1 of this appendix. For dual-duct units, measure the indoor room cooling capacity and overall power input in accordance with ambient conditions for test configuration 3, condition A (Capacity₉₅, P₉₅), and a second time in accordance with the ambient conditions for test configuration 3, condition B (Capacity₈₃, P₈₃), presented in Table 1 of this appendix.

TABLE 1—EVAPORATOR AND CONDENSER INLET TEST CONDITIONS

Test configuration	Evaporator inlet air, °F (°C)		Condenser inlet air, °F (°C)	
	Dry bulb	Wet bulb	Dry bulb	Wet bulb
3 (Condition A)	80 (26.7)	67 (19.4)	95 (35.0)	75 (23.9)
3 (Condition B)	80 (26.7)	67 (19.4)	83 (28.3)	67.5 (19.7)
5	80 (26.7)	67 (19.4)	80 (26.7)	67 (19.4)

4.1.1. *Duct Heat Transfer.* Measure the surface temperature of the condenser exhaust duct and condenser inlet duct, where applicable, throughout the cooling mode test. Calculate the average temperature at each individual location, and then calculate the average surface temperature of each duct by averaging the four average temperature measurements taken on that duct. Calculate the surface area (A_{duct_j}) of each duct according to the following:

$$A_{duct_j} = \pi \times d_j \times L_j$$

Where:

d_j = the outer diameter of duct “j”.

L_j = the extended length of duct “j” while under test.

j represents the condenser exhaust duct and, for dual-duct units, condenser inlet duct.

Calculate the total heat transferred from the surface of the duct(s) to the indoor conditioned space while operating in cooling mode for the outdoor test conditions in Table 1 of this appendix, as follows. For single-duct portable air conditioners:

$$Q_{duct_SD} = h \times A_{duct_j} \times (T_{duct_SD_j} - T_{ei})$$

For dual-duct portable air conditioners:

$$Q_{duct_95} = \Sigma j \{ h \times A_{duct_j} \times (T_{duct_95_j} - T_{ei}) \}$$

$$Q_{duct_83} = \Sigma j \{ h \times A_{duct_j} \times (T_{duct_83_j} - T_{ei}) \}$$

Where:

Q_{duct_SD} = for single-duct portable air conditioners, the total heat transferred from the duct to the indoor conditioned space in cooling mode when tested according to the test conditions in Table 1 of this appendix, in Btu/h.

Q_{duct_95} and Q_{duct_83} = for dual-duct portable air conditioners, the total heat transferred from the ducts to the indoor conditioned space in cooling mode when tested according to the 95 °F dry-bulb and 83 °F dry-bulb outdoor test conditions in Table 1 of this appendix, in Btu/h.

h = convection coefficient, 4 Btu/h per square foot per °F.

A_{duct_j} = surface area of duct “j”, in square feet.

T_{duct_SD_j} = average surface temperature for the condenser exhaust duct of single-duct portable air conditioners, as measured during testing according to the

test condition in Table 1 of this appendix, in °F.

T_{duct_95_j} and T_{duct_83_j} = average surface temperature for duct “j” of dual-duct portable air conditioners, as measured during testing according to the two outdoor test conditions in Table 1 of this appendix, in °F.

j represents the condenser exhaust duct and, for dual-duct units, condenser inlet duct.

T_{ei} = average evaporator inlet air dry-bulb temperature, in °F.

4.1.2 *Infiltration Air Heat Transfer.*

Measure the heat contribution from infiltration air for single-duct portable air conditioners and dual-duct portable air conditioners that draw at least part of the condenser air from the conditioned space. Calculate the heat contribution from infiltration air for single-duct and dual-duct portable air conditioners for both cooling mode outdoor test conditions, as described in this section. The dry air mass flow rate of infiltration air shall be calculated according to the following equations. For single-duct portable air conditioners:

$$\dot{m}_{SD} = \frac{V_{co_SD} \times \rho_{co_SD}}{(1 + \omega_{co_SD})}$$

For dual-duct portable air conditioners:

$$\dot{m}_{95} = \left[\frac{V_{co_95} \times \rho_{co_95}}{(1 + \omega_{co_95})} \right] - \left[\frac{V_{ci_95} \times \rho_{ci_95}}{(1 + \omega_{ci_95})} \right]$$

$$\dot{m}_{83} = \left[\frac{V_{co_83} \times \rho_{co_83}}{(1 + \omega_{co_83})} \right] - \left[\frac{V_{ci_83} \times \rho_{ci_83}}{(1 + \omega_{ci_83})} \right]$$

Where:

\dot{m}_{SD} = dry air mass flow rate of infiltration air for single-duct portable air conditioners, in pounds per minute (lb/m).

\dot{m}_{95} and \dot{m}_{83} = dry air mass flow rate of infiltration air for dual-duct portable air conditioners, as calculated based on testing according to the test conditions in Table 1 of this appendix, in lb/m.

V_{co_SD} , V_{co_95} , and V_{co_83} = average volumetric flow rate of the condenser outlet air during cooling mode testing for single-duct portable air conditioners; and at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in cubic feet per minute (cfm).

V_{ci_95} , and V_{ci_83} = average volumetric flow rate of the condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in cfm.

ρ_{co_SD} , ρ_{co_95} , and ρ_{co_83} = average density of the condenser outlet air during cooling mode testing for single-duct portable air conditioners, and at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in pounds mass per cubic foot (lb_m/ft³).

ρ_{ci_95} , and ρ_{ci_83} = average density of the condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in lb_m/ft³.

ω_{co_SD} , ω_{co_95} , and ω_{co_83} = average humidity ratio of condenser outlet air during cooling mode testing for single-duct portable air conditioners, and at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}).

ω_{ci_95} , and ω_{ci_83} = average humidity ratio of condenser inlet air during cooling mode testing at the 95 °F and 83 °F dry-bulb outdoor conditions for dual-duct portable air conditioners, respectively, in lb_w/lb_{da}.

For single-duct and dual-duct portable air conditioners, calculate the sensible component of infiltration air heat contribution according to the following:

$$Q_{s_95} = \dot{m} \times 60 \times [(C_{p_da} \times (T_{ia_95} - T_{indoor})) + C_{p_wv} \times (\omega_{ia_95} \times T_{ia_95} - \omega_{indoor} \times T_{indoor})]$$

$$Q_{s_83} = \dot{m} \times 60 \times [(C_{p_da} \times (T_{ia_83} - T_{indoor})) + C_{p_wv} \times (\omega_{ia_83} \times T_{ia_83} - \omega_{indoor} \times T_{indoor})]$$

Where:

Q_{s_95} and Q_{s_83} = sensible heat added to the room by infiltration air, calculated at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h.

\dot{m} = dry air mass flow rate of infiltration air, \dot{m}_{SD} or \dot{m}_{95} when calculating Q_{s_95} and \dot{m}_{SD} or \dot{m}_{83} when calculating Q_{s_83} , in lb/m.

C_{p_da} = specific heat of dry air, 0.24 Btu/lb_m-°F.

C_{p_wv} = specific heat of water vapor, 0.444 Btu/lb_m-°F.

T_{indoor} = indoor chamber dry-bulb temperature, 80 °F.

T_{ia_95} and T_{ia_83} = infiltration air dry-bulb temperatures for the two test conditions

in Table 1 of this appendix, 95 °F and 83 °F, respectively.

ω_{ia_95} and ω_{ia_83} = humidity ratios of the 95 °F and 83 °F dry-bulb infiltration air, 0.0141 and 0.01086 lb_w/lb_{da}, respectively.

ω_{indoor} = humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 = conversion factor from minutes to hours.

Calculate the latent heat contribution of the infiltration air according to the following:

$$Q_{l_95} = \dot{m} \times 60 \times H_{fg} \times (\omega_{ia_95} - \omega_{indoor})$$

$$Q_{l_83} = \dot{m} \times 60 \times H_{fg} \times (\omega_{ia_83} - \omega_{indoor})$$

Where:

Q_{l_95} and Q_{l_83} = latent heat added to the room by infiltration air, calculated at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h.

\dot{m} = mass flow rate of infiltration air, \dot{m}_{SD} or \dot{m}_{95} when calculating Q_{l_95} and \dot{m}_{SD} or \dot{m}_{83} when calculating Q_{l_83} , in lb/m.

H_{fg} = latent heat of vaporization for water vapor, 1061 Btu/lb_m.

ω_{ia_95} and ω_{ia_83} = humidity ratios of the 95 °F and 83 °F dry-bulb infiltration air, 0.0141 and 0.01086 lb_w/lb_{da}, respectively.

ω_{indoor} = humidity ratio of the indoor chamber air, 0.0112 lb_w/lb_{da}.

60 = conversion factor from minutes to hours.

The total heat contribution of the infiltration air is the sum of the sensible and latent heat:

$$Q_{infiltration_95} = Q_{s_95} + Q_{l_95}$$

$$Q_{infiltration_83} = Q_{s_83} + Q_{l_83}$$

Where:

$Q_{infiltration_95}$ and $Q_{infiltration_83}$ = total infiltration air heats in cooling mode, calculated at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h.

Q_{s_95} and Q_{s_83} = sensible heat added to the room by infiltration air, calculated at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h.

Q_{l_95} and Q_{l_83} = latent heat added to the room by infiltration air, calculated at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h.

4.2 Off-cycle mode. Establish the test conditions specified in section 3.1.1 of this appendix for off-cycle mode, except that the duct measurements in section 3.1.1.6 shall not be used and the wattmeter specified in section 3.2.3 of this appendix shall be used. Begin the off-cycle mode test period 5 minutes following the cooling mode test period. Adjust the setpoint higher than the ambient temperature to ensure the product will not enter cooling mode and begin the test 5 minutes after the compressor cycles off due to the change in setpoint. The off-cycle mode test

period shall be 2 hours in duration, during which the power consumption is recorded at the same intervals as recorded for cooling mode testing. Measure and record the average off-cycle mode power of the portable air conditioner, P_{oc} , in watts.

4.3 Standby mode and off mode.

Establish the testing conditions set forth in section 3.2 of this appendix, ensuring that the portable air conditioner does not enter any active modes during the test. For portable air conditioners that take some time to enter a stable state from a higher power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301, (incorporated by reference; see § 430.3), allow sufficient time for the portable air conditioner to reach the lowest power state before proceeding with the test measurement. Follow the test procedure specified in Section 5, Paragraph 5.3.2 of IEC 62301 for testing in each possible mode as described in sections 4.3.1 and 4.3.2 of this appendix.

4.3.1 If the portable air conditioner has an inactive mode, as defined in section 2.5 of this appendix, but not an off mode, as defined in section 2.7 of this appendix, measure and record the average inactive mode power of the portable air conditioner, P_{ia} , in watts.

4.3.2 If the portable air conditioner has an off mode, as defined in section 2.7 of this appendix, measure and record the average off mode power of the portable air conditioner, P_{om} , in watts.

5. Calculation of Derived Results From Test Measurements

5.1 Adjusted Cooling Capacity.

Calculate the adjusted cooling capacities for portable air conditioners, ACC_{95} and ACC_{83} , expressed in Btu/h, according to the following equations. For single-duct portable air conditioners:

$$ACC_{95} = Capacity_{SD} - \frac{Q_{duct_SD} - Q_{infiltration_95}}{Capacity_{SD}}$$

$$ACC_{83} = Capacity_{SD} - \frac{Q_{duct_SD} - Q_{infiltration_83}}{Capacity_{SD}}$$

For dual-duct portable air conditioners:

$$ACC_{95} = Capacity_{95} - \frac{Q_{duct_95} - Q_{infiltration_95}}{Capacity_{95}}$$

$$ACC_{83} = Capacity_{83} - \frac{Q_{duct_83} - Q_{infiltration_83}}{Capacity_{83}}$$

Where:

$Capacity_{SD}$, $Capacity_{95}$, and $Capacity_{83}$ = cooling capacity measured in section 4.1.1 of this appendix.

Q_{duct_SD} , Q_{duct_95} , and Q_{duct_83} = duct heat transfer while operating in cooling mode, calculated in section 4.1.1.1 of this appendix.

$Q_{infiltration_95}$ and $Q_{infiltration_83}$ = total infiltration air heat transfer in

cooling mode, calculated in section 4.1.1.2 of this appendix.

5.2 *Seasonally Adjusted Cooling Capacity.* Calculate the seasonally adjusted cooling capacity for portable air conditioners, SACC, expressed in Btu/h, according to the following:
 $SACC = ACC_{95} \times 0.2 + ACC_{83} \times 0.8$

Where:

ACC_{95} and ACC_{83} = adjusted cooling capacity, in Btu/h, calculated in section 5.1 of this appendix.

0.2 = weighting factor for ACC_{95} .

0.8 = weighting factor for ACC_{83} .

5.3 *Annual Energy Consumption.*

Calculate the annual energy consumption in each operating mode, AEC_m , expressed in kilowatt-hours per year (kWh/year). The annual hours of operation in each mode are estimated as follows:

Operating mode	Annual operating hours
Cooling Mode, Dual-Duct 95 °F ¹	750
Cooling Mode, Dual-Duct 83 °F ¹	750

Operating mode	Annual operating hours
Cooling Mode, Single-Duct	750
Off-Cycle	880
Inactive or Off	1,355

¹ These operating mode hours are for the purposes of calculating annual energy consumption under different ambient conditions for dual-duct portable air conditioners, and are not a division of the total cooling mode operating hours. The total dual-duct cooling mode operating hours are 750 hours.

$$AEC_m = P_m \times t_m \times k$$

Where:

AEC_m = annual energy consumption in each mode, in kWh/year.

P_m = average power in each mode, in watts.

m represents the operating mode (“95” and “83” cooling mode at the 95 °F and 83 °F dry-bulb outdoor conditions, respectively for dual-duct portable air conditioners, “SD” cooling mode for single-duct portable air conditioners, “oc” off-cycle, and “ia” inactive or “om” off mode).

t = number of annual operating time in each mode, in hours.

k = 0.001 kWh/Wh conversion factor from watt-hours to kilowatt-hours.

Total annual energy consumption in all modes except cooling, is calculated according to the following:

$$AEC_T = \sum_m AEC_m$$

Where:

AEC_T = total annual energy consumption attributed to all modes except cooling, in kWh/year;

AEC_m = total annual energy consumption in each mode, in kWh/year.

m represents the operating modes included in AEC_T (“oc” off-cycle, and “im” inactive or “om” off mode).

5.4 *Combined Energy Efficiency Ratio.* Using the annual operating hours, as outlined in section 5.3 of this appendix, calculate the combined energy efficiency ratio, CEER, expressed in Btu/Wh, according to the following:

$$CEER_{SD} = \left[\frac{(ACC_{95} \times 0.2 + ACC_{83} \times 0.8)}{\left(\frac{AEC_{SD} + AEC_T}{k \times t} \right)} \right]$$

$$CEER_{DD} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{k \times t} \right)} \right] \times 0.2 + \left[\frac{ACC_{83}}{\left(\frac{AEC_{83} + AEC_T}{k \times t} \right)} \right] \times 0.8$$

Where:

$CEER_{SD}$ and $CEER_{DD}$ = combined energy efficiency ratio for single-duct and dual-duct portable air conditioners, respectively, in Btu/Wh.

ACC_{95} and ACC_{83} = adjusted cooling capacity, tested at the 95 °F and 83 °F dry-bulb outdoor conditions in Table 1 of this appendix, in Btu/h, calculated in section 5.1 of this appendix.

AEC_{SD} = annual energy consumption in cooling mode for single-duct portable air conditioners, in kWh/year, calculated in section 5.3 of this appendix.

AEC_{95} and AEC_{83} = annual energy consumption for the two cooling mode test conditions in Table 1 of this appendix for dual-duct portable air conditioners, in kWh/year, calculated in section 5.3 of this appendix.

AEC_T = total annual energy consumption attributed to all modes except cooling, in kWh/year,

calculated in section 5.3 of this appendix.

t = number of cooling mode hours per year, 750.

k = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

0.2 = weighting factor for the 95 °F dry-bulb outdoor condition test.

0.8 = weighting factor for the 83 °F dry-bulb outdoor condition test.

[FR Doc. 2015-30057 Filed 11-25-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-5810; Directorate Identifier 2014-NM-116-AD]

RIN 2120-AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. This proposed AD was prompted by a design review that revealed that a wiring failure, external to the center wing fuel tank, could cause a hot short circuit to a maximum level sensor wire, and result

in excessive heating of the maximum level sensor element. This proposed AD would require modifying the wiring of the maximum level sensors in the center wing fuel tank, performing after-installation tests, and corrective action if necessary. This proposed AD would also require revising the airplane maintenance or inspection program to incorporate fuel airworthiness limitation items and critical design configuration control limitations. We are proposing this AD to prevent the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88-6280-350; fax +31 (0)88-6280-111; email technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5810; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will

be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1137; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2015-5810; Directorate Identifier 2014-NM-116-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014-0138, dated May 30, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. The MCAI states:

* * * [T]he FAA published Special Federal Aviation Regulation (SFAR) 88, and the Joint Aviation Authorities (JAA) published Interim Policy INT/POL/25/12.

The review conducted by Fokker Services on the Fokker 70/100 design, in response to these regulations, revealed that a wiring failure, external to the centre wing fuel tank, causing a hot short circuit to a maximum (max) level sensor wire may result in excessive heating of the max level sensor element.

This condition, if not corrected, could create an ignition source in the centre wing fuel tank vapour space, possibly resulting in a fuel tank explosion and consequent loss of the aeroplane.

EASA issued AD 2012-0240 [http://ad.easa.europa.eu/blob/easa_ad_2012_0240.pdf], to address this unsafe condition, which required installation of three fuses in the wiring of the max level sensor(s) in the centre wing fuel tank per Fokker Services Service Bulletin (SB)

SBF100-28-073. After that AD was issued, it was found that this technical solution caused fuel spills during refueling and, consequently, EASA cancelled AD 2012-0240.

More recently, Fokker Services issued SBF100-28-078, which cancelled SBF100-28-073, to correct the unsafe condition without the risk of fuel spills.

For the reasons described above, this [EASA] AD requires removal of one fuse from post-SBF100-28-073 aeroplanes, and installation of only two fuses on pre-SBF100-28-073 aeroplanes and, subsequently, the implementation of the associated Critical Design Configuration Control Limitation (CDCL) items.

More information this subject can be found in Fokker Services All Operators Message AOF100.186#03.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA-2015-5810.

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, we issued a regulation titled "Transport Airplane Fuel Tank System Design Review, Flammability Reduction and Maintenance and Inspection Requirements" (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, this rule included Special Federal Aviation Regulation No. 88 ("SFAR 88," Amendment 21-78, and subsequent Amendments 21-82 and 21-83).

Among other actions, SFAR 88 requires certain type design (*i.e.*, type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the rule, we intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, we have established four criteria intended to define the unsafe conditions associated with fuel tank systems that

require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation: single failures, combination of failures, and unacceptable (failure) experience. For all three failure criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

The Joint Aviation Authorities (JAA) has issued a regulation that is similar to SFAR 88. (The JAA is an associated body of the European Civil Aviation Conference (ECAC) representing the civil aviation regulatory authorities of a number of European States who have agreed to co-operate in developing and implementing common safety regulatory standards and procedures.) Under this regulation, the JAA stated that all members of the ECAC that hold type certificates for transport category airplanes are required to conduct a design review against explosion risks.

We have determined that the actions identified in this AD are necessary to reduce the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

Related Service Information Under CFR Part 51

Fokker has issued Service Bulletin SBF100-28-078, dated January 23, 2014. The service information describes procedures for modifying the wiring of the maximum level sensors in the center wing fuel tank, after-installation tests, and corrective action if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 15 airplanes of U.S. registry.

We also estimate that it would take up to 9 work-hours per product to modify the wiring of the maximum level sensors in the center wing fuel tank, as specified in this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$1,700 per product. Based on these figures, we estimate the cost of this proposed modification on U.S. operators to be up to \$36,975, or up to \$2,465 per product.

We also estimate that it would take about 1 work-hour per product to revise the maintenance or inspection program as specified in this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed revision on U.S. operators to be \$1,275, or \$85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Fokker Services B.V.: Docket No. FAA-2015-5810; Directorate Identifier 2014-NM-116-AD.

(a) Comments Due Date

We must receive comments by January 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category, equipped with a center wing tank.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by a design review which revealed that a wiring failure, external to the center wing fuel tank, could cause a hot short circuit to a maximum level sensor wire, and result in excessive heating of the maximum level sensor element. We are issuing this AD to prevent the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Wiring Modification

Within 24 months after the effective date of this AD: Modify the wiring of the maximum level sensors of the center wing fuel tank, as specified in paragraph (g)(1) or (g)(2) of this AD, as applicable. Before further flight after accomplishing the modification,

do all applicable tests and corrective actions, in accordance with Part 5 of the Accomplishment Instructions of Fokker Service Bulletin SBF100-28-078, dated January 23, 2014.

(1) For post-SBF100-28-073 configuration airplanes: Do the modification in accordance with Part 1 or Part 3, as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF100-28-078, dated January 23, 2014.

(2) For pre-SBF100-28-073 configuration airplanes: Do the modification in accordance with Part 2 or Part 4, as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF100-28-078, dated January 23, 2014.

(h) Revise Maintenance or Inspection Program

Within 30 days after installing the modification specified in paragraph (g)(1) or (g)(2) of this AD, as applicable: Revise the airplane maintenance or inspection program, as applicable, to incorporate the fuel airworthiness limitation items and critical design configuration control limitations (CDCCLs) specified in paragraph 2.L.(1)(c) of Fokker Service Bulletin SBF100-28-078, dated January 23, 2014.

(i) No Alternative Actions, Intervals, and/or CDCCLs

After accomplishing the revision required by paragraph (h) of this AD, no alternative actions (e.g., inspections), intervals, or CDCCLs may be used unless the actions, intervals, or CDCCLs are approved as an alternative method of compliance in accordance with the procedures specified in paragraph (j)(1) of this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1137; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Fokker B.V. Service's EASA Design Organization Approval (DOA). If

approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0138, dated May 30, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA-2015-5810.

(2) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88-6280-350; fax +31 (0)88-6280-111; email technicalservices@fokker.com; Internet <http://www.myfokkerfleet.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-30007 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-5815; Directorate Identifier 2015-NM-039-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A330-200 and -300 series airplanes; and all Model A340-200, -300, -500, and -600 series airplanes. This proposed AD was prompted by reports that the potable water service panel access door was lost during flight. This proposed AD would require modifying affected potable water service panel access doors. We are proposing this AD to prevent failure of the latching mechanism of the potable water service panel access door, which could result in the loss of the potable water service panel access door during flight, and resultant damage to the airplane (e.g., damage to the trimmable horizontal stabilizer) that could cause loss of control of the airplane.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email airworthiness.A330-A340@airbus.com; Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5815; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1138; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the

ADDRESSES section. Include “Docket No. FAA–2015–5815; Directorate Identifier 2015–NM–039–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0028R1, dated May 29, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A330–200 and –300 series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. The MCAI states:

Several cases have been reported in which the potable water service panel access door was lost during flight, causing damage to the trimmable horizontal stabilizer. The results of subsequent investigations showed that these events were due to failure of the latching mechanism of the potable water service panel access door.

This condition, if not corrected, could lead to further cases of in-flight loss of the potable water service panel access door, possibly resulting in injury to persons on ground and/or damage to the aeroplane [(e.g., damage to the trimmable horizontal stabilizer)].

To address this condition, Airbus developed a modification and published Service Bulletin (SB) A330–52–3086, SB A340–52–4094 and SB A340–52–5019, to provide instructions for in-service accomplishment of that modification.

Consequently, EASA issued AD 2015–0028 to require modification of the potable water service panel access door 164AR for A330/A340–200/–300 aeroplanes or 154BR for A340–500/–600 aeroplanes, which includes installation of reinforced hinge screws and more robust latches.

Since that [EASA] AD was issued, it was determined that aeroplanes that have embodied Airbus Mod 201938 (Improvement of latching mechanism of potable water service panel) are also not affected by the requirements of this [EASA] AD.

For the reason described above, this [EASA] AD is revised to exclude post-mod 201938 aeroplanes from the Applicability.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for

and locating Docket No. FAA–2015–5815.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information.

- Airbus Service Bulletin A330–52–3086, Revision 01, dated April 25, 2014.
- Airbus Service Bulletin A340–52–4094, Revision 01, dated April 25, 2014.
- Airbus Service Bulletin A340–52–5019, Revision 01, dated April 25, 2014.

The service information describes procedures for modifying the affected potable water service panel access door. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Explanation of “RC” Procedures and Tests in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which procedures and tests in the service information are required for compliance with an AD. Differentiating these procedures and tests from other tasks in the service information is expected to improve an owner’s/operator’s understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The procedures and tests identified as RC (required for compliance) in any service information have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As specified in a NOTE under the Accomplishment Instructions of the specified service information, procedures and tests that are identified as RC in any service information must be done to comply with the proposed

AD. However, procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC will require approval of an AMOC.

Costs of Compliance

We estimate that this proposed AD affects 63 airplanes of U.S. registry.

We also estimate that it would take about 21 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$15,280 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$1,075,095, or \$17,065 per product.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a

substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2015–5815; Directorate Identifier 2015–NM–039–AD.

(a) Comments Due Date

We must receive comments by January 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Airbus Model A330–201, –202, –203, –223, –243, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes, all manufacturer serial numbers, except those on which Airbus modification 201715, or Airbus modification 201796, or Airbus modification 201938 has been embodied in production.

(2) Airbus Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes, all manufacturing serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by reports that the potable water service panel access door was lost during flight. We are issuing this AD to prevent failure of the latching mechanism of the potable water service panel access door, which could result in the loss of the potable water service panel access door during flight, and resultant damage to the airplane (e.g., damage to the trimmable horizontal stabilizer) that could cause loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Modification

(1) Except as required by paragraph (g)(2) of this AD, within 36 months after the effective date of this AD, modify the affected potable water service panel access door, in accordance with the Accomplishment Instructions of the service information identified in paragraph (g)(1)(i), (g)(1)(ii), or (g)(1)(iii) of this AD, as applicable to airplane type and model.

(i) Airbus Service Bulletin A330–52–3086, Revision 01, dated April 25, 2014.

(ii) Airbus Service Bulletin A340–52–4094, Revision 01, dated April 25, 2014.

(iii) Airbus Service Bulletin A340–52–5019, Revision 01, dated April 25, 2014.

(2) For airplanes that have already been modified before the effective date of this AD, as specified in the service information identified in paragraph (g)(2)(i), (g)(2)(ii), or (g)(2)(iii) of this AD, as applicable to airplane type and model: Within 16 months after the effective date of this AD, modify the potable water service panel access door by accomplishing the actions identified as “additional work,” as specified in and in accordance with the Accomplishment Instructions of the service information identified in paragraph (g)(1)(i), (g)(1)(ii), or (g)(1)(iii) of this AD, as applicable to airplane type and model.

(i) Airbus Service Bulletin A330–52–3086, dated April 27, 2012.

(ii) Airbus Service Bulletin A340–52–4094, dated April 27, 2012.

(iii) Airbus Service Bulletin A340–52–5019, dated May 29, 2012.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: 9–ANM–116–

AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0028R1, dated May 29, 2015, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–5815.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email airworthiness.A330-A340@airbus.com; Internet <http://www.airbus.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–30024 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2015-5814; Directorate Identifier 2014-NM-247-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A318, A319, and A320 series airplanes. This proposed AD was prompted by reports of an operator finding chafing damage on the fuselage skin at the bottom of certain frames, underneath the fairing structure. This proposed AD would require a repetitive detailed inspection for damage on the fuselage skin at certain frames, and applicable related investigative and corrective actions. We are proposing this AD to detect and correct damage to the fuselage skin, which could lead to crack initiation and propagation, possibly resulting in reduced structural integrity of the fuselage.

DATES: We must receive comments on this proposed AD by January 11, 2016.**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue

SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5814; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2015-5814; Directorate Identifier 2014-NM-247-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2014-0259, dated December 5, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A318, A319, and A320 series airplanes. The MCAI states:

An operator reported finding chafing damage on the fuselage skin at the bottom of frame (FR) 34 junction between stringer

(STR) 43 left hand (LH) side and right hand (RH) side on several aeroplanes, underneath the fairing structure.

After investigation, a contact between the fairing nut plate and the fuselage was identified, causing damage to the fuselage.

This condition, if not detected and corrected, could lead to crack initiation and propagation, possibly resulting in reduced structural integrity of the fuselage.

For the reason described above, this [EASA] AD requires repetitive detailed inspections (DET) of the fuselage [for chafing] at FR 34 and provides an optional terminating action [modification of the belly fairing] to the repetitive inspections required by this [EASA] AD.

Related investigative actions include a special detailed inspection of external fuselage skin panel for any cracking, and measurement of crack length and remaining thickness. Corrective actions include repair or modification of the fuselage skin panel. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5814.

Related Service Information Under 14 CFR Part 51

Airbus has issued Service Bulletin A320-53-1281, Revision 01, dated December 1, 2014; and Service Bulletin A320-53-1287, dated July 29, 2014. The service information describes procedures for a detailed inspection for damage (including chafing marks) on the fuselage skin at FR34 between STR43 LH and RH sides, and applicable related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Explanation of “RC” Procedures and Tests in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation

Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which procedures and tests in the service information are required for compliance with an AD. Differentiating these procedures and tests from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The procedures and tests identified as Required for Compliance (RC) in any service information have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As specified in a Note under the Accomplishment Instructions of the specified service information, procedures and tests that are identified as RC in any service information must be done to comply with the proposed AD. However, procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC will require approval of an AMOC.

Costs of Compliance

We estimate that this proposed AD affects 642 airplanes of U.S. registry.

We also estimate that it would take about 12 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$90 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$712,620, or \$1,110 per product.

In addition, we estimate that any necessary follow-on actions would take about 21 work-hours and require parts costing \$3,550, for a cost of \$5,335 per product. We have no way of determining the number of aircraft that might need this action.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more

detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA-2015-5814; Directorate Identifier 2014-NM-247-AD.

(a) Comments Due Date

We must receive comments by January 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category, all manufacturer serial numbers, except those on which Airbus Modification 37878 has been embodied in production, or Airbus Service Bulletin A320-53-1281 has been done in service.

(1) Airbus Model A318-111, -112, -121, and -122 airplanes.

(2) Airbus Model A319-111, -112, -113, -114, -115, -131, -132, and -133 airplanes.

(3) Airbus Model A320-211, -212, -214, -231, -232, and -233 airplanes

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by reports of chafing damage on the fuselage skin at the bottom of certain frames, underneath the fairing structure. We are issuing this AD to detect and correct damage to the fuselage skin, which could lead to crack initiation and propagation, possibly resulting in reduced structural integrity of the fuselage.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspection and Corrective Action

(1) Within the compliance times identified in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD, whichever occurs later, do a detailed inspection for damage (including chafing marks) on the fuselage skin at frame (FR)34 between stringer (STR)43 on the left-hand and right-hand sides, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1287, dated July 29, 2014. Repeat the inspection thereafter at intervals not to exceed 12,000 flight cycles or 24,000 flight hours, whichever occurs first.

(i) Before exceeding 12,000 flight cycles or 24,000 flight hours, whichever occurs first since the airplane's first flight.

(ii) Within 5,000 flight cycles or 10,000 flight hours, whichever occurs first after the effective date of this AD.

(2) If any damage is detected during any inspection required by paragraph (g)(1) of this AD, before further flight, do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1287, dated July 29, 2014, except as required by paragraph (g)(3) of this AD.

(3) If any cracking is found during any related investigative action required by paragraph (g)(2) of this AD, or if any damage detected during the inspection required by paragraph (g)(1) of this AD exceeds the limits defined in the Accomplishment Instructions

of Airbus Service Bulletin A320-53-1287, dated July 29, 2014, before further flight, repair using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(h) Non-Terminating Repair Action

Accomplishment of a repair on an airplane as required by paragraphs (g)(2) and (g)(3) of this AD, does not constitute terminating action for the repetitive detailed inspection required by paragraph (g)(1) of this AD, unless the approved repair indicates otherwise.

(i) Terminating Action for the Repetitive Detailed Inspection

Modification of the belly fairing on any airplane in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1281, Revision 01, dated December 1, 2014, constitutes terminating action for the repetitive detailed inspection required by paragraph (g)(1) of this AD for that airplane.

(j) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320-53-1281, dated July 29, 2014, which is not incorporated by reference in this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply

with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0259, dated December 5, 2014, for related information.

This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5814.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-30023 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-5812; Directorate Identifier 2015-NM-077-AD]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2011-23-05, which applies to certain The Boeing Company Model 737-300, -400, and -500 series airplanes. AD 2011-23-05 currently requires repetitive inspections for cracking of the 1.04-inch nominal diameter wire penetration hole, and applicable related investigative and corrective actions. Since we issued AD 2011-23-05, an evaluation by the design approval holder (DAH) indicates

that the fuselage frames and frame reinforcements are subject to widespread fatigue damage (WFD). This proposed AD would add new inspection areas, a modification that terminates certain inspections, post-modification inspections, and repair if necessary. We are proposing this AD to detect and correct fatigue cracking of the fuselage frames and frame reinforcements, which could result in reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal*: Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax*: 202-493-2251.

- *Mail*: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery*: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5812.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5812; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Wayne Lockett, Aerospace Engineer,

Airframe Branch, ANM-120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, Washington 98057-3356; phone: 425-917-6447; fax: 425-917-6590; email: wayne.lockett@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2015-5812; Directorate Identifier 2015-NM-077-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Structural fatigue damage is progressive. It begins as minute cracks, and those cracks grow under the action of repeated stresses. This can happen because of normal operational conditions and design attributes, or because of isolated situations or incidents such as material defects, poor fabrication quality, or corrosion pits, dings, or scratches. Fatigue damage can occur locally, in small areas or structural design details, or globally. Global fatigue damage is general degradation of large areas of structure with similar structural details and stress levels. Multiple-site damage is global damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Global damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site-damage and multiple-element-damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane, in a condition known as WFD. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became

effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

On October 20, 2011, we issued AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), for certain Model 737-300, -400, and -500 series airplanes. AD 2011-23-05 superseded AD 2009-02-06 R1, Amendment 39-16015 (74 FR 45979, September 8, 2009). AD 2011-23-05 requires repetitive inspections for cracking of the 1.04-inch nominal diameter wire penetration hole, and applicable related investigative and corrective actions. AD 2011-23-05 resulted from reports of cracking in the frame, or in the frame and frame reinforcement, common to the 1.04-inch nominal diameter wire penetration hole intended for wire routing; and recent reports of multiple adjacent frame cracking found before the compliance time required by AD 2009-02-06 R1. We issued AD 2011-23-05 to detect and correct cracking in the fuselage frames and frame reinforcements, which could reduce the structural capability of the frames to sustain limit loads, and result in cracking in the fuselage skin and

subsequent rapid depressurization of the airplane.

Actions Since AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), Was Issued

Since we issued AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), an evaluation by the DAH indicates that the fuselage frames and frame reinforcements are subject to WFD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737-53A1279, Revision 2, dated April 21, 2015. The service information describes procedures for the following actions.

- Inspections of wire penetration holes, standoff/tooling holes, and the production fastener holes for cracking in the forward cargo compartment frames and frame reinforcements, between stringer (S) S-19 and S-22, on both left and right sides of the airplane.
- A preventive modification of frames between S-19 and S-22.
- Post-modification inspections.
- Repairs.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011). This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Differences Between this Proposed AD and the Service Information." For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5812.

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin 737-53A1279, Revision 2, dated April 21, 2015, specifies to contact the manufacturer for instructions on how to

repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom

we have authorized to make those findings.

Explanation of Compliance Time

The compliance time for the modification specified in this proposed AD for addressing WFD was established to ensure that discrepant structure is modified before WFD develops in airplanes. Standard inspection techniques cannot be relied on to detect WFD before it becomes a hazard to

flight. We will not grant any extensions of the compliance time to complete any AD-mandated service bulletin related to WFD without extensive new data that would substantiate and clearly warrant such an extension.

Costs of Compliance

We estimate that this proposed AD affects 605 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections [retained actions from AD 2011–23–05, Amendment 39–16856 (76 FR 67343, November 1, 2011).	16 work-hours × \$85 per hour = \$1,360 per inspection cycle.	\$0	\$1,360 per inspection cycle.	\$822,800 per inspection cycle.
Inspections [new proposed action]	32 work-hours × \$85 per hour = \$2,720 per inspection cycle.	0	\$2,720 per inspection cycle.	\$1,645,600 per inspection cycle.
Modification [new proposed action]	32 work-hours × \$85 per hour = \$2,720.	0	\$2,720	\$1,645,600.

We estimate the following costs to do any necessary repairs that would be

required based on the results of the proposed inspection. We have no way of

determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair	18 work-hours × \$85 per hour = \$1,530	None	\$1,530

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the

States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2011–23–05, Amendment 39–16856 (76 FR 67343, November 1, 2011), and adding the following new AD:

The Boeing Company: Docket No. FAA–2015–5812; Directorate Identifier 2015–NM–077–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by January 11, 2016.

(b) Affected ADs

This AD replaces AD 2011–23–05, Amendment 39–16856 (76 FR 67343, November 1, 2011).

(c) Applicability

This AD applies to The Boeing Company Model 737–300, –400, and –500 series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicates that the fuselage frames and frame reinforcements are subject to widespread fatigue damage (WFD). We are issuing this AD to detect and correct fatigue cracking of the fuselage frames and frame reinforcements, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspection, With References To Terminating Actions

This paragraph restates the requirements of paragraph (g) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with references to terminating actions. At the applicable time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, except as required by paragraphs (k)(1), (k)(2), and (k)(4) of this AD: Do a high frequency eddy current (HFEC) surface or HFEC hole/edge inspection for any cracking of the 1.04-inch nominal diameter wire penetration hole in the frame and frame reinforcement between stringer (S) S-20 and S-21, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011. Accomplishment of the applicable inspections required by paragraphs (m) and (n) of this AD terminates the inspections required by this paragraph. Accomplishment of the modification required by paragraph (p) of this AD terminates the inspections required by this paragraph for the modified area only.

(h) Retained Repetitive Inspections, With References To Terminating Actions

This paragraph restates the requirements of paragraph (h) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with references to terminating actions. Within 4,500 flight cycles after accomplishment of the most recent inspection specified in Part 2 or Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, or within 90 days after November 16, 2011 (the effective date of AD 2011-23-05), whichever occurs later: Do an HFEC hole/edge inspection for cracking of the 1.04-inch nominal diameter wire penetration hole in the frame and frame reinforcement between S-20 and S-21, in accordance with Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011. Repeat the inspection thereafter at intervals not to exceed 4,500 flight cycles. Accomplishment of the applicable inspections required by paragraphs (m) and (n) of this AD, terminates the inspections required by this paragraph.

Accomplishment of the modification specified in paragraph (j) or (p) of this AD terminates the repetitive inspections required by this paragraph for the modified area only. Accomplishment of the repair specified in paragraph (i) of this AD terminates the repetitive inspections required by this paragraph for the repaired area only.

(i) Retained Repair, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with no changes. If any cracking is found during any inspection required by paragraph (g) or (h) of this AD: Before further flight, repair the crack including doing all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, except as required by paragraph (k)(3) of this AD. All applicable related investigative and corrective actions must be done before further flight. Accomplishment of the requirements of this paragraph terminates the repetitive inspection requirements of paragraph (h) of this AD for the repaired location of that frame.

(j) Retained Optional Terminating Action, With New Limitation

This paragraph restates the optional action provided in paragraph (j) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with new limitation. Accomplishment of the preventive modification before the effective date of this AD, including doing all related investigative and applicable corrective actions, specified in Part 5 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, except as required by paragraph (k)(3) of this AD, terminates the repetitive inspection requirements of paragraph (h) of this AD for the modified location of that frame, provided the modification is done before further flight after an inspection required by paragraph (g) or (h) of this AD has been done, and no cracking was found on that frame location during that inspection.

(k) Retained Exceptions to Service Information Specifications, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with no changes. The following exceptions apply as specified in paragraphs (g), (i), and (j) of this AD.

(1) Where paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, refers to a compliance time "from date on Revision 1 of this service bulletin," this AD requires compliance within the specified compliance time after November 16, 2011 (the effective date of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011)).

(2) For airplanes meeting all of the criteria specified in paragraphs (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of this AD: The compliance time for the initial inspection specified in Part 2 of the Accomplishment Instructions of

Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, and required by paragraph (g) of this AD, may be extended to 90 days after November 16, 2011 (the effective date of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011)).

(i) Model 737-300 series airplanes in Group 1, line numbers 1001 through 2565 inclusive;

(ii) Airplanes that have accumulated 40,000 or more total flight cycles as of November 16, 2011 (the effective date of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011)); and

(iii) Airplanes on which the modification specified in Boeing Service Bulletin 737-53-1273, dated September 20, 2006; Revision 1, dated December 21, 2006; Revision 2, dated June 4, 2007; Revision 3, dated December 7, 2009; or Revision 4, dated July 23, 2010; has been done, including any configuration or deviation that has been approved as an AMOC during accomplishment of these service bulletins, by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle Aircraft Certification Office (ACO) to make those findings.

(3) Where Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, specifies to contact Boeing for appropriate repair instructions: Before further flight, repair the crack using a method approved in accordance with the procedures specified in paragraph (u) of this AD.

(4) The "Condition" column of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, refers to total flight cycles "at the date of/on this service bulletin." However, this AD applies to the airplanes with the specified total flight cycles as of November 16, 2011 (the effective date of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011)).

(l) Retained Credit for Previous Actions, With No Changes

This paragraph restates the requirements of paragraph (l) of AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011), with no changes. Actions done in accordance with Boeing Alert Service Bulletin 737-53A1279, dated December 18, 2007, before November 16, 2011 (the effective date of AD 2011-23-05), are acceptable for compliance with the corresponding actions required by paragraphs (g), (h), (i), and (j) of this AD.

(m) New Requirement of This AD: Inspections of Frames and Frame Reinforcements Between S-19 and S-22 for Certain Airplanes on Which Certain Inspections Have Not Been Accomplished

For airplanes identified as Groups 1 through 6, Configuration 3, in Boeing Alert Service Bulletin 737-53A1279, Revision 2, dated April 21, 2015, with 30,000 total flight cycles or fewer as of the effective date of this AD, on which any inspections specified in Boeing Alert Service Bulletin 737-53A1279, Revision 1, dated September 2, 2011, have not been accomplished: Except as required by paragraphs (t)(1) and (t)(2) of this AD, at

the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later, do inspections for cracking at certain locations in the frames and frame reinforcements in accordance with “Part 2—Initial Detail and HFEC Inspection” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Repeat the inspections for cracking at certain locations in the frames and frame reinforcements as specified in “Part 4—Repeat Detail and HFEC Inspections” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, thereafter at the applicable interval specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015; or, before further flight after accomplishing an inspection and no cracking was found, do “Part 5—Preventative Modification” as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Accomplishment of the preventive modification specified in this paragraph terminates the repetitive inspections required by this paragraph for the modified area only. Do all actions specified in this paragraph in accordance with Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015.

(n) New Requirement of This AD: Inspections of Frames and Frame Reinforcements Between S–19 and S–22 for Groups 1–6, Configuration 3, Airplanes

For airplanes identified as Groups 1 through 6, Configuration 3, in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, with more than 30,000 total flight cycles as of the effective date of this AD, or that have been inspected as specified in Boeing Alert Service Bulletin 737–53A1279, Revision 1, dated September 2, 2011: Except as required by paragraphs (t)(1) and (t)(2) of this AD, at the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, do inspections for cracking at certain locations of the frames and frame reinforcements in accordance with “Part 4—Repeat Detail and HFEC Inspections” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Repeat the inspections thereafter at the applicable interval specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015; or, before further flight after accomplishing an inspection and no cracking was found, do “Part 5—Preventative Modification” as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Accomplishment of the preventive modification specified in this paragraph terminates the repetitive inspections required by this paragraph for the modified area only.

(o) New Requirement of This AD: Repairs

If any crack is found during any inspection required by paragraph (m) or (n) of this AD: Before further flight, repair, in accordance with “Part 3—Repair” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, except where Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, specifies to contact Boeing for damage removal and repair instructions, repair before further flight using a method approved in accordance with the procedures specified in paragraph (u) of this AD. Accomplishing a repair terminates the inspections required by paragraphs (m) and (n) of this AD in the repaired area only. Accomplishment of a repair terminates the modification required by paragraph (p) of this AD at the repaired location only.

(p) New Requirement of This AD: Preventative Modification of the Frames Between S–19 and S–22

For airplanes identified as Groups 1 through 6, Configuration 3, in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015: Except as required by paragraphs (t)(1) and (t)(2) of this AD, at the applicable time specified in table 2 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, do the preventive modification of the frames between S–19 and S–22, in accordance with “Part 5—Preventative Modification” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Accomplishment of the modification required by this paragraph terminates the requirements of paragraphs (g), (h), (m), and (n) of this AD for the modified location only.

(q) New Requirement of This AD: Inspections of Preventative Modification for Groups 1–3, Configuration 1, Airplanes

For airplanes identified as Groups 1 through 3, Configuration 1, in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015: Except as required by paragraph (t)(1) of this AD, at the applicable time specified in table 3 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, do HFEC, LFEC, and detailed inspections for cracking in accordance with “Part 7—INSPECTION OF PREVENTATIVE MODIFICATION” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Repeat the inspections thereafter at the applicable interval specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. If any cracking is found during any inspection required by this paragraph, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (u) of this AD.

(r) New Requirement of This AD: Inspections of Preventive Modification for Groups 1–6, Configuration 2

For airplanes identified as Groups 1 through 6, Configuration 2, in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015: Except as required by paragraph (t)(1) of this AD, at the applicable time specified in table 4 or table 6 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, do HFEC, LFEC, and detailed inspections for cracking in accordance with “Part 8—INSPECTION OF PREVENTATIVE MODIFICATION” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Repeat the inspections thereafter at the applicable interval specified in table 4 or table 6 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. If any cracking is found during any inspection required by this paragraph, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (u) of this AD.

(s) New Requirement of This AD: Inspections of Preventive Modification for Group 4–6, Configuration 1, Airplanes

For airplanes identified as Group 4 through 6, Configuration 1, in Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015: At the applicable time specified in table 5 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, except as required by paragraph (t)(1) of this AD: Do HFEC, LFEC and detailed inspections for cracking in accordance with “Part 7—INSPECTION OF PREVENTATIVE MODIFICATION” of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. Repeat the inspections thereafter at the applicable time specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015. If any cracking is found during any inspection required by this paragraph, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (u) of this AD.

(t) New Requirement of This AD: Exceptions to Service Bulletin Specifications

(1) Where paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, refers to a compliance time “after the Revision 2 date of this service bulletin,” this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) The “Condition” column in table 1 and table 2 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1279, Revision 2, dated April 21, 2015, refers to total flight cycles “at the Revision 2 date of this service bulletin.” However, this AD applies to the airplanes with the specified total flight cycles as of the effective date of this AD.

(u) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (v)(1) of this AD. Information may be emailed to: 9-ANM-LAACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2009-02-06, Amendment 39-15796 (74 FR 10469, March 11, 2009); AD 2009-02-06 R1, Amendment 39-16015 (74 FR 45979, September 6, 2009); and AD 2011-23-05, Amendment 39-16856 (76 FR 67343, November 1, 2011); are approved as AMOCs for the corresponding provisions of this AD.

(v) Related Information

(1) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM-120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, Washington 98057-3356; phone: 425-917-6447; fax: 425-917-6590; email: wayne.lockett@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-30008 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2015-5816; Directorate Identifier 2015-NM-029-AD]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2006-10-16, which applies to all The Boeing Company Model 747-100, 747-100B, 747-100B SUD, 747-200B, 747-200C, 747-200F, 747-300, 747-400, 747-400D, 747-400F, 747SR, and 747SP series airplanes. AD 2006-10-16 requires, for certain airplanes, repetitive inspections for cracking of the outboard and center sections of the horizontal stabilizer, and repair if necessary. For certain other airplanes, AD 2006-10-16 requires a detailed inspection to determine the type of fasteners, and related investigative actions and repair if necessary. Since we issued AD 2006-10-16, additional cracking was found in the splice plates, hinge fittings, terminal fittings, the upper skin of the outboard and center sections, and the rear spar webs before reaching the inspection interval specified in AD 2006-10-16. Cracked and fractured Maraging steel fasteners were also found. This proposed AD would reduce the compliance time for certain inspections and would add repetitive inspections for cracking of the splice plates, hinge fittings, terminal fittings, the upper skin of the outboard and center sections, and the rear spar webs in Zone B. This proposed AD would also add an inspection to determine whether fasteners are magnetic in Zone C, repetitive ultrasonic inspections for cracking and fractures of affected fasteners, and related investigative and corrective actions if necessary. This proposed AD would also add an optional modification, which would terminate certain repetitive inspections, and would add post-modification inspections and corrective action if necessary. We are proposing this AD to detect and correct this cracking, which could lead to reduced structural capability of the outboard and center sections of the horizontal stabilizer and could result in loss of control of the airplane.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone: 206-544-5000, extension 1; fax: 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5816.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5816; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6428; fax: 425-917-6590; email: nathan.p.weigand@faa.gov.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to send any written relevant data, views, or arguments about

this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2015–5816; Directorate Identifier 2015–NM–029–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On May 8, 2006, we issued AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), for all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. AD 2006–10–16 requires, for certain airplanes, repetitive inspections for cracking of the outboard and center sections of the horizontal stabilizer, and repair if necessary. For certain other airplanes, AD 2006–10–16 requires a detailed inspection to determine the type of fasteners, related investigative actions, and repair if necessary. AD 2006–10–16 resulted from reports of cracking in the outboard and center section of the aft upper skin of the horizontal stabilizer, the rear spar chord, rear spar web, terminal fittings, and splice plates; and a report of fractured and cracked steel fasteners. We issued AD 2006–10–16 to detect and correct this cracking, which could lead to reduced structural capability of the outboard and center sections of the horizontal stabilizer and could result in loss of control of the airplane.

Actions Since AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), Was Issued

Since we issued AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), additional cracking was found in the splice plates, hinge fittings, terminal fittings, the upper skin of the outboard and center sections, and the rear spar webs before reaching the inspection interval specified in AD 2006–10–16. Cracked and fractured

Maraging steel fasteners were also found.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Service Bulletin 747–55A2050, Revision 2, dated January 23, 2015. The service information describes procedures for accomplishing Zone A, Zone B, and Zone C inspections for cracking of the upper skin and upper rear spar chord of the outboard and center sections of the horizontal stabilizer, and related investigative and corrective actions if necessary. The service information also describes procedures for a magnetic inspection to determine the type of fasteners, ultrasonic inspections for cracking and fractures of affected fasteners, and related investigative actions and corrective actions if necessary. The service information also describes procedures for an optional modification, which would end certain repetitive inspections, and procedures for post-modification inspections and corrective action if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA’s Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), this proposed AD would retain all of the requirements. Those requirements are referenced in the service information identified previously, which, in turn, is referenced in paragraph (g) of this proposed AD. This proposed AD would reduce the compliance time for certain inspections and add new repetitive inspections for cracking of the splice plates, hinge fittings, terminal fittings, the upper skin of the outboard and center sections, and the rear spar webs in Zone B. This proposed AD would also add an inspection to determine whether fasteners are magnetic in Zone C (made of H–11 steel), repetitive ultrasonic inspections for cracking and fractures of affected fasteners, and related

investigative and corrective actions if necessary. This proposed AD would also add an optional modification, which would end certain repetitive inspections, and procedures for post-modification inspections and corrective action if necessary. This proposed AD also adds optional open-hole NDT inspections (high frequency eddy current inspections) for certain airplanes, for Zone B inspections. This proposed AD would also require accomplishing the actions specified in the service information described previously, except as discussed under “Difference Between this Proposed AD and the Service Bulletin.” For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–5816.

The phrase “related investigative actions” is used in this proposed AD. “Related investigative actions” are follow-on actions that (1) are related to the primary action, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

The phrase “corrective actions” is used in this proposed AD. “Corrective actions” are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Difference Between This Proposed AD and the Service Bulletin

Although Boeing Service Bulletin 747–55A2050, Revision 2, dated January 23, 2015, specifies that operators may contact the manufacturer for disposition of certain repair conditions, this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 116 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS—REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Zone A Inspections (required by AD 2006–10–16, Amendment 39–14600).	8 work-hours × \$85 per hour = \$680.	\$0	\$680	Up to \$78,880.
Zone B Open-hole NDT Inspection (required by AD 2006–10–16, Amendment 39–14600 for Groups 3, 4, and 5 airplanes; and for Groups 1, 2, and 3 airplanes, if done).	30 work-hours × 85 per hour = 2,550.	0	2,550	Up to \$295,800.
Zone C Maraging or H–11 Steel Fastener Inspection (required by AD 2006–10–16, Amendment 39–14600 for Groups 1, 2, and 3 airplanes).	8 work-hours × 85 per hour = 680.	0	680	Up to \$78,880.
New Zone B proposed inspections	248 work-hours × 85 per hour = 21,080.	0	21,080	\$2,445,280.
New Zone C proposed inspection	26 work-hours × 85 per hour = 2,210.	0	2,210	\$256,360.

ESTIMATED COSTS—OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Open-hole NDT inspections (high frequency eddy current inspections).	Up to 298 work-hours × \$85 per hour = up to \$25,330.	\$0	Up to \$25,330.
Zone B Modification	Up to 313 work-hours × \$85 per hour = up to \$26,605.	Up to \$3,486	Up to \$30,091.
Post-Modification Inspections	Up to 298 work-hours × \$85 per hour = up to \$25,330.	\$0	Up to \$25,330.

We have received no definitive data that would enable us to provide a cost estimate for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the

national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), and adding the following new AD:

The Boeing Company: Docket No. FAA–2015–5816; Directorate Identifier 2015–NM–029–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by January 11, 2016.

(b) Affected ADs

This AD replaces AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006).

(c) Applicability

This AD applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes; certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by reports of cracking found in the splice plates, hinge fittings, terminal fittings, the upper skin of the outboard and center sections, and the rear spar webs before reaching the inspection interval specified in AD 2006–10–16. Cracked and fractured Maraging steel fasteners were also found. We are issuing this AD to detect and correct this cracking, which

could lead to reduced structural capability of the outboard and center sections of the horizontal stabilizer and could result in loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections/Investigative and Corrective Actions

At the applicable time specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, except as required by paragraphs (h)(1) and (h)(2) of this AD: Do the applicable actions specified in paragraphs (g)(1), (g)(2), (g)(3), and (g)(4) of this AD, and all applicable related investigative and corrective actions, in accordance with the applicable part of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, except as required by paragraph (h)(3) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the applicable inspections specified in paragraphs (g)(1), (g)(2), (g)(3), and (g)(4) of this AD at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(1) For Group 1 through 3 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Do non-destructive test (NDT) inspections (ultrasonic, high frequency eddy current, and low frequency eddy current inspections) or open-hole NDT inspections (high frequency eddy current inspections), of Zone B for cracking in accordance with Part 3 or Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, as applicable.

(2) For Group 4 through 6 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Do open-hole NDT inspections (high frequency eddy current inspections), of Zone B for cracking in accordance with Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(3) For Group 7 through 9 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Do inspections of Zone A (detailed or high frequency eddy current inspections) and Zone B (high frequency eddy current inspections) for cracking, in accordance with Part 1, Part 2, or Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, as applicable.

(4) For Group 1 through 3 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Do an inspection of Zone C Maraging or H-11 steel fasteners to determine whether fasteners are magnetic, in accordance with Part 6 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(h) Exceptions to Service Bulletin Specifications

(1) Where Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, specifies a compliance time "after the Revision 2 date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) The Condition column of Table 1 of paragraph 1.E., "Compliance," of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, refers to "airplanes with certain total flight cycles and total flight hours." This AD, however, applies to the airplanes with the specified total flight cycles and total flight hours as of the effective date of this AD.

(3) Where Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, specifies to contact Boeing for repair instructions: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(i) Optional Terminating Action

(1) For Group 1 through 3 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Accomplishing the Zone B modification, including all applicable related investigative and corrective actions, specified in Part 7 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, except as required by paragraph (h)(3) of this AD, terminates the repetitive inspections specified in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD for the modified area only.

(i) Inspections required by paragraph (g)(1) of this AD for Zone B, as specified in Part 3 and Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(ii) Inspections required by paragraph (g)(4) of this AD for Zone C, as specified in Part 5 and Part 6 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(2) For Group 1 through 3 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Accomplishing the Zone B open hole NDT inspection, repairing any cracking as applicable, and replacing fasteners as specified in Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, terminates the repetitive ultrasonic inspections required by paragraph (g)(4) of this AD for Zone C, as specified in Part 6 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, for the inspected area only.

(3) For Group 4 through 9 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Accomplishing the Zone B modification, including all applicable related investigative and corrective actions, specified in Part 7 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, except as required by paragraph (h)(3) of this AD, terminates the

repetitive inspections required by paragraph (g)(2) or (g)(3) of this AD, as applicable, only for Zone B, as specified in Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, for the modified area only.

(j) Repetitive Post-Modification Inspections and Corrective Actions

At the applicable time specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015: Do the applicable inspections specified in paragraphs (j)(1) and (j)(2) of this AD and all applicable corrective actions, in accordance with Part 8 of the Accomplishment Instructions of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, except as required by paragraph (h)(3) of this AD. Do all applicable corrective actions before further flight. Repeat the applicable inspections at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015.

(1) For Group 1 through 3 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015 on which the Zone B modification specified in paragraph (i)(1) of this AD is done: Do non-destructive test (NDT) inspections (ultrasonic, high frequency eddy current, and low frequency eddy current inspections) or open-hole NDT inspections (high frequency eddy current inspections) of Zone B for cracking.

(2) For Group 4 through 9 airplanes identified in Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015 on which the Zone B modification specified in paragraph (i)(3) of this AD is done: Do open-hole NDT inspections (high frequency eddy current inspections) of Zone B for cracking.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install any Maraging or H-11 steel fasteners in the locations specified in this AD. Where Boeing Service Bulletin 747-55A2050, Revision 2, dated January 23, 2015, specifies to install H-11 bolts (kept fasteners), this AD requires installation of Inconel bolts.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2006–10–16, Amendment 39–14600 (71 FR 28570, May 17, 2006), are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD, except for approved AMOCs that allow installation of Maraging or H–11 steel fasteners.

(m) Related Information

(1) For more information about this AD, contact Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6428; fax: 425–917–6590; email: nathan.p.weigand@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 19, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–30120 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–5813; Directorate Identifier 2014–NM–111–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Dassault Aviation Model FALCON 7X airplanes. This proposed AD was prompted by a fuel leak that occurred in the baggage compartment during fuel system pressurization. This proposed AD would require opening the fuel

boxes and restoring the sealing. We are proposing this AD to detect and correct failure of a connector or coupling on a fuel line, which, in combination with a leak in the corresponding enclosure (*i.e.*, fuel box), could result in a fire in the baggage compartment and affect the safe flight of the airplane.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: 202–493–2251.
- Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet <http://www.dassaultfalcon.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–5813; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2015–5813; Directorate Identifier 2014–NM–111–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0116, dated May 13, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Dassault Aviation Model FALCON 7X airplanes. The MCAI states:

During the fuel system pressurization of a production line Falcon 7X aeroplane, a fuel leak occurred in the baggage compartment. The technical investigations concluded that a double failure of a connector (or coupling) on a fuel line, in combination with a defective fuel tightness of the corresponding enclosure (fuel box), caused the leak.

Failure of the second barrier (fuel box) is a dormant failure, as this will only manifest itself in case of connector (or fuel pipe coupling) failure in flight.

This condition, if not corrected, could result in a fire in the baggage compartment, which would affect the aeroplane safe flight.

To address this potential unsafe condition, Dassault Aviation issued Service Bulletin (SB) F7X–284, which provides instructions to restore the sealing of the Left Hand (LH) and Right Hand (RH) fuel boxes.

For the reasons described above, this [EASA] AD requires opening of the fuel boxes and restoration of the sealing of the fuel boxes to meet the initial design specifications.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–5813.

Related Service Information Under 14 CFR Part 51

Dassault Aviation has issued Service Bulletin 7X–284, Revision 1, dated

April 8, 2014. The service information describes procedures for opening the fuel boxes and restoring the sealing. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 39 airplanes of U.S. registry.

We also estimate that it would take about 16 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts are negligible. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$53,040, or \$1,360 per product.

According to the manufacturer, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition

that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Dassault Aviation: Docket No. FAA-2015-5813; Directorate Identifier 2014-NM-111-AD.

(a) Comments Due Date

We must receive comments by January 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, serial numbers (S/Ns) 1 through 140 inclusive, S/Ns 142 through 156 inclusive, S/Ns 158 through 176 inclusive, S/Ns 178 through 181 inclusive, and S/N 183, 184, 187, 188, 190, 194, and 200.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by a fuel leak that occurred in the baggage compartment during fuel system pressurization. We are issuing this AD to prevent failure of a connector or coupling on a fuel line, which, in combination with a leak in the corresponding enclosure (*i.e.*, fuel box), could result in a fire in the baggage compartment and affect the safe flight of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Open the Fuel Box and Restore the Sealing

Within 98 months after the effective date of this AD, open the left-hand and right-hand fuel boxes and restore the sealing, in accordance with the Accomplishment Instructions of Dassault Service Bulletin 7X-284, Revision 1, dated April 8, 2014.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone (425) 227-1137; fax (425) 227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0116, dated May 13, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by

searching for and locating Docket No. FAA–2015–5813.

(2) For service information identified in this AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet <http://www.dassaultfalcon.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–30022 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–5811; Directorate Identifier 2014–NM–158–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2004–19–11 for certain Airbus Model 320 series airplanes. AD 2004–19–11 currently requires modification of the inner rear spar web of the wing, cold expansion of the attachment holes of the forward pintle fitting and the actuating cylinder anchorage of the main landing gear (MLG), repetitive ultrasonic inspections for cracking of the rear spar of the wing, and corrective action if necessary. AD 2004–19–11 also provides optional terminating action for the repetitive inspections. Since we issued AD 2004–19–11, we have determined that the terminating action is necessary to address the unsafe condition. This proposed AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. This proposed AD would retain the requirements of AD 2004–19–11 and would require the previously optional terminating action. We are proposing this AD to prevent fatigue cracking of the inner rear spar, which may lead to reduced structural integrity of the wing and the MLG.

DATES: We must receive comments on this proposed AD by January 11, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–5811; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2015–5811; Directorate Identifier

2014–NM–158–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On September 21, 2004, we issued AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004). AD 2004–19–11 requires actions intended to address an unsafe condition on certain Airbus Model 320 series airplanes. AD 2004–19–11 superseded AD 2000–10–15, Amendment 39–17739 (65 FR 34069, May 26, 2000).

Since we issued AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004), we have determined that the modification of the inner rear spar that is an optional terminating action of AD 2004–19–11 must be accomplished in order to address the identified unsafe condition.

As described in FAA Advisory Circular 120–104 (http://www.faa.gov/documentLibrary/media/Advisory_Circular/120-104.pdf), several programs have been developed to support initiatives that will ensure the continued airworthiness of aging airplane structure. The last element of those initiatives is the requirement to establish a limit of validity (LOV) of the engineering data that support the structural maintenance program under 14 CFR 26.21. This proposed AD is the result of an assessment of the previously established programs by the design approval holder (DAH). The actions specified in this proposed AD are necessary to complete certain programs to ensure the continued airworthiness of aging airplane structure and to support an airplane reaching its LOV.

The European Aviation Safety Agency, which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0169, corrected July 22, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition on certain Airbus Model A320 series airplanes. The MCAI states:

During centre fuselage certification full scale fatigue test, cracks were found on the

inner rear spar at holes position 52 on the right hand wing due to fatigue aspects.

This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.

To prevent such cracks, Airbus developed modifications, which were introduced in production and in service through several Airbus Service Bulletins (SB). DGAC France issued * * * [an earlier AD], which was subsequently superseded by [DGAC] AD 2001-249 [which corresponds with FAA AD 2004-19-11, Amendment 39-13805 (69 FR 58828, October 1, 2004)], to require modification of the rear spar on some aeroplanes, post-modification repetitive inspections and, depending on findings, accomplishment of a repair. DGAC France AD 2001-249 also specified that modification in accordance with Airbus SB A320-57-1089 (in-service equivalent to Airbus mod 24591) constituted (optional) terminating action for the repetitive inspections.

Since that [DGAC] AD [2001-249] was issued, in the framework of the A320 Extended Service Goal (ESG), it has been determined that Airbus mod 24591 is necessary to allow aeroplanes to operate up to the new ESG limit.

For the reasons described above, this [EASA] AD retains the requirements of DGAC France AD 2001-249, which is superseded, and requires modification of all pre-mod 24591 aeroplanes.

The modification includes modifying all specified fastener holes in the inner rear spar of the wing. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5811.

Related Service Information Under 14 CFR part 51

Airbus has issued the following service information.

- Airbus Service Bulletin A320-57-1004, Revision 02, dated June 14, 1993. This service information describes procedures for modifying the inner rear spar web of the wing.
- Airbus Service Bulletin A320-57-1060, Revision 2, dated December 16, 1994. This service information describes procedures for a cold expansion of all the attachment holes for the forward pintle fitting of the main landing gear (MLG), except for the holes that are for taper-lok bolts; and for a cold expansion of the holes at the actuating cylinder anchorage of the MLG.
- Airbus Mandatory Service Bulletin A320-57-1088, Revision 04, dated August 6, 2001. This service information describes procedures for doing ultrasonic inspections for cracking of the rear spar of the wing.
- Airbus Service Bulletin A320-57-1089, Revision 03, dated February 9, 2001. This service information describes modification of the airplane by accomplishing cold reexpansion of the

holes in the inner rear spar for the attachment of gear rib 5, forward pintle fitting, and actuating cylinder anchorage; and the installation of interference fit fasteners in the rear spar and gear rib 5.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 84 airplanes of U.S. registry.

The actions required by AD 2004-19-11, Amendment 39-13805 (69 FR 58828, October 1, 2004), and retained in this proposed AD take about 684 work-hours per product, at an average labor rate of \$85 per work-hour. Required parts cost about \$13,644 per product. Based on these figures, the estimated cost of the actions that are required by AD 2004-19-11 is \$71,784 per product.

We also estimate that it would take about 980 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$32,727 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$9,746,268, or \$116,027 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII,

Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2004-19-11, Amendment 39-13805 (69 FR 58828, October 1, 2004), and adding the following new AD:

Airbus: Docket No. FAA-2015-5811; Directorate Identifier 2014-NM-158-AD.

(a) Comments Due Date

We must receive comments by January 11, 2016.

(b) Affected ADs

This AD replaces AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2014).

(c) Applicability

This AD applies to Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes, certificated in any category, all manufacturer serial numbers, except those on which Airbus modification (mod) 24591 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by reports of fatigue cracking of the inner rear spar of the wing and also by the determination that the modification of the inner rear spar is necessary to address the unsafe condition. We are issuing this AD to prevent fatigue cracking of the inner rear spar, which may lead to reduced structural integrity of the wing and the main landing gear (MLG).

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Modification of Inner Rear Spar Web of the Wing, With Change to Acceptable Service Information

This paragraph restates the requirements of paragraph (a) of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004), with a change to acceptable service information. For airplanes having manufacturer's serial numbers (MSNs) 003 through 008 inclusive, and 010 through 021 inclusive, except airplanes modified as specified in Airbus Service Bulletin A320–57–1089, dated December 22, 1996; Revision 01, dated April 17, 1997; Revision 02, dated November 6, 1998; or Revision 03, dated February 9, 2001: Prior to the accumulation of 12,000 total flight cycles, or within 500 flight cycles after June 11, 1993 (the effective date of AD 93–08–15, Amendment 39–8563 (58 FR 27923, May 12, 1993)), whichever occurs later, modify the inner rear spar web of the wing in accordance with Airbus Service Bulletin A320–57–1004, Revision 1, dated September 24, 1992; or Revision 2, dated June 14, 1993. As of the effective date of this AD, only Airbus Service Bulletin A320–57–1004, Revision 2, dated June 14, 1993, may be used for the actions required by this paragraph.

(h) Retained Cold Expansion of Holes at Forward Pintle Fitting and Actuating Cylinder Anchorage of the Main Landing Gear, With Change to Acceptable Service Information

This paragraph restates the requirements of paragraph (b) of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004), with a change to acceptable service information. For airplanes having MSNs 002 through 051 inclusive, except airplanes modified as specified in Airbus Service Bulletin A320–57–1089, dated December 22, 1996; Revision 01, dated April 17, 1997; Revision 02, dated November 6, 1998; or Revision 03, dated February 9, 2001: Prior to the accumulation of 12,000 total flight cycles, or within 2,000 flight cycles after February 14, 1994 (the effective date of AD 93–25–13, Amendment 39–8777 (59 FR 1903, January 13, 1994)), whichever occurs later, accomplish the requirements of paragraphs (h)(1) and (h)(2) of this AD in accordance with Airbus Service Bulletin A320–57–1060, dated December 8, 1992; Revision 1, dated April 26, 1993; or Revision 2, dated December 16, 1994. As of the effective date of this AD, only Airbus Service Bulletin A320–57–1060, Revision 2, dated December 16, 1994, may be used for the actions required by this paragraph.

(1) Perform a cold expansion of all the attachment holes for the forward pintle fitting of the main landing gear (MLG), except for the holes that are for taper-loc bolts.

(2) Perform a cold expansion of the holes at the actuating cylinder anchorage of the MLG.

(i) Retained Repetitive Ultrasonic Inspections for Cracking of the Rear Spar of the Wing, With No Changes

This paragraph restates the requirements of paragraphs (c), (d), and (e) of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004), with no changes. Except for airplanes modified as specified in Airbus Service Bulletin A320–57–1089, dated December 22, 1996; Revision 01, dated April 17, 1997; Revision 02, dated November 6, 1998; or Revision 03, dated February 9, 2001: Do the actions specified in paragraphs (i)(1) and (i)(2) of this AD.

(1) Do an ultrasonic inspection for cracking of the rear spar of the wing, in accordance with Airbus Service Bulletin A320–57–1088, Revision 04, dated August 6, 2001. Inspect at the applicable time specified in paragraph 1.E. of Airbus Service Bulletin A320–57–1088, Revision 04, dated August 6, 2001,

except as required by paragraphs (i)(1)(i) and (i)(1)(ii) of this AD.

(i) For any airplane that has not been inspected but has exceeded the applicable specified compliance time in paragraph 1.E. of Airbus Service Bulletin A320–57–1088, Revision 04, dated August 6, 2001, as of November 5, 2004 (the effective date of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004)): Inspect within 18 months after November 5, 2004.

(ii) For any airplane that has been inspected before November 5, 2004 (the effective date of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004)): Repeat the inspection within 3,600 flight cycles after the most recent inspection.

(2) Repeat the inspection required by paragraph (i)(1) of this AD at intervals not to exceed 3,600 flight cycles or 6,700 flight hours, whichever occurs first, until the requirements of paragraph (k) of this AD have been done.

(j) Retained Corrective Action for Inspections Required by Paragraphs (i)(1) and (i)(2) of This AD, With Specific Delegation Approval Language.

This paragraph restates the requirements of paragraph (f) of AD 2004–19–11, Amendment 39–13805 (69 FR 58828, October 1, 2004), with specific delegation approval language. If any crack is found during any inspection required by paragraph (i)(1) or (i)(2) of this AD: Before further flight, repair in accordance with a method approved by either the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Direction Générale de l'Aviation Civile (or its delegated agent); or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). Accomplishment of a repair as required by this paragraph does not constitute terminating action for the repetitive inspections required by paragraph (i)(2) of this AD.

(k) New Requirement of This AD: Modification of Inner Rear Spar

Before exceeding 48,000 flight cycles or 96,000 flight hours, whichever occurs first since first flight of the airplane: modify all specified fastener holes in the inner rear spar of the wing, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1089, Revision 03, dated February 9, 2001; except where Airbus Service Bulletin A320–57–1089, Revision 03, dated February 9, 2001, specifies to contact Airbus for certain conditions, before further flight, repair using a method approved by the

Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA. Modification of all specified fastener holes in the rear spar of the wing terminates the initial and repetitive inspections required by paragraphs (i)(1) and (i)(2) of this AD. If the modification is done both before the airplane accumulates 12,000 total flight cycles and before the effective date of this AD, the modification also terminates the actions required by paragraphs (g) and (h) of this AD.

(l) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320-57-1088, Revision 02, dated July 29, 1999; or Revision 03, dated February 9, 2001, which are not incorporated by reference in this AD.

(2) This paragraph provides credit for actions required by paragraph (k) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320-57-1089, Revision 02, dated November 6, 1998, which is not incorporated by reference in this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(ii) AMOCs approved previously in accordance with AD 2004-19-11, Amendment 39-13805 (69 FR 58828, October 1, 2004), are approved as AMOCs for the corresponding provisions of paragraphs (g) through (j) of this AD.

(2) *Contacting the Manufacturer*: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be

accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0169, corrected July 22, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5811.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 17, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-30006 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2015-4452; Airspace Docket No. 15-AWA-7]

RIN 2120-AA66

Proposed Amendment of Class C Airspace; Capital Region International Airport, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class C airspace at Capital Region International Airport, formerly Lansing Capital City Airport, Lansing, MI, by removing a cutout from the surface area that was put in place to accommodate operations around Davis Airport, now permanently closed. Also, this proposal would update the airport's name and geographic coordinates to reflect the current information in the FAA's aeronautical database. The FAA is proposing this action to enable more efficient operations at Capital Region International Airport.

DATES: Comments must be received on or before January 26, 2016.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001; telephone: (202) 366-9826. You must identify FAA Docket No. FAA-2015-4452 and Airspace Docket No. 15-AWA-7 at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use

of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify terminal airspace as required to preserve the safe and efficient flow of air traffic in the Lansing, MI, area.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2015-4452 and Airspace Docket No. 15-AWA-7) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at <http://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2015-4452 and Airspace Docket No. 15-AWA-7." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at <http://www.regulations.gov>.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during

normal business hours at the office of the Central Service Center, Operations Support Group, Federal Aviation Administration, 2601 Meacham Blvd., Fort Worth, TX 76137.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify the Capital Region International Airport Class C airspace area by removing the cutout from the Class C surface area that excluded the airspace within a 1-mile radius of the former Davis Airport and the airspace 1 mile either side of the 090° bearing from the former Davis Airport. The exclusion from the Class C surface area was in place solely to accommodate operations at Davis Airport, which was located about 3.5 NM east of the Capital Region International Airport. Davis Airport was permanently closed in 2000, and removed from the FAA's aeronautical database in 2006. Since the original purpose of the exclusion no longer exists, the FAA is proposing to remove the words ". . . excluding that airspace within a 1-mile radius of the Davis Airport and excluding that airspace 1 mile either side of the 090° bearing from Davis Airport to the 5-mile radius from Capital City Airport . . ." from the Class C airspace description. This would restore the Class C surface area to a standard configuration of a 5-NM radius around Capital Region International Airport and enhance the management of aircraft operations at the airport.

Also, this action would update the airport name and geographic coordinates to reflect the current information in the FAA's aeronautical database. This change would replace "Capital City Airport" with "Capital Region International Airport" and

replace "lat. 42°46'43" N., long. 84°35'15" W." with "lat. 42°46'43" N., long. 84°35'10" W."

Class C airspace areas are published in paragraph 4000 of FAA Order 7400.9Z, dated August 6, 2015 and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class C airspace area modification proposed in this document would be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9Z,

Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 4000—Subpart C—Class C Airspace

* * * * *

AGL MI C Lansing, MI [Amended]

Capital Region International Airport, MI
(Lat. 42°46'43" N., long. 84°35'10" W.)

That airspace extending upward from the surface to and including 4,900 feet MSL within a 5-mile radius of Capital Region International Airport; and that airspace extending upward from 2,100 feet MSL to and including 4,900 feet MSL within a 10-mile radius of Capital Region International Airport.

Issued in Washington, DC, on November 16, 2015.

Gary A. Norek,

Manager, Airspace Policy Group.

[FR Doc. 2015-29912 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2015-3675; Airspace
Docket No. 15-ANM-19]

Proposed Amendment of Class D and Class E Airspace; Walla Walla, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class D airspace, Class E surface area airspace, Class E surface area airspace designated as an extension, and Class E airspace extending upward from 700 feet above the surface at Walla Walla Regional Airport, Walla Walla, WA. After a review of the airspace, the FAA found it necessary to amend the airspace area for the safety and management of Instrument Flight Rules (IFR) operations for arriving and departing aircraft at the airport. This action would also update the geographic coordinates of Walla Walla Regional Airport in the respective Class D and E airspace areas above.

DATES: Comments must be received on or before January 11, 2016.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366-9826. You must identify FAA Docket No. FAA-2015-3675; Airspace

Docket No. 15-ANM-19, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202-267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT:

Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4563.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D and Class E airspace at Walla Walla Regional Airport, Walla Walla, WA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking

by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2015-3675; Airspace Docket No. 15-ANM-19." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas,

air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class D airspace, Class E surface area airspace, Class E surface area airspace designated as an extension, and Class E airspace extending upward from 700 feet above the surface at Walla Walla Regional Airport, Walla Walla, WA. The Class E airspace area designated as an extension would extend from the 4.3-mile radius of Walla Walla Regional Airport to 7.5 miles southwest and 13.4 miles northeast of the airport. Class E airspace extending upward from 700 feet above the surface would be modified to an area 5.7 miles to the west, 16.5 miles to the southwest, 22.5 miles northeast and within a 13.4-mile radius of a point in space location east of Walla Walla Regional Airport. This action would also update the geographic coordinates of the airport for the Class D and E airspace areas listed above.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance

with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 5000: Class D Airspace.

* * * * *

ANM WA D Walla Walla, WA [Modified]

Walla Walla Regional Airport, WA
(Lat. 46°05'43" N., long. 118°17'09" W.)

That airspace extending upward from the surface to and including 3,700 feet MSL within a 4.3-mile radius of Walla Walla Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002: Class E Airspace Designated as Surface Areas.

* * * * *

ANM WA E2 Walla Walla, WA [Modified]

Walla Walla Regional Airport, WA
(Lat. 46°05'43" N., long. 118°17'09" W.)

That airspace extending upward from the surface within a 4.3-mile radius of Walla Walla Regional Airport.

Paragraph 6004: Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM WA E4 Walla Walla, WA [Modified]

Walla Walla Regional Airport, WA
(Lat. 46°05'43" N., long. 118°17'09" W.)

That airspace extending upward from the surface within 2.7 miles each side of the Walla Walla 215° bearing from the airport extending from the 4.3-mile radius of Walla Walla Regional Airport to 7.5 miles southwest of the airport, and within 4.1 miles

each side of the Walla Walla 35° bearing from the airport extending from the 4.3-mile radius of Walla Walla Regional Airport to 13.4 miles northeast of the airport.

Paragraph 6005: Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

ANM WA E5 Walla Walla, WA [Modified]

Walla Walla Regional Airport, WA
(Lat. 46°05'43" N., long. 118°17'09" W.)

Walla Walla Regional Airport, point in space coordinates

(Lat. 46°03'27" N., long. 118°12'20" W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 45°52'29" N., long. 118°23'027" W.; to lat. 45°49'51" N., long. 118°26'02" W.; to lat. 45°57'17" N., long. 118°40'49" W.; to lat. 46°10'22" N., long. 118°27'48" W.; to lat. 46°08'46" N., long. 118°24'32" W.; to lat. 46°14'38" N., long. 118°18'44" W.; to lat. 46°16'07" N., long. 118°21'47" W.; to lat. 46°29'20" N., long. 118°08'35" W.; to lat. 46°22'02" N., long. 117°53'24" W.; to lat. 46°14'25" N., long. 118°01'11" W.; and that airspace within a 13.4-mile radius of point in space coordinates at lat. 46°03'27" N., long. 118°12'20" W., from the 052° bearing from the Walla Walla Regional Airport clockwise to the 198° bearing.

Issued in Seattle, Washington, on November 10, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–29784 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

RIN 1506–AB27

Imposition of Special Measure Against FBME Bank Ltd., Formerly Known as the Federal Bank of the Middle East Ltd., as a Financial Institution of Primary Money Laundering Concern

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Proposed rule; re-opening of comment period and availability of supplemental information.

SUMMARY: On July 29, 2015, FinCEN issued a Final Rule imposing the fifth special measure against FBME Bank Ltd. (FBME), formerly known as the Federal Bank of the Middle East, Ltd., with an effective date of August 28, 2015. On August 27, 2015, the United States District Court for the District of Columbia granted FBME's motion for a preliminary injunction and enjoined the

Final Rule from taking effect. On November 6, 2015, the Court granted the Government's motion for voluntary remand to allow for further rulemaking proceedings. FinCEN is hereby re-opening the Final Rule to solicit additional comment in connection with the rulemaking, particularly with respect to the unclassified, non-protected documents that support the rulemaking and whether any alternatives to the prohibition of the opening or maintaining of correspondent accounts with FBME would effectively mitigate the risk to domestic financial institutions.

DATES: Written comments on this document must be submitted on or before January 26, 2016.

ADDRESSES: You may submit comments, identified by 1506-AB27, by any of the following methods:

- *Federal E-rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Include 1506-AB27 in the submission.
- *Mail:* The Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Include 1506-AB27 in the body of the text. Please submit comments by one method only.

- Absent a sufficient showing that a submission warrants confidential treatment, comments submitted in response to this document will become a matter of public record. Therefore, you should generally only submit information that you wish to make publicly available.

Inspection of comments: The public dockets for FinCEN can be found at www.Regulations.gov. Proposed and final rules published by FinCEN in the **Federal Register** are searchable by docket number, RIN, or document title, among other things, and the docket number, RIN, and title may be found at the beginning of the document. FinCEN uses the electronic, Internet-accessible dockets at [Regulations.gov](http://www.regulations.gov) as their complete docket; all hard copies of materials that should be in the docket, including public comments, are electronically scanned and placed in the docket. In general, FinCEN will make all comments publicly available by posting them on <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at (800) 767-2825.

SUPPLEMENTARY INFORMATION:

I. Regulatory Background

On July 22, 2014, FinCEN published in the **Federal Register** a Notice of Finding (NOF) in which the Director of FinCEN explained that reasonable grounds exist for concluding that FBME

Bank Ltd. (FBME) is a financial institution of primary money laundering concern pursuant to Section 311 of the USA PATRIOT Act (Section 311),¹ which is codified at 31 U.S.C. 5318A. FinCEN's NOF identified two main areas of concern: (i) FBME's facilitation of money laundering, terrorist financing, transnational organized crime, fraud schemes, sanctions evasion, weapons proliferation, corruption by politically-exposed persons, and other financial crime; and (ii) FBME's weak anti-money laundering controls, which allow its customers to perform a significant volume of obscured transactions and activities through the U.S. financial system. Simultaneously with the issuance of the NOF, FinCEN also published in the **Federal Register** a related Notice of Proposed Rulemaking (NPRM) proposing the imposition of the fifth special measure available under Section 311 against FBME.² In particular, FinCEN proposed to prohibit covered U.S. financial institutions from opening or maintaining a correspondent account in the United States for, or on behalf of, FBME. On July 29, 2015, after considering comments from the public on these documents, and other information available to FinCEN, including both public and non-public reporting, FinCEN published in the **Federal Register** a Final Rule imposing the fifth special measure as proposed in the NPRM, with an effective date of August 28, 2015.³

FBME filed suit on August 7, 2015 in the United States District Court for the District of Columbia and sought a preliminary injunction against the Final Rule. On August 27, 2015, the Court granted the motion for preliminary injunction and enjoined the Final Rule from taking effect.⁴ In its order, the Court found that FBME was likely to succeed on the merits of two of its claims: (i) That FinCEN provided insufficient notice of unclassified, non-protected information on which it relied during the rulemaking proceedings, and (ii) that FinCEN failed to adequately consider at least one potentially significant, viable, and obvious alternative to the special measure it imposed.⁵ On November 6, 2015, the Court granted FinCEN's motion for voluntary remand so that FinCEN may engage in further rulemaking to address

the procedural issues identified by the Court in enjoining the Final Rule. Accordingly, FinCEN is issuing this document to solicit additional comment regarding the Section 311 rulemaking related to FBME. In addition, FinCEN is making available for comment the unclassified, non-protected material that FinCEN relied upon and intends to rely upon during the rulemaking proceeding.⁶ That unclassified, non-protected material is available at www.regulations.gov [Fincen-2014-0007]. Those comments previously submitted in connection with the rulemaking need not be resubmitted, as FinCEN will consider all comments received to date. In addition, if FinCEN decides to consider any additional unclassified, non-protected material other than that provided in the comments, such information will be added to www.regulations.gov [Fincen-2014-0007].

II. Proposed Imposition of the Fifth Special Measure

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56 (the USA PATRIOT Act). Title III of the USA PATRIOT Act amends the anti-money laundering provisions of the Bank Secrecy Act (BSA), codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5314, 5316-5332, to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism. Regulations implementing the BSA appear at 31 CFR chapter X. The authority of the Secretary of the Treasury to administer the BSA and its implementing regulations has been delegated to the Director of FinCEN.

Section 311 of the USA PATRIOT Act grants the Director of FinCEN the authority, upon finding that reasonable grounds exist for concluding that a foreign jurisdiction, foreign financial institution, class of transactions, or type of account is of "primary money laundering concern," to require domestic financial institutions and financial agencies to take certain "special measures" to address the primary money laundering concern. The special measures enumerated under Section 311 are prophylactic safeguards

¹ Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56.

² 79 FR 42486 (July 22, 2014) (RIN 1506-AB27).

³ 80 FR 45057 (July 29, 2015) (RIN 1506-AB27).

⁴ *FBME Bank Ltd. v. Lew*, No. 1:15-cv-01270, 2015 WL 5081209 (D.D.C. Aug. 27, 2015).

⁵ *Id.* at *5.

⁶ As previously disclosed in the litigation involving the Final Rule, FinCEN notes that it does not intend to rely on three documents that were originally included in its administrative record supporting the NOF and NPRM: Two were law enforcement sensitive documents and the other was mistakenly included.

that defend the U.S. financial system from money laundering and terrorist financing. FinCEN may impose one or more of these special measures in order to protect the U.S. financial system from these threats. To that end, special measures one through four, codified at 31 U.S.C. 5318A(b)(1–4), impose additional recordkeeping, information collection, and information reporting requirements on covered U.S. financial institutions. The fifth special measure, codified at 31 U.S.C. 5318A(b)(5), allows the Director to prohibit or impose conditions on the opening or maintaining of correspondent or payable-through accounts for the identified institution by U.S. financial institutions.

Given FinCEN's finding that FBME is of primary money laundering concern, in the Final Rule, FinCEN imposed the fifth special measure's prohibition on the opening or maintaining of a correspondent account in the United States for FBME. In further evaluation of alternative measures pursuant to the Court's November 6, 2015 opinion and order, FinCEN is reopening the Final Rule to solicit additional comment. First, FinCEN seeks comment on whether any of special measures one through four under Section 311 with respect to covered U.S. financial institutions' activities involving FBME would be an effective alternative to mitigate the risk posed by FBME, as explained in the Notice of Finding. FinCEN also seeks comment on whether, pursuant to special measure five of Section 311, FinCEN should impose conditions, rather than a prohibition, on the opening or maintaining of correspondent accounts with FBME.

III. Request for Comments

FinCEN invites comments on all aspects of this rulemaking, including, but not limited to, the following:

1. The unclassified, non-protected information that FinCEN intends to rely upon during the rulemaking proceeding;⁷

2. Whether any of special measures one through four under Section 311 with respect to covered U.S. financial institutions' activities involving FBME would be an effective alternative to mitigate the risk posed by FBME as explained in the Notice of Finding;

3. Whether, pursuant to special measure five of Section 311, FinCEN

should impose conditions, rather than a prohibition, on the opening or maintaining of correspondent accounts with FBME as an effective alternative to mitigate the risk posed by FBME as explained in the Notice of Finding; and

4. Any material developments that have occurred with respect to FBME since the issuance of the NOF and NPRM on July 22, 2014, including whether reasonable grounds continue to exist for concluding that FBME is a primary money laundering concern.

IV. Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis" that will "describe the impact of the proposed rule on small entities." (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities. FinCEN previously provided information about the number and types of entities that would be affected by the earlier proposal to impose special measure five.⁸ FinCEN is restating that information in this document so that persons may comment on FinCEN's proposed certification concerning whether the imposition of any of the special measures would have a significant economic impact on a substantial number of small entities. As explained in more detail, the limited number of foreign banking institutions with which FBME maintains or will maintain accounts will likely limit the number of affected covered financial institutions to the largest U.S. banks, which actively engage in international transactions.

A. Estimate of the Number of Small Entities to Whom Any of Special Measures One Through Five Would Apply

For purposes of the RFA, both banks and credit unions are considered small entities if they have less than \$500,000,000 in assets.⁹ Of the estimated 7,000 banks, 80 percent have less than \$500,000,000 in assets and are considered small entities.¹⁰ Of the

estimated 7,000 credit unions, 94 percent have less than \$500,000,000 in assets.¹¹

Broker-dealers are defined in 31 CFR 1010.100(h) as those broker-dealers required to register with the Securities and Exchange Commission (SEC). Because FinCEN and the SEC regulate substantially the same population, for the purposes of the RFA, FinCEN relies on the SEC's definition of small business as previously submitted to the Small Business Administration (SBA). The SEC has defined the term "small entity" to mean a broker or dealer that: (a) Had total capital (net worth plus subordinated liabilities) of less than \$500,000 on the date in the prior fiscal year as of which its audited financial statements, were prepared pursuant to Rule 17a-5(d) or, if not required to file such statements, a broker or dealer that had total capital (net worth plus subordinated debt) of less than \$500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business if shorter); and (b) is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined in this release.¹² Based on SEC estimates, 17 percent of broker-dealers are classified as "small" entities for purposes of the RFA.¹³

Futures commission merchants (FCMs) are defined in 31 CFR 1010.100(x) as those FCMs that are registered or required to be registered as a FCM with the Commodity Futures Trading Commission (CFTC) under the Commodity Exchange Act (CEA), except persons who register pursuant to section 4f(a)(2) of the CEA, 7 U.S.C. 6f(a)(2). Because FinCEN and the CFTC regulate substantially the same population, for the purposes of the RFA, FinCEN relies on the CFTC's definition of small business as previously submitted to the SBA. In the CFTC's "Policy Statement and Establishment of Definitions of 'Small Entities' for Purposes of the Regulatory Flexibility Act," the CFTC concluded that registered FCMs should not be considered to be small entities for purposes of the RFA.¹⁴ The CFTC's determination in this regard was based, in part, upon the obligation of registered

select Size or Performance: Total Assets, type Equal or less than \$: "500000" and select Find.

¹¹ National Credit Union Administration, *Credit Union Data*, <http://webapps.ncua.gov/customquery/> select Search Fields: Total Assets, select Operator: Less than or equal to, type Field Values: "500000000" and select Go.

¹² 17 CFR 240.0-10(c).

¹³ 76 FR 37572, 37602 (June 27, 2011) (the SEC estimates 871 small broker-dealers of the 5,063 total registered broker-dealers).

¹⁴ 47 FR 18618, 18619 (Apr. 30, 1982).

⁷ FinCEN anticipates that certain confidential business information ("CBI") pertaining to FBME will not be made available. To the extent documents containing such CBI can be disclosed publicly in redacted form, they will be added to www.regulations.gov.

⁸ 79 FR 42486, 42489 (July 22, 2014) and 80 FR 45057, 45063 (July 29, 2015).

⁹ *Table of Small Business Size Standards Matched to North American Industry Classification System Codes*, Small Business Administration Size Standards (SBA Jan. 22, 2014) [hereinafter *SBA Size Standards*].

¹⁰ Federal Deposit Insurance Corporation, *Find an Institution*, <http://www2.fdic.gov/idasp/main.asp>;

FCMs to meet the capital requirements established by the CFTC.

For purposes of the RFA, an introducing broker-commodities dealer is considered small if it has less than \$35,500,000 in gross receipts annually.¹⁵ Based on information provided by the National Futures Association (NFA), 95 percent of introducing brokers-commodities dealers have less than \$35.5 million in Adjusted Net Capital and are considered to be small entities.

Mutual funds are defined in 31 CFR 1010.100(gg) as those investment companies that are open-end investment companies that are registered or are required to register with the SEC. Because FinCEN and the SEC regulate substantially the same population, for the purposes of the RFA, FinCEN relies on the SEC's definition of small business as previously submitted to the SBA. The SEC has defined the term "small entity" under the Investment Company Act to mean an investment company that, together with other investment companies in the same group of related investment companies, has net assets of \$50 million or less as of the end of its most recent fiscal year.¹⁶ Based on SEC estimates, 7 percent of mutual funds are classified as "small entities" for purposes of the RFA under this definition.¹⁷

B. Special Measures One Through Five

As noted above, 80 percent of banks, 94 percent of credit unions, 17 percent of broker-dealers, 95 percent of introducing brokers-commodities, zero FCMs, and 7 percent of mutual funds are small entities. The limited number of foreign banking institutions with which FBME maintains or will maintain accounts will likely limit the number of affected covered financial institutions to the largest U.S. banks, which actively engage in international transactions. Thus, the imposition of the recordkeeping, information collection, or reporting provisions in any of special measures one through four would not impact a substantial number of small entities. Similarly, the imposition of the prohibition on maintaining correspondent accounts for foreign banking institutions that engage in transactions involving FBME under the fifth special measure, together with related notice and special due diligence, would not impact a substantial number of small entities. Finally, imposing conditions on the opening or maintenance of such a correspondent

account under special measure five would not impact a substantial number of small entities.

C. Certification

For these reasons, FinCEN certifies that the proposals contained in this rulemaking would not have a significant impact on a substantial number of small businesses.

FinCEN invites comments from members of the public who believe there would be a significant economic impact on small entities from the imposition of any of special measures one through five.

Jamal El-Hindi,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2015-30119 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-02-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2015-0686; FRL- 9939-37-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revision to the Definition of Volatile Organic Compound

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of revising the definition of volatile organic compound (VOC). In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by December 28, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2015-0686 by one of the following methods:

A. www.regulations.gov. Follow the on-line instructions for submitting comments.

B. Email: fernandez.cristina@epa.gov.

C. Mail: EPA-R03-OAR-2015-0686, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2015-0686. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

¹⁵ SBA Size Standards at 28.

¹⁶ 17 CFR 270.0-10.

¹⁷ 78 FR 23637, 23658 (April 19, 2013).

is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in www.regulations.gov or may be viewed during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT:

Irene Shandruk, (215) 814-2166, or by email at shandruk.irene@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the “Rules and Regulations” section of this **Federal Register** publication.

Dated: November 12, 2015.

Shawn M. Garvin,

Regional Administrator, Region III.

[FR Doc. 2015-30105 Filed 11-25-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2015-0747; FRL-9937-04-OAR]

RIN 2060-AS13

Oil and Natural Gas Sector: National Emission Standards for Hazardous Air Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for information.

SUMMARY: This action requests information related to hazardous air pollutant (HAP) emissions from sources in the oil and natural gas production and natural gas transmission and storage segments of the oil and natural gas sector. In 2012, the Environmental Protection Agency (EPA) revised the National Emission Standards for Hazardous Air Pollutants (NESHAP) for

the Oil and Natural Gas Production Facilities and the Natural Gas Transmission and Storage Facilities major source categories. This action requests additional data and information that was not available at that time. In particular, we are requesting data on storage vessels without potential flash emissions (PFE) and data on HAP emissions from regulated small glycol dehydrators. With regard to the small glycol dehydrators we are particularly interested in data regarding any emissions of HAP other than benzene, toluene, ethylbenzene, and xylene (BTEX), information on available control options for any such HAP and information regarding a potential compliance demonstration issue with respect to the 2012 standards for small glycol dehydration units, as they apply to units with very low emissions.

DATES: Comments must be received on or before January 26, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2015-0747, to the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

Docket. All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the U.S. Environmental Protection Agency, EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For further information about this action, contact Mr. Matthew Witosky, Sector Policies and Programs Division (E143-05), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541-2865; facsimile number: (919) 541-3740; email address: witosky.matthew@epa.gov. For further information on the EPA’s oil and natural gas sector regulatory program, contact Mr. Bruce Moore, Sector Policies and Programs Division (E143-05), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541-5460; facsimile number: (919) 541-3470; email address: moore.bruce@epa.gov. For additional contact information, see the following **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Categories and entities potentially affected by this action include:

TABLE 1—INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS ACTION

Category	NAICS code ¹	Examples of regulated entities
Industry	211111	Crude Petroleum and Natural Gas Extraction.
	211112	Natural Gas Liquid Extraction.
	221210	Natural Gas Distribution.
	486110	Pipeline Distribution of Crude Oil.
	486210	Pipeline Transportation of Natural Gas.
Federal government		Not affected.

TABLE 1—INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS ACTION—Continued

Category	NAICS code ¹	Examples of regulated entities
State/local/tribal government	Not affected.

¹ North American Industry Classification System.

This table is not intended to be exhaustive, but rather is meant to provide a guide for readers regarding entities likely to be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permitting authority for the entity or your EPA Regional representative as listed in 40 CFR 60.4 or 40 CFR 63.13 (General Provisions).

B. What should I consider as I prepare my information/comments to the EPA?

Do not submit information containing CBI to the EPA through www.regulations.gov or email. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention: Docket ID No. EPA–HQ–OAR–2015–0747. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

II. Background

In 2012, the EPA issued a final rule titled “Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews,” 77 FR 49490 (August 16, 2012). The final rule contains final actions on two different national standards for the oil and natural gas industry promulgated by the EPA under the Clean Air Act (CAA): (1) The new source performance standards (NSPS), promulgated under section 111 of the CAA, and (2) the NESHAP, promulgated under section 112 of the CAA. The NESHAP portion of the final rule (“the 2012 NESHAP revisions”) included the EPA’s residual

risk and technology review of the NESHAP for the Oil and Natural Gas Production Facilities and the NESHAP for the Natural Gas Transmission and Storage Facilities major source categories (40 CFR part 63 subpart HH¹ and HHH, respectively) pursuant to sections 112(f)(2) and (d)(6) of the CAA. In addition, pursuant to section 112(d)(2) and (3) of the CAA, the EPA established emission standards for BTEX based on maximum achievable control technology (MACT) for a subcategory of glycol dehydrators referred to as the “small glycol dehydration units.”

This request is to obtain additional data and information. We are interested in receiving information on HAP emissions from some affected facilities in the oil and natural gas production, and the natural gas transmission and storage segments of the oil and natural gas sector. In particular, the EPA is interested in the following information:

1. HAP emissions from storage vessels without PFE from the oil and natural gas production segment;

2. Emission information on HAP other than BTEX from small glycol dehydrators and available control options.

In addition, the EPA recently learned of a potential compliance demonstration issue with respect to the 2012 BTEX MACT standards for small glycol dehydration units as they apply to units with very low BTEX emissions. The EPA is also soliciting comment and information related to this issue. The Agency also requests any additional relevant information for sources covered by the NESHAP.

Section III of this action discusses in more detail the information identified above. The EPA is providing a 60-day period for the public to submit the requested information.

III. Solicitation of Data and Comments

The following presents the issues on which we are particularly interested in receiving feedback, data, and information.

¹ 40 CFR part 63, subpart HH also includes standards for certain area source glycol dehydration units, which were not a subject of the 2012 NESHAP revisions.

A. Storage Vessels Without Potential Flash Emissions

We request available data on storage vessels without PFE. Crude oil, condensate, and produced water are typically stored in fixed-roof storage vessels. Some vessels used for storing produced water may be open-top tanks. These fixed-roof vessels, which are operated at or near atmospheric pressure conditions, are typically located in tank batteries at well sites and at centralized gathering facilities. A tank battery refers to the collection of process components used to separate, treat, and store crude oil, condensate, intermediate hydrocarbon liquids, and produced water. The extracted products from production wells enter the tank battery through the production header, which may collect product from many wells.

Emissions from storage vessels are a result of working, breathing, and flash losses. Working losses occur due to the emptying and filling of storage vessels. Breathing losses are the release of gas associated with daily temperature fluctuations and other equilibrium effects. Flash losses occur when a liquid with entrained gases is transferred from a vessel with higher pressure to a vessel with lower pressure, and thus, allowing entrained gases or a portion of the liquid to vaporize or flash. In the oil and natural gas production segment, flashing losses occur when crude oil or condensate flows into a storage vessel from a processing vessel operated at a higher pressure. Typically, the larger the pressure drop, the more flash emissions will occur in the storage vessel. Temperature of the liquid may also influence the amount of flash emissions.

In 1999, the EPA promulgated the NESHAP for the Oil and Natural Gas Production Facilities major source category (40 CFR part 63, subpart HH). The 1999 NESHAP included the MACT standards for storage vessels with PFE, which are defined in subpart HH, 40 CFR 63.761.

The 1999 NESHAP left unregulated storage vessels without PFE (*i.e.*, storage vessels that do not meet the above definition). In the 2011 proposal to revise the Oil and Natural Gas

NESHAP,² the EPA proposed MACT standards for storage vessels without PFE pursuant to CAA section 112(d)(2) and (3), but did not take final action on that proposal. As explained in the preamble to the 2012 NESHAP revisions, “we need (and intend to gather) additional data on these sources in order to analyze and establish MACT emission standards for this subcategory of storage vessels under section 112(d)(2) and (3) of the CAA.” 77 FR 49503.

We request available data regarding storage vessels without PFE. In particular, we are interested in data and other relevant information characterizing emissions and emission rates of storage vessels in the oil and natural gas production segment that do not have PFE, but that nonetheless emit HAP. We also request information on technologies and/or practices for reducing emissions from storage vessels without PFE.

B. Studies of HAP Emissions From Small Glycol Dehydrators

The EPA is specifically interested in receiving data for units with low inlet concentration of BTEX and the amount of these HAP emissions from small glycol dehydration units. In 2012,

²Proposed Rule, *Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews*, 76 FR 52738 (August 23, 2011).

pursuant to CAA section 112(d)(2) and (3), the EPA revised 40 CFR part 63, subparts HH and HHH to include MACT standards for “small glycol dehydration units.” See 40 CFR 63.761 and 63.1271. The standards for both existing and new sources of small glycol dehydration units are in the form of a unit-specific BTEX emission limit determined by the equations provided in that subpart.

The EPA recently learned of a potential compliance demonstration issue for certain small glycol dehydration units with very low BTEX emissions. Specifically, we were informed that for certain small glycol dehydrators that operate with low BTEX inlet concentrations, the equations may result in emission standards that are below the detection limit for the reference method used for compliance purposes. If there are units that fit this criterion, it is theoretically possible that neither the source nor the EPA could verify compliance using the methods specified in the rule. To enable us to fully evaluate this issue, we are requesting source data that demonstrates whether compliance with the standard can be verified at small glycol dehydration units for which this is a potential issue. We request that commenters submit estimates on the number of units where this is a potential

problem and the data showing the HAP inlet concentrations for these units.³

We are also requesting information on emissions of HAP other than BTEX from small glycol dehydrators. As explained above, in the 2012 NESHAP revisions, the EPA established MACT standards for BTEX emitted from small glycol dehydration units. While our data indicate that there is potential for other HAP to be emitted from small glycol dehydration units, we do not have sufficient information to establish MACT standards for other HAP emitted from these units. We are, therefore, requesting data that show the types and quantities of HAP emissions other than BTEX from small glycol dehydration units. In addition to non-BTEX HAP emissions data, we are requesting information on methods employed to control these non-BTEX HAP, including whether BTEX control measures are an effective method for other non-BTEX HAP emitted by the units.

Dated: November 3, 2015.

Janet G. McCabe,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2015–30103 Filed 11–25–15; 8:45 am]

BILLING CODE 6560–50–P

³The EPA is not requesting information that would identify the units. Rather, we are requesting information demonstrating that for an affected facility, the applicable standard would be below the detection limit of the EPA method used to show compliance.

Notices

Federal Register

Vol. 80, No. 228

Friday, November 27, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Federal Claims Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this Notice invites the general public and other public agencies to comment on proposed information collections. This revision of an existing collection announces the intent of the Food and Nutrition Service to revise and continue the requirements associated with initiating and conducting Federal collection actions against households with delinquent Supplemental Nutrition Assistance Program (SNAP) recipient debts.

DATES: Written comments must be submitted on or before January 26, 2016 to be assured consideration.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate, automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Jane Duffield, Chief, State Administration Branch, Supplemental Nutrition Assistance Program, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 818, Alexandria, Virginia, 22302. Comments may also be submitted via fax to the attention of Jane Duffield at 703-605-0795. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov> and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia 22302, Room 818.

All comments will be summarized and included in the request for Office of Management and Budget approval of the information collection. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Kelly Stewart at (703) 305-2425.

SUPPLEMENTARY INFORMATION:

Title: Federal Claims Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims.

OMB Number: 0584-0446.

Form Number: None.

Expiration Date: April 30, 2016.

Type of Request: Revision of a currently approved collection.

Abstract: Section 13(b) of the Food Stamp Act of 1977, as amended (7 U.S.C. 2022(b)), and Supplemental Nutrition Assistance Program (SNAP) regulations at 7 CFR 273.18 require State agencies to refer delinquent debtors for SNAP benefit over-issuance to the U.S. Department of the Treasury for collection. The Debt Collection Improvement Act of 1996 (Pub. L. 104-134), as amended by the Digital Accountability and Transparency Act of 2014 (Pub. L. 113-101), requires these debts to be referred to Treasury for collection when they are 120 days or more delinquent. Through the Treasury Offset Program (TOP), 31 CFR part 285, payments such as Federal income tax refunds, Federal salaries and other Federal payments payable to these delinquent debtors will be offset and the amount applied to the delinquent debt.

TOP places a burden on States agencies and/or former SNAP recipients who owe delinquent debts in three areas: (1) 60-day notices from State agencies to debtors that their debt will be referred to TOP; (2) State-level submissions; and (3) automated data processing (ADP). Below, the burden narrative and chart depicts the burden estimates by these three areas and affected public.

TOP 60-Day Notice Burden

The burden associated with the information collection involves both the households (debtors) and the State agencies. The TOP 60-day notice notifies the household of the proposed referral to TOP and provides the right for review and appeal. The State agency prepares and mails the notices as well as responds to inquiries and appeals. The household, in turn, receives and reads the notice and may make an inquiry or appeal the impending action. Based on an average of the number of records for claims the States sent to TOP for calendar years 2012, 2013 and 2014, we estimate that State agencies will produce and send and that households will read 237,014 TOP 60-day notices. We estimate that the households will submit and State agencies will respond to about 16,591 phone and informal inquiries. Households will file and the States will respond to an estimated 1,421 appeals each. An additional 3,000 notices will be sent directly from FNS to Federal employees concerning the potential offset of their Federal salary. Historically, 30 percent of these notices will result in a phone inquiry from a household; and approximately 20 will result in a formal appeal to FNS requiring documentation from the State. Thus, the total number of responses for the 60-day notice and household inquiry is 513,992 responses (258,946 household responses + 255,046 State Agency responses) per year resulting in an annual reporting burden of 33,960.80 hours. The existing burden for activity relating to the 60-day notice is 34,510.28 hours. The net decrease of 549.48 hours is due to a decrease in the average number of 60-day notices sent to debtors by State agencies between 2012 and 2014.

TOP State-Level Submissions

Treasury prescribes specific processes and file formats for FNS to use to send debts to TOP. FNS provides guidance

and file formats to State agencies and monitors their compliance with such. State agencies must submit an annual letter to FNS certifying that all of the debts submitted in the past and all debts to be submitted in the upcoming calendar year by the State agency to TOP are valid and legally enforceable in the amount stated. FNS estimates that it will take State agencies a total of 26.5 hours per year for these State submissions. This burden has not changed with this activity. State agencies also report TOP collections on the FNS-209 form, "Status of Claims Against Households." The burden for completing the FNS-209 is covered under OMB number 0584-0594.

TOP ADP Burden

The burden for ADP includes weekly file processing, monthly address requests and system maintenance. Weekly and monthly file processing includes requesting addresses to use to send out 60-day notices, adding and maintaining debts in TOP, correcting errors on unprocessable records, and posting weekly collection files. Much of this activity is completed using automation and involves an estimated 1.4 million records annually. FNS estimates that this activity takes

12,374.82 annual reporting and 689 recordkeeping burden hours. This burden has not changed with this activity.

Summary of Estimated Burden

The net aggregate change from the existing to the revised annual burden for this entire Information Collection is a decrease of 549.48 hours from the previous submission. For the activity relating to the 60-day notice, we are decreasing the estimated annual burden for State agencies and households from 34,510.28 hours to 33,960.80 hours to reflect a decrease in the number of notices and the resulting inquiries and appeals. The State-level submissions portion of the reporting and recordkeeping burden is estimated to require the same number of hours as the currently approved collection, 26.5 hours. The annual ADP portion of this burden package is also estimated to require the same number of hours as the currently approved collection, 12,374.82 reporting and 689 recordkeeping hours. This results in a final total of 47,051 annual burden hours.

Reporting Burden

Affected Public: Households/Debtors.
Estimated Number of Respondents: 237,014.

Estimated Number of Responses per Respondent: 1.09253.

Estimated Total Number of Annual Responses: 258,946.

Estimated Hours per Response: 0.097064.

Estimated Total Annual Burden: 25,134.42.

Affected Public: State and local government.

Estimated Number of Respondents: 53.

Estimated Number of Responses per Respondent: 4,935.25.

Estimated Total Number of Annual Responses: 261,570.

Estimated Hours per Response: .08115.

Estimated Total Annual Burden: 21,227.70.

State Agency Recordkeeping Burden

Affected Public: State and local government.

Estimated Number of Respondents: 53.

Estimated Number of Responses per Respondent: 52.

Estimated Total Number of Annual Responses: 2,756.

Estimated Hours per Response: .25.
Estimated Total Annual Burden: 689.

REPORTING AND RECORDKEEPING BURDEN ESTIMATES

Section of reg	Description	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total annual burden hours
Households (Debtors) A. Due-Process Notice Requirements:	Reading State Issued Notice	237,014	1.00	237,014	0.08	19,790.67
	Informal Inquiries to State ...	16,591	1.00	16,591	0.25	4,147.75
	Formal Appeals to State	1,421	1.00	1,421	0.50	710.50
	Reading FNS issued letter to Federal employees.	3,000	1.00	3,000	0.0835	250.5
	Phone Inquiries and informal appeals for FNS letter.	900	1.00	900	0.25	225
	Formal appeals to FNS	20	1.00	20	0.5	10
Totals	237,014	1.09253	258,946	0.097064	25,134.42
State Agencies A. Due-Process Notice Requirements:	State Notice Production	53	4,471.96	237,014	0.02	3,958.13
	Responding to State Phone/informal Inquires.	53	313.04	16,591	0.25	4,147.75
	Responding to State Formal Appeals.	53	26.81132	1,421	0.50	710.50
	Providing documents for formal appeals to FNS.	53	0.377358	20	0.5	10
B. State Agency Reporting: C. TOP Automated Data Processing:	Certification Letter	53	1.00	53	0.50	26.50
	System Compatibility File	53	1.00	53	11.50	609.50
	Address File	53	8.00	424	1.63	693.07
	Collections File	53	8.00	424	6.50	2,756.00
	State Agency Profile	53	1.00	53	0.25	13.25
	Testing New System	5	1.00	5	7.00	35.00
	Weekly Files	53	52.00	2,756	1.50	4,134.00
	Weekly Files—Post TOP Data.	53	52.00	2,756	1.50	4,134.00

REPORTING AND RECORDKEEPING BURDEN ESTIMATES—Continued

Section of reg	Description	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total annual burden hours
Totals	53	4,935.28	261,570	0.08115	21,227.70
Overall Reporting Totals	237,067	2.20	520,516	0.09	46,362

State Agency Recordkeeping

Per 7 CFR 272.1(f), State agencies are required to retain all records associated

with the administration of SNAP for no less than 3 years. The burden for the

retention of weekly TOP files is displayed below.

RECORDKEEPING

Number of recordkeepers	Annual records per recordkeeper	Total records per recordkeeper	Hours per record	Total recordkeeping burden
53	52	2,756	0.25	689.00

Dated: November 18, 2015.
Audrey Rowe,
Administrator, Food and Nutrition Service.
 [FR Doc. 2015-30068 Filed 11-25-15; 8:45 am]
BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of the Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to the production and marketing of foods directly from farm producers to consumers or retailers. In addition NASS will collect some whole-farm data to be used to classify and group operations for summarizing and publication of results.

FOR FURTHER INFORMATION CONTACT: R. Renee Picanso, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720-2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS-OMB Clearance Officer, at (202) 690-2388 or at *ombofficer@nass.usda.gov*.

Correction

In the **Federal Register** of October 26, 2015 in FR Doc. 2015-27139 on page

65196, in the SUPPLEMENTARY INFORMATION, para 5, the Estimate of Burden section, read as follows:

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30 minutes per response. NASS plans to mail out publicity materials with the questionnaires to inform producers of the importance of this survey. NASS will also use multiple mailings, followed up with phone and limited personal enumeration to increase response rates and to minimize data collection costs. The sample will consist of farm operators believed to market their products directly to consumers or retailers. These operators will be drawn from two sources: (1) NASS's list of farm operators, and (2) farm operators obtained from publically available sources, including those obtained from web harvesting.

Respondents: Farmers and Ranchers.

Estimated Number of Respondents: 56,000.

Estimated Total Annual Burden on Respondents: 29,000 hours.

Yvette Anderson,

Federal Register Liaison Officer for ARS, ERS, and NASS.

[FR Doc. 2015-30159 Filed 11-25-15; 8:45 am]

BILLING CODE 3410-20-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE332

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting via webinar.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a public meeting of its Law Enforcement Advisory Panel (LEAP) via webinar.

DATES: The meeting/webinar will be held Monday, December 14, 2015, beginning at 1 p.m. EST and concluding by 3 p.m. EST.

ADDRESSES: The public documents can be obtained by contacting the Gulf of Mexico Fishery Management Council at (813) 348-1630 or on their Web site at *www.gulfcouncil.org*.

Meeting address: The meeting will be held via webinar. You may register to participate at: *https://attendee.gotowebinar.com/register/1596747440417850881*.

Council address: Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Steven Atran, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; telephone: (813) 348-1630; fax: (813) 348-1711; email: *steven.atran@gulfcouncil.org*.

SUPPLEMENTARY INFORMATION: The agenda for the meeting is as follows: The meeting will begin with adoption of agenda and review of scope of work. The Advisory Panel (AP) will discuss the ability of state enforcement agencies to provide background checks on advisory panel applicants for fishery violations in state waters involving federally managed stocks. The AP will also review the procedure for selecting candidates for the new Officer of the Year Program, and will discuss LEAP Representatives duties during council meetings. Lastly, any Other Business items, if any, may be discussed.

Special Accommodations

Requests for auxiliary aids should be directed to Kathy Pereira (see **ADDRESSES**), at least 5 working days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 23, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015-30186 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE302

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 41 Assessment Workshop for South Atlantic *red snapper* (*Lutjanus campechanus*) and *gray triggerfish* (*Balistes capriscus*).

SUMMARY: The SEDAR 41 assessments of the South Atlantic stocks of *red snapper* and *gray triggerfish* will consist of a series of workshops and webinars: Data Workshops; an Assessment Workshop and webinars; and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 41 Assessment Workshop will be held on December 14, 2015 from 9 a.m. until 6 p.m.; December 15-16, 2015 from 8 a.m. until 6 p.m., and December 17, 2015 from 8 a.m. until 1 p.m. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or

completed prior to the time established by this notice. Additional Assessment Webinars and the Review Workshop dates and times will publish in a subsequent issue in the **Federal Register**.

ADDRESSES:

Meeting address: The SEDAR 41 Assessment Workshop will be held at the Crystal Coast Civic Center, 3505 Arendell Street, Morehead City, NC 28557, 252-247-3883.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; www.sedarweb.org.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571-4366; email: julia.byrd@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs);

international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment Workshop are as follows:

1. Participants will use datasets provided by the Data Workshop to develop population models to evaluate stock status, estimate population benchmarks and Sustainable Fisheries Act criteria, and project future conditions, as specified in the Terms of Reference.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

3. Participants will prepare a workshop report, compare and contrast various assessment approaches, and determine whether the assessments are adequate for submission to the review panel.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 23, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015-30169 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of

information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Expenditure Survey of Highly Migratory Species Tournaments and Participants.

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection).

Number of Respondents: 3,225.

Average Hours Per Response:

Operator's survey, 30 minutes;

participant survey, 15 minutes.

Burden Hours: 863.

Needs and Uses: This request is for a new collection of information.

The objective of the study is to collect information on the earnings and expenditures of Atlantic and Hawaii Highly Migratory Species (HMS) tournament operators and participants. The study will use two survey instruments to collect information from tournament operators and participants. One survey will ask tournament operators to characterize and quantify their operating costs and income sources in addition to describing their tournament participants. The other survey instrument will ask fishing tournament participants to estimate their expenditures associated with travel to, entering, and participating in the tournament.

The National Marine Fisheries Service (NMFS) will collect cost and earnings data from all Atlantic and Hawaii HMS tournaments registered within the year (approximately 300 based on recent years' tournament registration data). In addition, NMFS will select fifty percent of registered tournaments to distribute expenditure surveys to anglers registered for those tournament events. The Atlantic HMS Management Division is currently consulting with tournament organizers and participants to design the survey instruments to ensure NMFS captures data on all relevant expenditures.

As specified in the Magnuson-Stevenson Fishery Conservation and Management Act of 1996 (and reauthorized in 2007), NMFS is required to enumerate the economic impacts of the policies it implements on fishing participants and coastal communities. The cost and earnings data collected in this survey will be used to estimate the economic contributions and impacts of Atlantic HMS tournaments regionally.

Affected Public: Business and other for-profit organizations; individuals or households.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 23, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–30166 Filed 11–25–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE322

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council (Council) will hold its 154th meeting.

DATES: The meeting will be held on December 15–16, 2015. The Council will convene on Tuesday, December 15, 2015, from 9 a.m. to 6 p.m., and will reconvene on Wednesday, December 16, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Marriott Frenchman's Reef Beach Resort, #5 Estate Bakkeroe, St. Thomas, USVI 00801.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918, telephone (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 154th regular Council Meeting to discuss the items contained in the following agenda: *December 15, 2015, 9 a.m.–5 p.m.*

°Call to Order

°Adoption of Agenda

°Consideration of 153rd Council Meeting Verbatim Transcriptions

°Executive Director's Report

°Report of Public Hearings on Timing of Accountability Measures-Based Closures Amendment

°SSC Report—Dr. Richard Appeldoorn

°SEDAR 46 Workshop (Nov. 2015)

Report

°Island Based FMP Developments Status and Next Steps

°AM-Based Season Closure Schedule for 2016

°NOAA Fisheries Ecosystem Based Fisheries Management Policy and Planning—Heather Sagar—PUBLIC COMMENT PERIOD—(5-minutes presentations)

December 15, 2015, 5:15 p.m.–6 p.m.

°Administrative Matters

—Budget Update FY 2015/16

—Other Administrative Business

—Closed Session

December 16, 2015, 9 a.m.–5 p.m.

°Outreach and Education Report—Dr.

Alida Ortiz

°MREP Update—Helena Antoun

°USVI Coral Reef Initiative—Ms. Leslie Henderson

°Coral Habitat and Queen Snapper Ecosystem—Dr. Jorge R. García-Sais

°Enforcement Issues:

—Puerto Rico-DNER

—U.S. Virgin Islands-DPNR

—U.S. Coast Guard

—NMFS/NOAA

°Meetings Attended by Council Members and Staff

—PUBLIC COMMENT PERIOD—(5-minute presentations)

°Other Business

°Next Council Meetings in 2016

°DAPs/SSC Meeting in March 2016

The established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. To further accommodate discussion and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date established in this notice.

The meeting is open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be subjects for formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice, and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. For more information or request for sign language interpretation and/or other auxiliary aids, please contact Mr. Miguel A. Rolón,

Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918, telephone (787) 766-5926, at least 5 days prior to the meeting date.

Dated: November 23, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015-30171 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE310

Fisheries of the Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 46 post-workshop webinar for Caribbean Data-limited Species.

SUMMARY: The SEDAR 46 assessment of the Caribbean Data-limited Species will consist of one in-person workshop and a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 46 post-workshop webinar will be held from 2 p.m. to 4 p.m. on December 14, 2015.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; phone: (843) 571-4366; email: Julie.neer@safmc.net

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in

the Southeast Region. SEDAR is a multi-step process including: (1) Data/Assessment Workshop, and (2) a series of webinars. The product of the Data/Assessment Workshop is a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment Process webinars are as follows:

1. Using datasets and initial assessment analysis recommended from the In-person Workshop, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 23, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015-30170 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE323

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Pier Maintenance Project

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued an incidental harassment authorization (IHA) to the U.S. Navy (Navy) to incidentally harass, by Level B harassment only, three species of marine mammals during construction activities associated with a pier maintenance project at Naval Base Kitsap Bremerton, WA.

DATES: This authorization is effective from December 1, 2015, through November 30, 2016.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Availability

An electronic copy of the Navy's application and supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the Internet at: www.nmfs.noaa.gov/pr/permits/incidental/construction.htm. A memorandum describing our adoption of the Navy's Environmental Assessment (2015) and our associated Finding of No Significant Impact, prepared pursuant to the National Environmental Policy Act, are also available at the same site. In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct

the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "... an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization. Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as "any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]."

Summary of Request

On April 14, 2015, we received a request from the Navy for authorization to take marine mammals incidental to pile driving and removal associated with the Pier 4 maintenance project at Naval Base Kitsap Bremerton, WA (NBKB). The Navy submitted revised versions of the request on May 20 and June 12, 2015, the latter of which we

deemed adequate and complete. The Navy submitted additional information related to a small amount of necessary maintenance work at the adjacent Pier 5 on November 18, 2015. The Navy plans to conduct this project, involving vibratory pile driving only, within the approved in-water work window. Hereafter, use of the generic term "pile driving" may refer to both pile installation and removal unless otherwise noted.

The use of vibratory pile driving is expected to produce underwater sound at levels that have the potential to result in behavioral harassment of marine mammals. Species with the expected potential to be present during the in-water work window include the Steller sea lion (*Eumetopias jubatus monteriensis*), California sea lion (*Zalophus californianus*), and harbor seal (*Phoca vitulina richardii*). All of these species may be present throughout the period of validity for this IHA.

Description of the Specified Activity

Overview

NBKB serves as the homeport for a nuclear aircraft carrier and other Navy vessels and as a shipyard capable of overhauling and repairing all types and sizes of ships. Other significant capabilities include alteration, construction, deactivation, and dry-docking of naval vessels. Pier 4 was completed in 1922 and requires substantial maintenance to maintain readiness. The Navy plans to remove up to 92 deteriorating fender piles and to replace them with new steel fender piles.

Dates and Duration

The allowable season for in-water work for this project is July 16 through February 15, a window related to bull trout (*Salvelinus confluentus*) occurrence in the project area. Under the specified activity a maximum of thirty pile driving days would occur. Pile driving may occur only during daylight hours. The IHA is valid for one year, from December 1, 2015, through November 30, 2016. The Navy requested a one-year period of validity for this IHA due to uncertainty regarding the project start date. However, the in-water work would occur within only a single work window; *i.e.*, would occur from December 1, 2015, through February 15, 2016, or would occur from July 16, 2016, through November 30, 2016.

Specific Geographic Region

NBKB is located on the north side of Sinclair Inlet in Puget Sound (see Figures 1–1 and 2–1 of the Navy's

application). Sinclair Inlet, an estuary of Puget Sound extending 3.5 miles southwesterly from its connection with the Port Washington Narrows, connects to the main basin of Puget Sound through Port Washington Narrows and then Agate Pass to the north or Rich Passage to the east. Sinclair Inlet has been significantly modified by development activities. Fill associated with transportation, commercial, and residential development of NBKB, the City of Bremerton, and the local ports of Bremerton and Port Orchard has resulted in significant changes to the shoreline. The area surrounding Pier 4 is industrialized, armored and adjacent to railroads and highways. Sinclair Inlet is also the receiving body for a wastewater treatment plant located just west of NBKB. Sinclair Inlet is relatively shallow and does not flush fully despite freshwater stream inputs.

Detailed Description of Activities

The Navy plans to remove eighty deteriorated 14-in timber fender piles at Pier 4 and replace them with eighty new 12 to 14-in steel fender piles. The Navy assumes a notional production rate of eight piles per day (removal) and four piles per day (installation) in determining the number of days of pile driving expected, and scheduling (as well as exposure analysis) is based on this assumption. All pile driving and removal would be accomplished with a vibratory driver (except where removal is accomplished by direct pull or other mechanical means, *e.g.*, clamshell, cutting). Vibratory driving and/or removal could occur on any work day during the period of the IHA. Only one pile driving rig is planned for operation at any given time.

Changes from the Notice of Proposed Authorization—The Navy requested an expansion of the specified activity to include additional maintenance work at the immediately adjacent Pier 5. This additional work will involve the removal and replacement of an additional twelve piles. The piles would be the same as those considered for Pier 4 (14-in timber piles to be removed and replaced with 12- to 14-in steel piles) and all pile driving and removal would be accomplished with a vibratory driver. This work would require an additional five in-water work days, but would not involve use of any additional or concurrent pile driving. We have determined that this additional work represents an inconsequential increase to the scope of work considered in our notice of proposed authorization (July 24, 2015; 80 FR 44033).

Comments and Responses

We published a notice of receipt of the Navy’s application and proposed IHA in the **Federal Register** on July 24, 2015 (80 FR 44033). We received a letter from the Marine Mammal Commission, which concurred with our preliminary findings and recommended that we issue the requested IHA, subject to inclusion of the proposed mitigation and monitoring measures. All mitigation and monitoring measures described in our notice of proposed IHA have been included in the IHA as issued. The Commission also recommended that we ensure that the Navy is sufficiently aware of the requirements set forth in the authorization, and we agree with the recommendation.

Description of Marine Mammals in the Area of the Specified Activity

There are five marine mammal species with records of occurrence in waters of Sinclair Inlet in the action area. These are the California sea lion, harbor seal, Steller sea lion, gray whale (*Eschrichtius robustus*), and killer whale (*Orcinus orca*). The harbor seal is a year-round resident of Washington inland waters, including Puget Sound, while the sea lions are absent for portions of the summer. For the killer whale, both transient (west coast stock) and resident (southern stock) animals have occurred in the area. However, southern resident animals are known to have occurred only once, with the last confirmed sighting from 1997 in Dyes Inlet. A group of 19 whales from the L-25 subpod entered and stayed in Dyes Inlet, which connects to Sinclair Inlet northeast of NBKB, for 30 days. Dyes

Inlet may be reached only by traversing from Sinclair Inlet through the Port Washington Narrows, a narrow connecting body that is crossed by two bridges, and it was speculated at the time that the whales’ long stay was the result of a reluctance to traverse back through the Narrows and under the two bridges. There is one other unconfirmed report of a single southern resident animal occurring in the project area, in January 2009. Of these stocks, the southern resident killer whale is listed (as endangered) under the Endangered Species Act (ESA).

An additional seven species have confirmed occurrence in Puget Sound, but are considered rare to extralimital in Sinclair Inlet and the surrounding waters. These species—the humpback whale (*Megaptera novaeangliae*), minke whale (*Balaenoptera acutorostrata scammoni*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), harbor porpoise (*Phocoena phocoena vomerina*), Dall’s porpoise (*Phocoenoides dalli dalli*), and northern elephant seal (*Mirounga angustirostris*), along with the southern resident killer whale—are considered extremely unlikely to occur in the action area or to be affected by the specified activities, and are not considered further in this document. A review of sightings records available from the Orca Network (www.orcanetwork.org; accessed July 13, 2015) confirms that there are no recorded observations of these species in the action area (with the exception of the southern resident sightings described above).

We have reviewed the Navy’s detailed species descriptions, including life history information, for accuracy and

completeness and refer the reader to Sections 3 and 4 of the Navy’s application instead of reprinting the information here. Please also refer to NMFS’ Web site (www.nmfs.noaa.gov/pr/species/mammals) for generalized species accounts and to the Navy’s Marine Resource Assessment for the Pacific Northwest, which documents and describes the marine resources that occur in Navy operating areas of the Pacific Northwest, including Puget Sound (DoN, 2006). The document is publicly available at www.navfac.navy.mil/products_and_services/ev/products_and_services/marine_resources/marine_resource_assessments.html (accessed November 13, 2015). We provided additional information for marine mammals with potential for occurrence in the area of the specified activity in our **Federal Register** notice of proposed authorization (July 24, 2015; 80 FR 44033).

Table 1 lists the marine mammal species with expected potential for occurrence in the vicinity of NBKB during the project timeframe and summarizes key information regarding stock status and abundance. Taxonomically, we follow Committee on Taxonomy (2014). Please see NMFS’ Stock Assessment Reports (SAR), available at www.nmfs.noaa.gov/pr/sars, for more detailed accounts of these stocks’ status and abundance. The harbor seal, California sea lion, and gray whale are addressed in the Pacific SARs (e.g., Carretta *et al.*, 2015), while the Steller sea lion and transient killer whale are treated in the Alaska SARs (e.g., Allen and Angliss, 2015).

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF NBKB

Species	Stock	ESA/MMPA status; strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR ³	Annual M/SI ⁴	Relative occurrence in Sinclair Inlet; season of occurrence
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae						
Gray whale	Eastern North Pacific ...	–; N	20,990 (0.05; 20,125; 2010–11).	624	132 ⁹	Rare; year-round.
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Killer whale	West coast transient ⁵ ..	–; N	243 (n/a; 2009)	2.4	0	Rare; year-round.
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
California sea lion.	U.S.	–; N	296,750 (n/a; 153,337; 2011).	9,200	389	Common; year-round (excluding July).

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF NBKB—Continued

Species	Stock	ESA/MMPA status; strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR ³	Annual M/SI ⁴	Relative occurrence in Sinclair Inlet; season of occurrence
Steller sea lion ..	Eastern U.S.	–; N ⁷	60,131–74,448 (n/a; 36,551; 2008–13) ⁸ .	1,645	92.3	Occasional/seasonal; Oct-May.
Family Phocidae (earless seals)						
Harbor seal	Washington northern inland waters ⁶ .	–; N	11,036 (0.15; 7,213; 1999).	undetermined	>2.8	Common; year-round.

¹ ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (–) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR (see footnote 3) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

² CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For killer whales, the abundance values represent direct counts of individually identifiable animals; therefore there is only a single abundance estimate with no associated CV. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the specie's (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore. The most recent abundance survey that is reflected in the abundance estimate is presented; there may be more recent surveys that have not yet been incorporated into the estimate.

³ Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP).

⁴ These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value.

⁵ The abundance estimate for this stock includes only animals from the "inner coast" population occurring in inside waters of southeastern Alaska, British Columbia, and Washington—excluding animals from the "outer coast" subpopulation, including animals from California—and therefore should be considered a minimum count. For comparison, the previous abundance estimate for this stock, including counts of animals from California that are now considered outdated, was 354.

⁶ Abundance estimates for these stocks are greater than eight years old and are therefore not considered current. PBR is considered undetermined for these stocks, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates and PBR values, as these represent the best available information for use in this document.

⁷ The eastern distinct population segment of the Steller sea lion, previously listed under the ESA as threatened, was delisted on December 4, 2013 (78 FR 66140; November 4, 2013).

⁸ Best abundance is calculated as the product of pup counts and a factor based on the birth rate, sex and age structure, and growth rate of the population. A range is presented because the extrapolation factor varies depending on the vital rate parameter resulting in the growth rate (i.e., high fecundity or low juvenile mortality).

⁹ Includes annual Russian harvest of 127 whales.

Potential Effects of the Specified Activity on Marine Mammals

Our Federal Register notice of proposed authorization (July 24, 2015; 80 FR 44033) provides a general background on sound relevant to the specified activity as well as a detailed description of marine mammal hearing and of the potential effects of these construction activities on marine mammals.

Anticipated Effects on Habitat

We described potential impacts to marine mammal habitat in detail in our Federal Register notice of proposed authorization (July 24, 2015; 80 FR 44033). In summary, we have determined that given the short daily duration of sound associated with individual pile driving events and the relatively small areas being affected, pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. The area around NBKB, including the adjacent ferry terminal and nearby marinas, is heavily altered with significant levels of industrial and

recreational activity, and is unlikely to harbor significant amounts of forage fish. Thus, any impacts to marine mammal habitat are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

Measurements from similar pile driving events were coupled with practical spreading loss to estimate zones of influence (ZOI; see "Estimated Take by Incidental Harassment"); these values were used to develop mitigation measures for pile driving activities at NBKB. The ZOIs effectively represent the mitigation zone that would be established around each pile to prevent

Level A harassment to marine mammals, while providing estimates of the areas within which Level B harassment might occur. In addition to the specific measures described later in this section, the Navy will conduct briefings between construction supervisors and crews, marine mammal monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

Monitoring and Shutdown for Pile Driving

The following measures apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—For all pile driving activities, the Navy will establish a shutdown zone intended to contain the area in which SPLs equal or exceed the acoustic injury criteria for pinnipeds (190 dB root mean square [rms]). The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a

marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury of marine mammals (as described previously under “Potential Effects of the Specified Activity on Marine Mammals” in our notice of proposed authorization [July 24, 2015; 80 FR 44033], serious injury or death are unlikely outcomes even in the absence of mitigation measures). Modeled radial distances for shutdown zones are shown in Table 2. Although no potential for injury is predicted, a minimum shutdown zone of 10 m will be established during all pile driving activities. This precautionary measure is intended to prevent the already unlikely possibility of physical interaction with construction equipment and to further reduce any possibility of acoustic injury.

Disturbance Zone—Disturbance zones are the areas in which SPLs equal or exceed 160 and 120 dB rms (for impulse and continuous sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (*i.e.*, shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see “Monitoring and Reporting”). Nominal radial distances for disturbance zones are shown in Table 2.

In order to document observed incidents of harassment, monitors record all marine mammal observations, regardless of location. The observer’s location, as well as the location of the pile being driven, is known from a GPS. The location of the animal is estimated as a distance from the observer, which is then compared to the location from the pile. It may then be estimated whether the animal was exposed to sound levels constituting incidental harassment on the basis of predicted distances to relevant thresholds in post-processing of observational and acoustic data, and a precise accounting of observed incidences of harassment created. This information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes.

Monitoring Protocols—Monitoring will be conducted before, during, and after pile driving activities. In addition, observers shall record all incidents of

marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment would be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities must be halted. Monitoring will take place from fifteen minutes prior to initiation through thirty minutes post-completion of pile driving activities. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes. Please see the Monitoring Plan (Appendix C in the Navy’s application), developed by the Navy in consultation with NMFS, for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water’s surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Advanced education in biological science or related field (undergraduate degree or higher required);
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown

zone; and marine mammal behavior; and

- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for fifteen minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (*i.e.*, must leave of their own volition) and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (*i.e.*, when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity must be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile.

Special Conditions

The Navy did not request the authorization of incidental take for killer whales or gray whales (see discussion below in “Estimated Take by Incidental Harassment”). Therefore, shutdown will be implemented in the event that either of these species is observed in the vicinity, prior to entering the defined disturbance zone. As described later in this document, we believe that occurrence of these species during the in-water work window would be uncommon and that the occurrence of an individual or group would likely be highly noticeable and would attract significant attention in local media and with local whale watchers and interested citizens. Prior to the start of pile driving on any day, the Navy will contact and/or review the latest sightings data from the Orca Network and/or Center for Whale Research to determine the location of the nearest marine mammal sightings. The Orca Sightings Network consists of a list of over 600 residents, scientists, and government agency personnel in the U.S. and Canada, and includes passive acoustic detections. The presence of a killer whale or gray whale in the

southern reaches of Puget Sound would be a notable event, drawing public attention and media scrutiny. With this level of coordination in the region of activity, the Navy should be able to effectively receive real-time information on the presence or absence of whales, sufficient to inform the day's activities. Pile driving will not occur if there was the risk of incidental harassment of a species for which incidental take was not authorized.

One land-based observer will be positioned at the pier work site. Additionally, one vessel-based observer will travel through the monitoring area, completing an entire loop approximately every thirty minutes (please see Figure 1 of Appendix C in the Navy's applications). If any killer whales or gray whales are detected, activity would not begin or would shut down.

Timing Restrictions

In the project area, designated timing restrictions exist to avoid in-water work when salmonids and other spawning forage fish are likely to be present. The in-water work window is July 16–February 15. All in-water construction activities will occur only during daylight hours (sunrise to sunset).

Soft Start

The use of a soft start procedure is believed to provide additional protection to marine mammals by warning or providing a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from the hammer at reduced energy followed by a waiting period. This procedure is repeated two additional times. It is difficult to specify the reduction in energy for any given hammer because of variation across drivers. The pier maintenance project will utilize soft start techniques, which require the Navy to initiate sound from vibratory hammers for fifteen seconds at reduced energy followed by a thirty-second waiting period, with the procedure repeated two additional times. Soft start will be required at the beginning of each day's pile driving work and at any time following a cessation of pile driving of thirty minutes or longer.

We have carefully evaluated the Navy's proposed mitigation measures and considered their effectiveness in past implementation to determine whether they are likely to effect the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one

another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(3) A reduction in the number (total number or number at biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(4) A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing the severity of behavioral harassment only).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation, an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the Navy's proposed measures, as well as any other potential measures that may be relevant to the specified activity, we have determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Any monitoring requirement we prescribe should improve our understanding of one or more of the following:

- Occurrence of marine mammal species in action area (*e.g.*, presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) Affected species (*e.g.*, life history, dive patterns); (3) Co-occurrence of marine mammal species with the action; or (4) Biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas).
- Individual responses to acute stressors, or impacts of chronic exposures (behavioral or physiological).
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of an individual; or (2) Population, species, or stock.
- Effects on marine mammal habitat and resultant impacts to marine mammals.
- Mitigation and monitoring effectiveness.

The Navy marine mammal monitoring plan can be found as Appendix C of the Navy's application, on the Internet at www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy will monitor the shutdown zone and disturbance zone before, during, and

after pile driving, with observers located at the best practicable vantage points. Based on our requirements, the Navy would implement the following procedures for pile driving:

- MMOs will be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.
- During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.
- If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity must be halted.

• The shutdown and disturbance zones around the pile will be monitored for the presence of marine mammals before, during, and after any pile driving or removal activity.

Two observers will be deployed as described under Mitigation, including one land-based observer and one-vessel-based observer traversing the extent of the Level B harassment zone. Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use approved data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, the Navy will attempt to distinguish between the number of individual animals taken and the number of incidents of take. We require that, at a minimum, the following information be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.*, percent cover, visibility);
- Water conditions (*e.g.*, sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns,

including bearing and direction of travel and distance from pile driving activity;

- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Description of implementation of mitigation measures (*e.g.*, shutdown or delay);
- Locations of all marine mammal observations; and
- Other human activity in the area.

Reporting

A draft report will be submitted to NMFS within 45 days of the completion of marine mammal monitoring, or sixty days prior to the issuance of any subsequent IHA for this project, whichever comes first. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any behavioral responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and an extrapolated total take estimate based on the number of marine mammals observed during the course of construction. A final report must be submitted within thirty days following resolution of comments on the draft report.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines “harassment” as: “. . . any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].”

All anticipated takes would be by Level B harassment resulting from vibratory and impact pile driving and involving temporary changes in behavior. The planned mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by Level A harassment, serious injury, or mortality is considered extremely unlikely. However, it is unlikely that injurious or lethal takes would occur even in the absence of the planned mitigation and monitoring measures.

If a marine mammal responds to a stimulus by changing its behavior (*e.g.*,

through relatively minor changes in locomotion direction/speed or vocalization behavior), the response may or may not constitute taking at the individual level, and is unlikely to affect the stock or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on animals or on the stock or species could potentially be significant (*e.g.*, Lusseau and Bejder, 2007; Weilgart, 2007). Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound. In practice, depending on the amount of information available to characterize daily and seasonal movement and distribution of affected marine mammals, it can be difficult to distinguish between the number of individuals harassed and the instances of harassment and, when duration of the activity is considered, it can result in a take estimate that overestimates the number of individuals harassed. In particular, for stationary activities, it is more likely that some smaller number of individuals may accrue a number of incidences of harassment per individual than for each incidence to accrue to a new individual, especially if those individuals display some degree of residency or site fidelity and the impetus to use the site (*e.g.*, because of foraging opportunities) is stronger than the deterrence presented by the harassing activity.

The project area is not believed to be particularly important habitat for marine mammals, nor is it considered an area frequented by marine mammals, although harbor seals may be present year-round and sea lions are known to haul-out on man-made objects at the NBKB waterfront. Sightings of other species are rare. Therefore, behavioral disturbances that could result from anthropogenic sound associated with these activities are expected to affect only a relatively small number of individual marine mammals, although those effects could be recurring over the life of the project if the same individuals remain in the project vicinity.

The Navy requested authorization for the incidental taking of small numbers of Steller sea lions, California sea lions, and harbor seals in Sinclair Inlet and nearby waters that may result from pile driving during construction activities associated with the pier maintenance project described previously in this document. In order to estimate the

potential incidents of take that may occur incidental to the specified activity, we first estimated the extent of the sound field that may be produced by the activity and then considered that in combination with information about marine mammal density or abundance in the project area. We provided detailed information on applicable sound thresholds for determining effects to marine mammals as well as describing the information used in

estimating the sound fields, the available marine mammal density or abundance information, and the method of estimating potential incidents of take, in our **Federal Register** notice of proposed authorization (July 24, 2015; 80 FR 44033). The only change to that information is the addition of five days of in-water pile driving to account for the additional work to be conducted at the adjacent Pier 5, increasing the total in-water work days from thirty to 35.

Our take estimates were calculated in the same manner and on the basis of the same information as what was described in the **Federal Register** notice. Modeled distances to relevant thresholds are shown in Table 2 and total estimated incidents of take are shown in Table 3. Please see our **Federal Register** notice of proposed authorization (July 24, 2015; 80 FR 44033) for full details of the process and information used in estimating potential incidents of take.

TABLE 2—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION, UNDERWATER

Description	Distance to threshold (m) and associated area of ensonification (km ²) ¹			
	190 dB	180 dB	160 dB	120 dB
Steel piles, vibratory	0	0	n/a	2,154 ² , 7.5
Timber piles, vibratory	0	0	n/a	1,585; 5.0

¹ SPLs used for calculations were: 170 dB for vibratory removal of steel piles, and 168 dB for vibratory removal of timber piles.
² Areas presented take into account attenuation and/or shadowing by land. Please see Appendix B in the Navy's applications.

Sinclair Inlet does not represent open water, or free field, conditions. Therefore, sounds would attenuate according to the shoreline topography. Distances shown in Table 2 are estimated for free-field conditions, but areas are calculated per the actual

conditions of the action area. See Appendix B of the Navy's application for a depiction of areas in which each underwater sound threshold is predicted to occur at the project area due to pile driving.
 The additional five days of pile driving work result in an increase in the

estimated take numbers from what was considered in our notice of proposed authorization. The total numbers of authorized takes shown in Table 3 represent an increase of approximately seventeen percent for each species.

TABLE 3—CALCULATIONS FOR INCIDENTAL TAKE ESTIMATION

Species	n (animals/km ²) ¹	n * ZOI (vibratory steel pile removal) ²	Abundance ³	Total authorized takes (% of total stock)
California sea lion	0.1266	1	48	1,680 (0.6)
Steller sea lion	0.0368	0	1	35 (0.06)
Harbor seal	1.219 ⁴	9	11	385 (3.5)
Killer whale (transient)	0.0024 (fall)	0	n/a	0
Gray whale	0.0005 (winter)	0	n/a	0

¹ Best available species- and season-specific density estimate, with season noted in parentheses where applicable (Hanser *et al.*, 2015).
² Product of density and largest ZOI (7.5 km²) rounded to nearest whole number; presented for reference only.
³ Best abundance numbers multiplied by expected days of activity (35) to produce take estimate.
⁴ Uncorrected density; presented for reference only.

Analyses and Determinations

Negligible Impact Analysis

NMFS has defined “negligible impact” in 50 CFR 216.103 as “. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.” A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of Level B harassment takes alone is not enough information on which to base an impact determination. In addition to

considering estimates of the number of marine mammals that might be “taken” through behavioral harassment, we consider other factors, such as the likely nature of any responses (*e.g.*, intensity, duration), the context of any responses (*e.g.*, critical reproductive time or location, migration), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

Pile driving activities associated with the pier maintenance project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B

harassment (behavioral disturbance) only, from underwater sounds generated from pile driving. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving is happening.

No injury, serious injury, or mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. The potential for these outcomes is minimized through the construction method and the implementation of the planned mitigation measures. Specifically, piles will be installed and removed via vibratory means, an activity that does not have the potential to cause injury to

marine mammals due to the relatively low source levels produced (less than 180 dB) and the lack of potentially injurious source characteristics.

Environmental conditions in Sinclair Inlet are expected to generally be good, with calm sea states, although Sinclair Inlet waters may be more turbid than waters further north in Puget Sound or in Hood Canal. Nevertheless, we expect conditions in Sinclair Inlet will allow a high marine mammal detection capability for the trained observers required, enabling a high rate of success in implementation of shutdowns. In addition, the topography of Sinclair Inlet should allow for placement of observers sufficient to detect cetaceans, should any occur (see Figure 1 of Appendix C in the Navy's application).

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (e.g., Thorson and Reyff, 2006; HDR, 2012). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in San Francisco Bay and in the Puget Sound region, which have taken place with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment will be reduced to the level of least practicable impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring.

We preliminarily determined in our notice of proposed authorization that the effects of the specified activity would represent a negligible impact on the affected marine mammal stocks. Here, we have added an additional five

days of in-water pile driving (of the same size and type of piles, by the same methods, and adhering to the same mitigation and monitoring requirements) and determine that the likely total impacts to the affected marine mammal stocks, considering the additional activity, remains within the scope of analysis provided in our notice of proposed authorization.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable; (2) the anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior; (3) the absence of any significant habitat within the project area, including rookeries, significant haul-outs, or known areas or features of special significance for foraging or reproduction; (4) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of least practicable impact. In addition, these stocks are not listed under the ESA or considered depleted under the MMPA. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The specified activity is not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the planned monitoring and mitigation measures, we find that the total marine mammal take from Navy's pier maintenance activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers Analysis

The number of incidents of take authorized for these stocks would be considered small relative to the relevant stocks or populations (less than one percent for both sea lion stocks and three percent for harbor seals; Table 3) even if each estimated taking occurred to a new individual. This is an extremely unlikely scenario as, for pinnipeds in estuarine/inland waters, there is likely to be some overlap in individuals present day-to-day.

We preliminarily determined in our notice of proposed authorization that the total taking proposed for authorization would be small relative to

the populations of the affected species or stocks. The additional takes authorized due to the addition of five in-water pile driving days result in slight increases for each species (0.5 percent to 0.6 percent for California sea lions; 0.05 percent to 0.06 percent for Steller sea lions; 3.0 percent to 3.5 percent for harbor seals). These increases do not affect the preliminary small numbers determination.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, we find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

No marine mammal species listed under the ESA are expected to be affected by these activities. Therefore, we have determined that a section 7 consultation under the ESA is not required.

National Environmental Policy Act (NEPA)

In compliance with the NEPA of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (CEQ; 40 CFR parts 1500–1508), the Navy prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from the pier maintenance project. We made the Navy's EA available to the public for review and comment, in relation to its suitability for adoption in order to assess the impacts to the human environment of issuance of an IHA to the Navy. In compliance with NEPA, the CEQ regulations, and NOAA Administrative Order 216–6, we subsequently adopted that EA and signed a Finding of No Significant Impact (FONSI) on November 5, 2015. The 2015 NEPA documents are available for review at www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.

We considered the addition of five days of in-water pile driving work at the same location and time, involving the same size and type of piles and conducted by the same means (*i.e.*, vibratory hammer), and determined that the addition of this activity remains within the scope of analysis provided by the Navy's EA and considered in our adoption memorandum and FONSI. Therefore, we do not need to conduct additional analysis under NEPA.

Authorization

As a result of these determinations, we have issued an IHA to the Navy for conducting the described pier maintenance activities in Sinclair Inlet, from December 1, 2015, through November 30, 2016, provided the previously described mitigation, monitoring, and reporting requirements are incorporated.

Dated: November 20, 2015.

Perry F. Gayaldo,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015-30125 Filed 11-25-15; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE315

Endangered Species; File Nos. 19331 and 19642

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of applications.

SUMMARY: Notice is hereby given that Harold Brundage [Responsible Party], Environmental Research and Consulting, Inc.; 126 Bancroft Rd; Kennett Square, PA 19348, has applied in due form for a permit [File No. 19331] to take shortnose sturgeon (*Acipenser brevirostrum*) and Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*) for purposes of conducting scientific research; and that Jason Kahn [Responsible Party], NOAA Fisheries, 1315 East-West Highway, Silver Spring, MD 20910, has applied in due form for a permit to take shortnose sturgeon and Atlantic sturgeon for purposes of scientific research.

DATES: Written, telefaxed, or email comments must be received on or before December 28, 2015.

ADDRESSES: The applications and related documents are available for

review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting either File No. 19331 or File No. 19642 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on these applications should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713-0376, or by email to NMFS.Pr1Comments@noaa.gov. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on either of these applications would be appropriate.

FOR FURTHER INFORMATION CONTACT:

Malcolm Mohead or Rosa L. González, (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject permits are requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

File No. 19331: The applicant proposes to combine and continue similar shortnose and Atlantic sturgeon research currently authorized in the Delaware River and Estuary by Permit No 14604 (expiring on April 19, 2016) and Permit No. 16438 (expiring on April 5, 2017), respectively. At issuance of Permit No. 19331, both of the former permits would be terminated. The applicant's new objectives would be to characterize Atlantic and shortnose sturgeon habitat use in the lower Delaware River (between rkm 0 to rkm 245), studying the relative abundance, recruitment, temporal-spatial distributions, and reproduction, as well as assessing the potential for entrainment and impingement of various life stages of Atlantic and shortnose sturgeon at the intakes of selected industrial sites on the Delaware River. The permit would be valid for five years from the date of issuance.

File No. 19642: The applicant has proposed two studies to study Atlantic

and shortnose sturgeon in the Chesapeake Bay and other river systems of the Atlantic coast. The primary objective of Study No. 1 would be discovering and quantifying new populations of Atlantic and shortnose sturgeon in the York, Rappahannock, Potomac, and Susquehanna Rivers, and other Chesapeake Bay tributaries of Virginia and Maryland. Researchers would also attempt to monitor spawning activity, movement, and habitat use of individuals of these populations through telemetry and side-scan sonar technology. In Study No. 2, researchers would opportunistically sample Atlantic and shortnose sturgeon legally captured under ESA incidental take permits or incidental take statements authorized by NMFS in other actions. Goals would be to track coastal movements of both species in mixed marine stocks. The permit would be valid for five years from the date of issuance.

Dated: November 23, 2015.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015-30133 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Technical Information Service

National Technical Information Service Advisory Board Meeting

AGENCY: National Technical Information Service, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice announces the next meeting of the National Technical Information Service Advisory Board (the Advisory Board), which advises the Secretary of Commerce and the Director of the National Technical Information Service (NTIS) on policies and operations of the Service.

DATES: The Advisory Board will meet on Monday, December 7, 2015 from 10:00 a.m. to approximately 2:30 p.m.

ADDRESSES: The Advisory Board will be held in Room 116 of the NTIS Facility at 5301 Shawnee Road, Alexandria, Virginia 22312. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Borzino, (703) 605-6405, bborzino@ntis.gov.

SUPPLEMENTARY INFORMATION: The NTIS Advisory Board is established by section 3704b(c) of title 15 of the United States

Code. The charter has been filed in accordance with the requirements of the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

The meeting will focus on a review of NTIS data mission and strategic direction. A final agenda and summary of the proceedings will be posted at NTIS Web site as soon as they are available (<http://www.ntis.gov/about/advisorybd.aspx>).

The NTIS Facility is a secure one. Accordingly persons wishing to attend should call the NTIS Visitors Center, (703) 605-6040, to arrange for admission no later than Thursday, December 3, 2015. If there are sufficient expressions of interest, up to one-half hour will be reserved for public comments during the session. Questions from the public will not be considered by the Board but any person who wishes to submit a written question for the Board's consideration should mail or email it to the NTIS Visitor Center, bookstore@ntis.gov, Subject: NTIS Advisory Board, not later than Thursday, December 3, 2015.

Dated: November 23, 2015.

Bruce Borzino,
Director.

[FR Doc. 2015-30198 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-04-P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Digital Economy Board of Advisors, Establishment and Call for Nominations

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of establishment and call for nominations to serve on the Digital Economy Board of Advisors.

SUMMARY: The Assistant Secretary for Communications and Information announces the establishment of the Digital Economy Board of Advisors on behalf of the Secretary of Commerce. The Board will advise and provide recommendations to the Secretary, through the Assistant Secretary, on a broad range of issues concerning the digital economy and Internet policy. This Notice also requests nominations of individuals for membership on the Board.

DATES: Nominations should be submitted electronically using the online nomination form on or before December 23, 2015, at midnight Eastern Standard Time.

ADDRESSES: Applicants should submit nominations electronically, with the information specified below, using the online nomination form located at www.ntia.doc.gov/digital-economy.

FOR FURTHER INFORMATION CONTACT:

Evelyn Remaley, Designated Federal Officer (DFO), at (202) 482-3821 or DEBA@ntia.doc.gov.

SUPPLEMENTARY INFORMATION: Pursuant the Federal Advisory Committee Act, as amended (5 U.S.C. App.) and the National Telecommunications & Information Administration's authorizing statute, 47 U.S.C. 904(b), the Assistant Secretary for Communications and Information (Assistant Secretary) announces the establishment of the Digital Economy Board of Advisors (the Board) on behalf of the Secretary of Commerce. The Board is established under the direction of the Secretary and with the concurrence of the General Services Administration.

I. Background

Economic prosperity is increasingly tied to the digital economy, which is a key driver of jobs, business creation, and innovation. Indeed, virtually every modern company relies on the Internet to grow and thrive. As a result, the Department of Commerce (Department) has made technology and Internet policy a top priority, investing resources to address the challenges and opportunities businesses face in a global economy.

On November 9, 2015, the Secretary of Commerce unveiled the Department's new Digital Economy Agenda, which will help businesses and consumers realize the potential of the digital economy to advance growth and opportunity. The Agenda focuses on four key objectives: promoting a free and open Internet worldwide; promoting trust online; ensuring access for workers, families, and companies; and promoting innovation. To support the Agenda, the Secretary has directed the creation of a Digital Economy Board of Advisors to enable the Department to have a mechanism for receiving regular advice from leaders in industry, academia, and civil society. The Secretary determined that the establishment of the Board is necessary and serves the public interest.

II. Description of Duties

The Board's primary duty will be to provide independent advice and recommendations to the Secretary, through the Assistant Secretary, on a broad range of policy issues impacting the digital economy. The Board will serve as a centralized forum for

gathering consensus input from a wide range of stakeholders and experts. The Board's mission is to provide advice in furtherance of increasing domestic prosperity, improving education, and facilitating participation in political and cultural life through the application and expansion of digital technologies.

The Board's advice will focus on ensuring that the Internet continues to thrive as an engine of growth, innovation, and free expression. In carrying out its duties, the Board's activities may include, but are not limited to:

- Gathering information and providing an analysis of challenges related to the global free flow of information on the Internet, including policies that could restrict cross-border information flows;
- Providing advice on other policy matters that impact the digital economy, such as expanding broadband capacity, enhancing cybersecurity, protecting privacy, and examining the role of intermediaries;
- Promoting the development of new digital technologies, and
- Analyzing the impact of the Internet on job growth and the economy as a whole.

The Department will use the advice provided by the Board to inform its decision-making process and advance Administration goals.

III. Board Structure and Composition

The Board will be comprised of no fewer than five (5) and no more than 30 members, including the Chair(s). The Secretary will appoint members of the Board for two-year terms. Members will serve at the Secretary's pleasure and discretion and may be reappointed for additional terms. The Assistant Secretary, with input from the Secretary, will appoint one or more members to serve as Chair or Co-Chairs. The Chair(s) will serve at the pleasure and discretion of the Assistant Secretary. The Board will meet approximately quarterly, or as determined by the DFO.

The Board will consist of leaders in industry and civil society who are prominent experts in their fields and recognized for their professional achievements. The Secretary will appoint objective members and ensure balanced representation. Membership is voluntary and, thus, members will not receive compensation for their time or reimbursement for travel or per diem expenses.

Members of the Board will be appointed as Special Government Employees (SGEs). See <http://www.oge.gov/Topics/Selected->

Employee-Categories/Special-Government-Employees. As SGEs, members must comply with certain federal conflict of interest statutes and ethics regulations, including some financial disclosure requirements. To permit evaluation of possible sources of conflicts of interest, selected candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Board.

Appointments will be made without regard to political affiliation. Each nominee will need to certify that he or she is not currently a registered federal lobbyist pursuant to the Lobbying Disclosure Act of 1995 (codified at 2 U.S.C. 1601 *et seq.*). See *Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions*, Office of Management and Budget, 79 FR 47482 (Aug. 13, 2014). Each nominee will also be required to certify that he or she is not currently an agent of a foreign principal required to register pursuant to the Foreign Agents Registration Act of 1938, as amended (codified at 22 U.S.C. 611 *et seq.*).

If a term expires or a vacancy occurs during the life of the Board, the Assistant Secretary may recommend any of the following:

- Reappointment of an incumbent;
- Solicitation for new applications published in the **Federal Register** in accordance with regular procedures; or
- Selection of a replacement from a list of candidates whose applications were received within the previous year.

IV. Nominations

Individuals may nominate themselves or other individuals. Professional associations and other organizations may nominate one or more qualified persons for membership on the Board. Nominations shall state that the nominee has been consulted and is willing to serve as a Special Government Employee. All nominations must provide the following information:

- A letter of nomination stating the full name, affiliation, and contact information for the nominee, the basis for the nomination, and the nominee's field(s) of expertise;
- a biographical sketch of the nominee and/or a copy of his or her curriculum vitae; and
- if applicable, the name, return address, email address, and daytime phone number at which the nominator can be contacted.

Nominations should be submitted electronically using the online

nomination form located at www.ntia.doc.gov/digital-economy.

The Assistant Secretary will review the nominations and make recommendations to the Secretary for appointments. Among other factors, the Secretary and Assistant Secretary will consider nominees' experience and knowledge of digital economy issues in addition to:

- Educational background (e.g., advance degree in engineering, economics, law, business, or public policy);
- Professional experience and accomplishments (e.g., nature of work, job function, projects, or publications); and
- Current employment and membership in associations (e.g., technology developers, manufacturers, academia, civil society, service providers with customers in domestic and international markets).

All appointments will be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, disability, or cultural, religious, or socioeconomic status.

Dated: November 23, 2015.

Lawrence E. Strickling,

Assistant Secretary for Communications and Information.

[FR Doc. 2015-30226 Filed 11-25-15; 8:45 am]

BILLING CODE 3510-60-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List, Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Effective Date: 12/27/2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603-7740, Fax: (703) 603-0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 8/4/2015 (80 FR 46250); 8/21/2015 (80 FR 50825-50826) and 9/25/2015 (80

FR 57792), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will provide the services to the Government.
2. The action will result in authorizing small entities to provide the services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following services are added to the Procurement List:

Services

Services

Service Type: Contractor Operated Parts Store (COPARS) Service

Service Is Mandatory For: US Marine Corps Garrison Mobile Equipment Branch, Marine Corps Logistics Base, Building 5400, Albany, GA

Mandatory Source(s) of Supply: Training, Rehabilitation, & Development Institute, Inc., San Antonio, TX

Contracting Activity: Dept of the Navy, Commanding General, Camp Lejeune, NC

The Commission was copied on a letter to the contracting officer from an incumbent contractor's law firm. While not received in response to the initial **Federal Register** notice, the Commission will, nevertheless, address the comments noted in the letter.

On behalf of the incumbent contractor, the law firm noted that the contractor has held the contract for three years and has retained experienced employees who have established a positive working relationship in providing the required services. The firm submitted that the contractor was the most capable and efficient provider of the required

services and could continue to perform with the best stewardship of the taxpayers' money. The firm questioned whether the proposed nonprofit agency could perform the required services within the restraints of the AbilityOne Program's requirement to employ people with severe disabilities and noted that some of its employees were contacted by the nonprofit agency and offered employment. Finally, while noting that the contract was not a major portion of the contractor's business portfolio, the loss of the contract would have a significant financial impact since it would result in the loss of a major profit margin contract without providing specific information to substantiate the impact or how the impact would be measured.

The U.S. AbilityOne Commission (statutorily identified as the Committee for Purchase from People Who Are Blind or Severely Disabled) (Commission) administers the AbilityOne® program under the authority of the Javits-Wagner-O'Day Act. Commission responsibilities include identifying products and services produced or provided by qualified nonprofit agencies employing people who are blind or severely disabled that the Commission determines are suitable for procurement by the Government. Prior to adding any project to the Procurement List (PL), the Commission reviews each project for suitability including, employment potential, nonprofit agency qualifications, capability, and level of impact on the current contractor. If the Commission is satisfied that each of these four criteria are met, then the service can be added to the PL and it becomes a mandatory requirement for the government agency to obtain the service from the designated nonprofit agency if available within the required time frame.

The Commission does not dispute that the contractor is effectively performing the required services; however, that does not mean that it is the only contractor that can effectively perform the services or that the AbilityOne Commission cannot add the work to the Procurement List for performance by a nonprofit agency in the AbilityOne Program. The Commission has reviewed and determined that the project will result in employment for people with severe disabilities and the designated nonprofit agency is qualified under the Commission's 75% ratio requirement and otherwise and capable of performing the services. Additionally, the Commission reviews financial information provided by current

contractors to determine whether severe adverse impact will occur if a project is added to the PL. The Commission did so in this instance and disagrees with the contractor's assertion that the addition of this project to the PL will result in severe adverse impact to the contractor company. The Commission has reviewed the specific requirements of this project and determined that this project is suitable for performance by a nonprofit agency employing people who are blind or severely disabled. Placing this project on the PL will result in employment and training opportunities for people with severe disabilities.

Accordingly, following a deliberative review of the facts of this project, the Commission determines that this project is appropriate for the AbilityOne Program and will be added to the Procurement List.

Service Type: Removal/Clean-up Bird Dropping Service

Service Is Mandatory For: Defense Logistics Agency, Defense Supply Center, 8000 Jefferson Davis Highway, Richmond, VA

Mandatory Source(s) of Supply: Richmond Area Association for Retarded Citizens, Richmond, VA

Contracting Activity: Defense Logistics Agency Contracting Services Office, Richmond, VA

Service Type: Custodial and Related Service

Service Is Mandatory For: GSA PBS Region 4, Benjamin P. Grogan and Jerry L. Dove Federal Building, 2030 SW. 145th Avenue, Miramar, FL

Mandatory Source(s) of Supply: CW Resources, Inc., New Britain, CT

Contracting Activity: Public Buildings Service, Acquisition Division/Services Branch, Atlanta, GA

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015-30145 Filed 11-25-15; 8:45 am]

BILLING CODE 6353-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 16-C0001]

Philips Lighting North America Corporation, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the **Federal Register** in accordance with the terms of 16 CFR 1118.20(e). Published below is a provisionally-accepted Settlement Agreement with Philips

Lighting North America Corporation containing a civil penalty in the amount of two million dollars (\$2,000,000), within thirty (30) days of service of the Commission's final Order accepting the Settlement Agreement.¹

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by December 14, 2015.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 16-C0001, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, Maryland 20814-4408.

FOR FURTHER INFORMATION CONTACT: Amy S. Colvin, Attorney, Office of the General Counsel, Division of Enforcement and Information, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814-4408; telephone (301) 504-7639.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: November 23, 2015.

Todd A. Stevenson,
Secretary.

United States of America Consumer Product Safety Commission

In the Matter of: Philips Lighting North America Corporation

CPSC Docket No.: 16-C0001

Settlement Agreement

1. In accordance with the Consumer Product Safety Act, 15 U.S.C. 2051 – 2089 (“CPSA”) and 16 CFR 1118.20, Philips Lighting North America Corporation (“Philips”), and the United States Consumer Product Safety Commission (“Commission”), through its staff, hereby enter into this Settlement Agreement (“Agreement”). The Agreement, and the incorporated attached Order, resolve staff's charges set forth below.

The Parties

2. The Commission is an independent federal regulatory agency, established pursuant to, and responsible for the

¹ The Commission voted (4-1) to provisionally accept the Settlement Agreement and Order regarding Philips Lighting North America Corporation. Chairman Kaye, Commissioner Adler, Commissioner Robinson and Commissioner Mohorovic voted to provisionally accept the Settlement Agreement and Order. Commissioner Buerkle voted to reject the Settlement Agreement and Order.

enforcement of, the CPSA, 15 U.S.C. 2051–2089. By executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16 CFR 1118.20(b). The Commission issues the Order under the provisions of the CPSA.

3. Philips is a corporation, organized and existing under the laws of the state of Delaware, with its principal corporate offices located in Somerset, New Jersey.

Staff Charges

4. Between March 2007 and July 2011, grocery and home center stores nationwide, online retailers, and professional electrical distributors sold in the United States approximately 1.86 million EnergySaver (a/k/a “Marathon” or “Marathon Classic”) compact fluorescent lamps enclosed inside glass envelopes (“Lamps”). Philips manufactured the Lamps.

5. The Lamps are a “consumer product” that was “distributed in commerce” as those terms are defined or used in sections 3(a)(5) and (8) of the CPSA, 15 U.S.C. 2052(a)(5) and (8). Philips is a “manufacturer” of the Lamps, as such term is defined in section 3(a)(11) of the CPSA, 15 U.S.C. 2052(a)(11).

6. The Lamps are defective and create an unreasonable risk of serious injury or death because the glue that attaches the glass outer envelope to the body of the Lamp can fail, allowing the glass envelope to fall and strike persons and objects below. This poses a laceration hazard to consumers.

7. Philips received numerous reports that glass envelopes separated or were loose, including 10 reports of lacerations and seven reports of property damage.

8. In response to these incident reports, Philips implemented multiple design changes to remedy the defect and unreasonable risk of serious injury or death associated with the Lamps.

9. Despite having information of a defect and the unreasonable risk of serious injury or death associated with the Lamps, Philips did not notify the Commission immediately of such defect or risk, as required by sections 15(b)(3) and (4) of the CPSA, 15 U.S.C. 2064(b)(3) and (4).

10. Because the information in Philips’s possession constituted actual and presumed knowledge, Philips knowingly violated section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4), as the term “knowingly” is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d).

11. Pursuant to section 20 of the CPSA, 15 U.S.C. 2069, Philips is subject to civil penalties for its knowing violation of section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4).

Response of Philips

12. Philips’s settlement of this matter does not constitute an admission that Philips knew that the Lamps were defective and created an unreasonable risk of serious injury or death pursuant to section 15(a) of the CPSA, 15 U.S.C. 2064(a), or that Philips knowingly violated the reporting requirements of section 15(b) of the CPSA, 15 U.S.C. 2064(b). In particular, Philips notes that the ten reported injuries were minor, requiring no medical attention.

Agreement of the Parties

13. Under the CPSA, the Commission has jurisdiction over the matter involving the Lamps and over Philips.

14. The parties enter into the Agreement for settlement purposes only. The Agreement does not constitute an admission by Philips or a determination by the Commission that Philips violated the CPSA’s reporting requirements.

15. In settlement of staff’s charges as set forth in paragraphs 4 through 11 above, and to avoid the cost, distraction, delay, uncertainty, and inconvenience of protracted litigation or other proceedings, Philips shall pay a civil penalty in the amount of two million dollars (\$2,000,000) within thirty (30) calendar days after receiving service of the Commission’s final Order accepting the Agreement. All payments to be made under the Agreement shall constitute debts owing to the United States and shall be made by electronic wire transfer to the United States via: <http://www.pay.gov> for allocation to and credit against the payment obligations of Philips under this Agreement. Failure to make such payment by the date specified in the Commission’s final Order shall constitute Default.

16. All unpaid amounts, if any, due and owing under the Agreement shall constitute a debt due and immediately owing by Philips to the United States, and interest shall accrue and be paid by Philips at the federal legal rate of interest set forth at 28 U.S.C. 1961(a) and (b) from the date of Default until all amounts due have been paid in full (hereinafter “Default Payment Amount” and “Default Interest Balance”). Philips shall consent to a Consent Judgment in the amount of the Default Payment Amount and Default Interest Balance; and the United States, at its sole option, may collect the entire Default Payment Amount and Default Interest Balance, or exercise any other rights granted by law or in equity, including, but not limited to, referring such matters for private collection, and Philips agrees not to contest, and hereby waives and discharges any defenses to, any

collection action undertaken by the United States or its agents or contractors pursuant to this paragraph. Philips shall pay the United States all reasonable costs of collection and enforcement under this paragraph, respectively, including reasonable attorney’s fees and expenses.

17. After staff receives this Agreement executed on behalf of Philips, staff shall promptly submit the Agreement to the Commission for provisional acceptance. Promptly following provisional acceptance of the Agreement by the Commission, the Agreement shall be placed on the public record and published in the **Federal Register**, in accordance with the procedures set forth in 16 CFR 1118.20(e). If the Commission does not receive any written request not to accept the Agreement within fifteen (15) calendar days, the Agreement shall be deemed finally accepted on the 16th calendar day after the date the Agreement is published in the **Federal Register**, in accordance with 16 CFR 1118.20(f).

18. This Agreement is conditioned upon, and subject to, the Commission’s final acceptance, as set forth above, and it is subject to the provisions of 16 CFR 1118.20(h). Upon the later of: (i) Commission’s final acceptance of this Agreement and service of the accepted Agreement upon Philips, and (ii) the date of issuance of the final Order, this Agreement shall be in full force and effect and shall be binding upon the parties.

19. Effective upon the later of: (i) the Commission’s final acceptance of the Agreement and service of the accepted Agreement upon Philips, and (ii) the date of issuance of the final Order, for good and valuable consideration, Philips hereby expressly and irrevocably waives and agrees not to assert any past, present, or future rights to the following, in connection with the matter described in this Agreement: (i) an administrative or judicial hearing; (ii) judicial review or other challenge or contest of the Commission’s actions; (iii) a determination by the Commission of whether Philips failed to comply with the CPSA and the underlying regulations; (iv) a statement of findings of fact and conclusions of law; and (v) any claims under the Equal Access to Justice Act.

20. Philips shall implement, maintain, and enforce a system of internal controls and procedures designed to ensure that, with respect to all consumer products, as that term is defined or used in section 3(a)(5) of the CPSA, 15 U.S.C. 2052(a)(5) (“consumer products”), imported, manufactured, distributed, or sold by Philips in the United States:

a. information required to be disclosed by Philips to the Commission is recorded, processed, and reported in accordance with applicable law;

b. all reporting made to the Commission is timely, truthful, complete, accurate, and in accordance with applicable law; and

c. prompt disclosure is made to Philips's management of any significant deficiencies or material weaknesses in the design or operation of such internal controls that are reasonably likely to affect adversely, in any material respect, Philips's ability to record, process, and report to the Commission in accordance with applicable law.

21. Philips shall implement and maintain a compliance program designed to ensure compliance with the CPSA and regulations enforced by the Commission with respect to any consumer product imported, manufactured, distributed, or sold by Philips in the United States, and which, at a minimum, shall contain the following elements:

a. written standards and policies;

b. written procedures that provide for the appropriate forwarding to compliance personnel of all information that may relate to, or impact, CPSA compliance, including all reports and complaints involving consumer products, whether an injury is referenced or not, and corresponding engineering analyses and risk assessments;

c. a mechanism for confidential employee reporting of compliance-related questions or concerns to either a compliance officer or to another senior manager with authority to act as necessary;

d. effective communication of company compliance-related policies and procedures regarding the CPSA to all applicable employees through training programs or otherwise;

e. Philips senior management responsibility for CPSA compliance and accountability for violations of the statutes and regulations enforced by the Commission;

f. Philips board oversight of CPSA compliance; and

g. retention of all CPSA compliance-related records for at least five (5) years, and availability of such records to staff upon reasonable request.

22. Upon reasonable request of staff, Philips shall provide written documentation of its improvements, processes, and controls, including, but not limited to, the effective dates of such improvements, processes, and controls as set forth in paragraphs 20 through 21 above. Philips shall cooperate fully and truthfully with staff

and shall make available all information, materials, and personnel deemed necessary by staff to evaluate Philips's compliance with the terms of the Agreement.

23. The parties acknowledge and agree that the Commission may publicize the terms of the Agreement and the Order.

24. Philips represents that the Agreement: (i) is entered into freely and voluntarily, without any degree of duress or compulsion whatsoever; (ii) has been duly authorized; and (iii) constitutes the valid and binding obligation of Philips, enforceable against Philips in accordance with its terms. Philips will not directly or indirectly receive any reimbursement, indemnification, insurance-related payment, or other payment in connection with the civil penalty to be paid by Philips pursuant to the Agreement and Order. The individuals signing the Agreement on behalf of Philips represent and warrant that they are duly authorized by Philips to execute the Agreement.

25. The signatories represent that they are authorized to execute this Agreement.

26. The Agreement is governed by the laws of the United States.

27. The Agreement and the Order shall apply to, and be binding upon, Philips and each of its successors, transferees, and assigns, and a violation of the Agreement or Order may subject Philips, and each of its successors, transferees, and assigns, to appropriate legal action.

28. The Agreement and the Order constitute the complete agreement between the parties on the subject matter contained therein.

29. The Agreement may be used in interpreting the Order. Understandings, agreements, representations, or interpretations apart from those contained in the Agreement and the Order may not be used to vary or contradict their terms. For purposes of construction, the Agreement shall be deemed to have been drafted by both of the parties and shall not, therefore, be construed against any party for that reason in any subsequent dispute.

30. The Agreement may not be waived, amended, modified, or otherwise altered, except as in accordance with the provisions of 16 CFR 1118.20(h). The Agreement may be executed in counterparts.

31. If any provision of the Agreement or the Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Agreement and the Order, such provision shall be fully severable. The

balance of the Agreement and the Order shall remain in full force and effect, unless the Commission and Philips agree in writing that severing the provision materially affects the purpose of the Agreement and the Order.

Philips Lighting North America Corporation
Dated: November 9, 2015

By:

Michael L. Manning
Vice President and General Counsel
Philips Lighting North America Corporation
3000 Minuteman Road
Andover, MA 01810

Dated: November 9, 2015

By:

Kathleen M. Sanzo
Counsel to Philips Lighting North America Corporation
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue NW
Washington, DC 20004

U.S. Consumer Product Safety Commission
Stephanie Tsacumis
General Counsel

Mary T. Boyle
Deputy General Counsel

Melissa V. Hampshire
Assistant General Counsel

Dated: November 10, 2015

By:

Amy S. Colvin
Attorney
Division of Enforcement and Information
Office of the General Counsel

United States of America Consumer Product Safety Commission

In the Matter of: Philips Lighting North America Corporation
CPSC Docket No.: 16-C0001

Order

Upon consideration of the Settlement Agreement entered into between Philips Lighting North America Corporation ("Philips"), and the U.S. Consumer Product Safety Commission ("Commission"), and the Commission having jurisdiction over the subject matter and over Philips, and it appearing that the Settlement Agreement and the Order are in the public interest, it is:

ORDERED that the Settlement Agreement be, and is, hereby, accepted; and it is

FURTHER ORDERED that Philips shall comply with the terms of the Settlement Agreement and shall pay a civil penalty in the amount of two million dollars (\$2,000,000) within thirty (30) days after service of the Commission's final Order accepting the Settlement Agreement. The payment shall be made by electronic wire transfer to the Commission via: <http://www.pay.gov>. Upon the failure of Philips to make the foregoing payment when due, interest on the unpaid

amount shall accrue and be paid by Philips at the federal legal rate of interest set forth at 28 U.S.C. 1961(a) and (b). If Philips fails to make such payment or to comply in full with any other provision of the Settlement Agreement, such conduct will be considered a violation of the Settlement Agreement and Order.

Provisionally accepted and provisional Order issued on the 23rd day of November, 2015.
By Order of the Commission:

Todd A. Stevenson, Secretary,
U.S. Consumer Product Safety Commission
[FR Doc. 2015-30129 Filed 11-25-15; 8:45 am]
BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA-2015-0011]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 28, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Employee Travel Files; 0702-XXXX.

Type of Request: Existing collection in use without an OMB Control Number.

Number of Respondents: 350.

Responses per Respondent: 1.

Annual Responses: 350.

Average Burden per Response: 45 minutes.

Annual Burden Hours: 263.

Needs and Uses: The information collection requirement is necessary to process official travel requests for military and civilian employees of the Army and Air Force Exchange Service; to determine eligibility of the individual's dependents to travel; to obtain the necessary clearance where foreign travel is involved, including assisting individuals in applying for passports and visas and counseling where proposed travel involves visiting/transiting communist countries and danger zones.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at Oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Dated: November 23, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015-30126 Filed 11-25-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

National Commission on the Future of the Army; Notice of Federal Advisory Committee Meeting

AGENCY: Deputy Chief Management Officer, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce two days of meetings of the National Commission on the Future of the Army ("the Commission"). The meetings will be partially closed to the public.

DATES: *Date of the Closed Meetings:* Wednesday, December 16, 2015, from 1:00 p.m. to 5:00 p.m. and Thursday, December 17, 2015, from 8:00 a.m. to 12:00 p.m.

Date of the Open Meeting: Thursday, December 17, 2015, from 3:00 p.m. to 5:00 p.m.

ADDRESSES: Address of Closed Meetings, December 16 and 17, 2015: Rm. 12110, 5th Floor, Zachary Taylor Building, 2530 Crystal Dr., Arlington, VA 22202.

Address of Open Meeting, December 17, 2015: Polk Conference Room, Room 12158, James Polk Building, 2521 S. Clark St., Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. Don Tison, Designated Federal Officer, National Commission on the Future of the Army, 700 Army Pentagon, Room 3E406, Washington, DC 20310-0700, Email: dfo.public@ncfa.ncr.gov. Desk (703) 692-9099. Facsimile (703) 697-8242.

SUPPLEMENTARY INFORMATION: This meeting will be held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.150.

Purpose of Meetings:

During the closed meeting on Wednesday, December 16, 2015, the Commission will review the rationale for potential recommendations sourced by classified data.

During the closed meeting on Thursday, December 17, 2015, the Commission will continue the review of the rationale for potential recommendations sourced by classified data.

During the open meeting on Thursday, December 17, 2015, the Commission will hear subcommittee interim reports and the public will have an opportunity to provide remarks.

Agendas:

December 16, 2015—Closed Meeting: The Commission will hold a closed meeting to discuss the rationale for proposals which the cited information will exceed report classification. All presentations and resulting discussion are classified.

December 17, 2015—Closed Meeting: The Commission will continue the discussion on the rationale for proposals which the cited information will exceed report classification. All presentations and resulting discussion are classified.

December 17, 2015—Open Meeting: The Commission will receive interim reports from representatives from the various subcommittees and time will be allotted for public comments.

Meeting Accessibility:

In accordance with applicable law, 5 U.S.C. 552b(c) and 41 CFR 102–3.155, the DoD has determined that portion of the meetings scheduled for December 16, 2015, and the morning of December 17, 2015, will be closed to the public. Specifically, the Assistant Deputy Chief Management Officer, with the coordination of the DoD FACA Attorney, has determined in writing that these portions of the meetings will be closed to the public because it will discuss matters covered by 5 U.S.C. 552b(c)(1).

Pursuant to 41 CFR 102–3.140 through 102–3.165 and the availability of space, the meeting scheduled for December 17, 2015 from 3:00 p.m. to 5:00 p.m. at the James Polk Building is open to the public. Seating is limited and pre-registration is strongly encouraged. Media representatives are also encouraged to register. Members of the media must comply with the rules of photography and video filming in the James Polk Building. The closest public parking facility is located in the basement and along the streets. Visitors will be required to present one form of photograph identification. Visitors to the James Polk Office Building will be screened by a magnetometer, and all items that are permitted inside the building will be screened by an x-ray device. Visitors should keep their belongings with them at all times. The following items are strictly prohibited in the James Polk Office Building: Any pointed object, *e.g.*, knitting needles and letter openers (pens and pencils are permitted.); any bag larger than 18" wide × 14" high × 8.5" deep; electric stun guns, martial arts weapons or devices; guns, replica guns, ammunition and fireworks; knives of any size; mace and pepper spray; razors and box cutters.

Written Comments:

Pursuant to section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written

comments to the Commission in response to the stated agenda of the open and/or closed meeting or the Commission's mission. The Designated Federal Officer (DFO) will review all submitted written statements. Written comments should be submitted to Mr. Donald Tison, DFO, via facsimile or electronic mail, the preferred modes of submission. Each page of the comment must include the author's name, title or affiliation, address, and daytime phone number. All comments received before Wednesday, December 16, 2015, will be provided to the Commission before the December 17, 2015, meeting. Comments received after Wednesday, December 16, 2015, will be provided to the Commission before its next meeting. All contact information may be found in the **FOR FURTHER INFORMATION CONTACT** section.

Registration:

Individuals and entities who wish to attend the public meeting on Thursday, December 17, 2015 are encouraged to register for the event with the DFO using the electronic mail and facsimile contact information found in the **FOR FURTHER INFORMATION CONTACT** section. The communication should include the registrant's full name, title, affiliation or employer, email address, day time phone number. This information will assist the Commission in contacting individuals should it decide to do so at a later date. If applicable, include written comments and a request to speak during the oral comment session. (Oral comment requests must be accompanied by a summary of your presentation.) Registrations and written comments should be typed.

Additional Information

The DoD sponsor for the Commission is the Deputy Chief Management Officer. The Commission is tasked to submit a report, containing a comprehensive study and recommendations, by February 1, 2016 to the President of the United States and the Congressional defense committees.

The report will contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for such legislation and administrative actions it may consider appropriate in light of the results of the study. The comprehensive study of the structure of the Army will determine whether, and how, the structure should be modified to best fulfill current and anticipated mission requirements for the Army in a manner consistent with available resources.

Dated: November 23, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–30165 Filed 11–25–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Transmittal No. 0M–15]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Sarah A. Ragan or Heather N. Harwell, DSCA/LMO, (703) 604–1546/(703) 607–5339.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 0M–15 with attached Policy Justification.

Dated: November 23, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, 9YE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

NOV 04 2015

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), we are forwarding Transmittal No. 0M-15, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Qatar for defense articles and services estimated to cost \$12.86 billion. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 12-58 of 06 November 2012.

Sincerely,

JWR J. W. Rixey
Vice Admiral, USN
Director

Enclosures:

1. Transmittal
2. Regional Balance (Classified Document Provided Under Separate Cover)



Transmittal No. 0M-15

*REPORT OF ENHANCEMENT OR
UPGRADE OF SENSITIVITY OF
TECHNOLOGY OR CAPABILITY (SEC.
36(B)(5)(C), AECA)*

(i) *Purchaser:* Government of Qatar
(QA-B-UAP)

(ii) *Sec. 36(b)(1), AECA Transmittal
No.:* 12-58

Date: 06 November 2012

Military Department: Army

(iii) *Description:* On 06 November 2012, Congress was notified by Congressional certification transmittal

number 12-58, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of 11 PATRIOT Configuration-3 Modernized Fire Units, 11 AN/MPQ-65 Radar Sets, 11 AN/MSQ-132 Engagement Control Systems, 30 Antenna Mast Groups, 44 M902 Launching Stations (LS), 246 PATRIOT MIM-104E Guidance Enhanced Missile-TBM (GEM-T) with canisters, 2 PATRIOT MIM-104E GEM-T Test Missiles, 768 PATRIOT Advanced Capability 3 (PAC-3) Missiles with canisters, 10 PAC-3 Test Missiles with

canisters, 11 Electrical Power Plants (EPPII), 8 Multifunctional Information Distribution Systems/Low Volume Terminals (MIDS/LVTs), communications equipment, tools and test equipment, support equipment, publications and technical documentation, personnel training and training equipment, spare and repair parts, facility design, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics and program support. The estimated total

cost was \$9.9 billion. Major Defense Equipment (MDE) constituted \$7.2 billion of this total.

This transmittal reports the upgrade of 34 of the previously notified (and purchased) M902 LS, and the addition of 300 PAC-3 PATRIOT Advanced Capability (PAC)-3 Missile Segment Enhancement (MSE) missiles and 10 PAC-3 MSE test missiles. In order to support MSE Integration, the M902 LS will require a modification kit to achieve the M903 LS configuration. The addition of the PAC-3 MSEs and the M902 LS upgrades will result in an MDE net increase of \$2.6 billion, and a non-MDE increase of \$360 million. The revised estimated total value is \$12.86 billion, with the revised MDE value constituting \$9.8 billion of this new total.

(iv) *Significance:* The LS M903 allows the PATRIOT system to fire PAC-3 MSE missiles.

The changes to the launcher for the M903 configuration are to account for the necessary cabling for power and signal interfaces with the PAC-3 MSE missiles. In order to change the launcher from the M902 configuration to the M903 configuration, the following items are added: Additional distribution cables, additional umbilical cables,

addition of a stowage box for storage of cables mentioned above, and the addition of a grounding cable. The PAC-3 MSE missile capability will allow for further and higher Tactical Ballistic Missile intercepts. This equipment will enhance Qatar's interoperability with the United States and its allies, making it a more valuable partner in an increasingly important area of the world. Qatar should have no difficulty including the PAC-3 MSE and the upgrade to M903 LS into its armed forces.

(v) *Justification:* This notification is being provided as the PAC-3 MSE was not specified in the original notification because the technology was not yet releasable to FMS customers and the M903 LS kit was not available/developed. This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a strategic partner. The PAC-3 MSE and the M903 LS kit will significantly improve Qatar's defense capabilities to meet current and future threats and deter regional aggression.

(vi) *Date Report Delivered to Congress:* 4 NOV 2015

[FR Doc. 2015-30176 Filed 11-25-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15-51]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Sarah A. Ragan or Heather N. Harwell, DSCA/LMO, (703) 604-1546/(703) 607-5339.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15-51 with attached Policy Justification and Sensitivity of Technology.

Dated: November 23, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001-06-C



DEFENSE SECURITY COOPERATION AGENCY
 201 12TH STREET SOUTH, STE 203
 ARLINGTON, VA 22202-5408

NOV 04 2015

The Honorable Paul D. Ryan
 Speaker of the House
 U.S. House of Representatives
 Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-51, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to the United Arab Emirates for defense articles and services estimated to cost \$380 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
 Vice Admiral, USN
 Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)



BILLING CODE 5001-06-P

Transmittal No. 15-51 Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* United Arab Emirates

(ii) *Total Estimated Value:*

(U) Major Defense Equipment*	\$ 365.0 million
(U) Other	\$ 15.0 million
(U) TOTAL	\$ 380.0 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* Major Defense Equipment (MDE) includes: Three thousand two hundred and fifty (3250) GBU-31V1 (KMU-556 Joint Direct Attack Munitions (JDAM) kits) Three thousand two hundred and fifty (3250) MK-84/BLU-117 bombs Seven hundred and fifty (750) GBU-31V3 (KMU-557 JDAM kits) Seven hundred and fifty (750) BLU-109 bombs One thousand (1000) GBU-12 Paveway II Laser Guided bomb kits

One thousand and two (1002) MK-82/BLU-111 bombs Four thousand two hundred and fifty (4,250) FMU-152 fuzes Two hundred and sixteen (216) GBU-24 tail kits (BSU-84) This sale also includes non-MDE related munitions items (fuzes and bomb components), sustainment, and support. (iv) *Military Department:* USAF: AE-D-AAF (v) *Prior Related Cases, if any:* FMS Case SAA \$113M SEP 98, APR 00, MAY 01

FMS Case YAB \$156M SEP 98, MAY 01
FMS Case YAC \$874M SEP 98, MAY 01,
DEC 07, DEC 09, JUN 11

FMS Case AAC \$13M JUN 11
FMS Case AAD \$11.8M JAN 15
FMS Case AAE \$130M MAY15

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 04 NOV 2015

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Arab Emirates (UAE) Joint Direct Attack Munitions (JDAM), Sustainment and Support

The United Arab Emirates requested approval to procure 3250 GBU-31V1 (KMU-556 JDAM kit) with 3250 MK-84/BLU-117 bombs, 750 GBU-31V3 (KMU-557 JDAM kit) with 750 BLU-109 bombs, 1000 GBU-12 with 1002 MK-82/BLU-111 bombs, 4,250 FMU-152 fuzes, and 216 GBU-24 tail kits (BSU-84). The sale also includes non-MDE related munitions items (fuzes and bomb components), sustainment, and support. The estimated total case value is \$380 million.

This proposed sale contributes to the foreign policy and national security of the United States by helping the UAE remain an active member of the OPERATION INHERENT RESOLVE (OIR) coalition working to defeat the Islamic State in Iraq and Levant (ISIL) and as part of the Saudi-led coalition to restore the legitimate government in Yemen. These munitions will sustain the UAE's efforts and support a key partner that remains an important force for political stability and economic progress in the Middle East.

The proposed sale provides the UAE additional precision guided munitions capability to meet the current threat. The UAE continues to provide host-nation support of vital U.S. forces stationed at Al Dhafra Air Base and plays a vital role in supporting U.S. regional interests. The UAE was a valued partner and an active participant in OPERATION IRAQI FREEDOM (OIF), OPERATION ENDURING FREEDOM (OEF), OPERATION UNIFIED PROTECTOR (OUP), and now is a valued partner in OIR coalition operations.

The proposed sale will not alter the basic military balance in the region.

The prime contractors will be determined during the contracting process. There are no known offset

agreements proposed in connection with this potential sale.

Implementation of this sale entails periodic Program Management Reviews in the United States or UAE. There are no additional U.S. Government or contractor representatives anticipated to be stationed in the UAE as a result of this potential sale.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 15-51

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. GBU-31 Joint Direct Attack Munition (JDAM) is a 2000-lb guidance tail kit that converts unguided free-fall bombs into accurate, Global Positioning System (GPS)-guided adverse weather "smart" munitions. With the addition of a new tail section that contains an inertial navigational system (INS) and a GPS guidance control unit, JDAM improves the accuracy of unguided, general-purpose (GP) bombs in any weather condition. The GBU-31V1 contains a KMU-556 JDAM tail, a general purpose 2000-lb BLU-117 or MK-84 bomb body and a fuse. The GBU-31V3 contains a KMU-557 JDAM tail, a 2000-lb BLU-109 penetrator bomb body and a fuse. The highest classification for the JDAM, its components, and technical data is SECRET. In addition to the JDAM tail kit, access to accurate target coordinates, INS/GPS capability, and operational test and evaluation plan are essential for successful employment.

2. GBU-12 is a 500-lb laser-guided ballistic bomb (LGB). The LGB is a maneuverable, free-fall weapon that guides to a spot of laser energy reflected off of the target. The LGB is delivered like a normal GP warhead and the semi-active guidance corrects for many of the normal errors inherent in any delivery system. Laser designation for the weapon can be provided by a variety of laser target markers or designators. The GBU-12 LGB consists of a laser guidance kit, a computer control group (CCG) and a warhead specific Air Foil Group (AFG), that attach to the nose and tail of MK-82 or BLU-111 500-lb GP bomb body and a fuse. The overall weapon is CONFIDENTIAL.

3. GBU-24 is a 2000-lb laser-guided ballistic bomb (LGB). The LGB is a maneuverable, free-fall weapon that guides to a spot of laser energy reflected off of the target. The LGB is delivered

like a normal GP warhead and the semi-active guidance corrects for many of the normal errors inherent in any delivery system. Laser designation for the weapon can be provided by a variety of laser target markers or designators. The GBU-24 LGB consists of a laser guidance kit, a computer control group (CCG) and a warhead specific BSU-84 Air Foil Group (AFG), that attaches to the tail of a MK-84 or BLU-117 2000-lb GP bomb body. The overall weapon is SECRET.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that the recipient country can provide substantially the same degree of protection of sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of U.S. foreign policy and national security objectives outlined in the Policy Justification. All defense articles and services listed in this transmittal have been authorized for release and export to the United Arab Emirates.

6. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from this sale, as outlined in the Policy Justification, outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

[FR Doc. 2015-30195 Filed 11-25-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15-56]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Sarah A. Ragan or Heather N. Harwell, DSCA/LMO, (703) 604-1546/(703) 607-5339.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15-56 with

attached Policy Justification and Sensitivity of Technology.

Dated: November 23, 2015.
Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

NOV 04 2015

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-56, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Kuwait for defense articles and services estimated to cost \$115 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)



BILLING CODE 5001-06-C

Transmittal No. 15-56
Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

- (i) *Prospective Purchaser:* The Government of Kuwait
- (ii) *Total Estimated Value:*

Major Defense Equipment* ..	\$ 50 million
Other	\$ 65 million
TOTAL	\$ 115 million

(iii) *Description and Quantity or Quantities of Articles or Services Under Consideration for Purchase:*

Major Defense Equipment (MDE):
Fourteen (14) AN/AAQ-33 Sniper
Advanced Targeting Pods (ATP)

Non-MDE items included in this request are associated equipment, spares, accessories, and airworthiness certification. The sale will include the integration of the ATPs on the purchaser's F/A-18 aircraft along with improvements in the on-board mission computer software suites. Also included in this request are systems integration and testing, software development/integration, test sets, support equipment, spares, repair parts, maintenance and pilot training, publications and technical documents, U.S. Government and contractor technical assistance, and other related elements of logistics, engineering and program support.

(iv) *Military Department:* Navy and Air Force (XX-P-LCI)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* Offset agreements associated with this proposed sale are expected and will be determined during negotiations between the purchaser and contractor.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 04 NOV 2015

*as defined in Section 47(6) of the Arms Export Control Act

POLICY JUSTIFICATION

The Government of Kuwait—Sniper Advanced Targeting Pods (ATP)

The Government of Kuwait has requested a possible sale of:

Major Defense Equipment (MDE):
Fourteen (14) AN/AAQ-33 Sniper
Advanced Targeting Pods (ATP)

Non-MDE items included in this request are associated equipment, spares, accessories, and airworthiness certification. The sale will include the above system integration on the purchaser's F/A-18 aircraft along with improvements in the on-board mission computer software suites. Operational support for these modifications will be provided through upgrades. Also included in this request are systems integration and testing, software development/integration, test sets, support equipment, spares, repair parts, maintenance and pilot training, publications and technical documents, U.S. Government and contractor technical assistance, and other related elements of logistics, engineering and program support. The estimated cost of

MDE is \$50 million. The total estimated cost is \$115 million.

Kuwait has requested the Sniper ATP due to its compatibility with the latest precision-guided weapons and capability of detecting, identifying, and engaging multiple moving and fixed targets in air-to-air and air-to-ground engagements. Integration of the Sniper ATP on Kuwait's F/A-18 aircraft would enhance its ability to protect itself against possible aggression from foreign forces.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been, and continues to be, an important force for political stability and economic progress in the Middle East. Kuwait plays a large role in U.S. efforts to advance stability in the Middle East, providing basing, access, and transit for U.S. forces in the region.

The proposed sale of this equipment, services, and support will not affect the basic military balance in the region.

The principal contractor will be Lockheed Martin Missile and Fire Control, Orlando, Florida.

Offset agreements associated with this proposed sale are expected and will be determined during negotiations between the purchaser and contractor.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 15-56

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The hardware and software being purchased is being used to upgrade the customer country's existing F/A-18C/D Hornet aircraft. Description and classification of the hardware and software being purchased are detailed in the following paragraphs.

2. The Sniper Advanced Targeting Pod (ATP), designated AN/AAQ-33, provides positive target identification, autonomous tracking, coordinate generation, and precise weapons guidance from extended standoff ranges. The latest version of the Sniper ATP provides an enhanced capability using new sensors, a two-way data link, advanced processors and automated non-traditional intelligence, surveillance and reconnaissance modes.

3. A software upgrade to the Kuwait F/A-18 Mission Computer Operational Flight Program (OFP) software will be

required to ensure that flight crews receive full capability of the Sniper ATP. The OFP will be upgraded at the Naval Air Warfare Center Weapons Division at China Lake, California, as part of continuing support of the Kuwait Air Force F/A-18 program.

4. The Sniper ATP will provide classified SECRET data to the Kuwait Air Force. Some technical information is classified SECRET because it describes the limitations and effectiveness of both the aircraft and its capabilities.

5. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software in this proposed sale, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

6. A determination has been made that the recipient country can provide the same degree of protection for the classified and sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Kuwait.

[FR Doc. 2015-30185 Filed 11-25-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Agency Information Collection Activities: Proposed Collection; Comment Request; Badge Replacement Request Form

AGENCY: Bonneville Power Administration (BPA), DOE.

ACTION: Notice of submission of information collection approval from the Office of Management and Budget (OMB) and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Bonneville Power Administration (BPA) will submit the collection abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual collection instrument.

DATES: Comments must be received on or before December 29, 2015.

ADDRESSES: Written comments may be submitted by mail to Christopher M. Frost, CGI-7, Bonneville Power Administration, 905 NE., 11th Avenue, Portland, Oregon 97232, or by email at IGLM@bpa.gov.

FOR FURTHER INFORMATION CONTACT: Additional information may be requested from Christopher M. Frost at the mailing address above or by email at IGLM@bpa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

BPA is seeking approval for an information collection on lost, stolen, or damaged badges that control access to BPA facilities. This information collection helps BPA control access to BPA facilities and track identification badges issued by BPA's Personnel Security office. The relevant form, Form BPA F 5632.27e, will collect the following information: type of badge (standard, smart card, proximity access), date of report, date lost, stolen or damaged, name and work phone number of reporting contractor or federal employee, and a brief description of either the type of damage or the incident resulting in loss.

The **Federal Register** Notice with a 60-day comment period was published on June 23, 2015 at 80 FR 35947.

II. Data

OMB Control Number: New.
Information Collection Request Title: Badge Replacement Request Form.

Type of Request: New.
Respondents: BPA employees and contractors seeking replacement ID badges.

Annual Estimated Number of Respondents: 75.

Annual Estimated Number of Total Responses: 75.

Average Minutes per Response: 10.
Annual Estimated Number of Burden Hours: 12.5.

Annual Estimated Reporting and Recordkeeping Cost Burden: \$0.

Issued in Portland, Oregon, on November 18, 2015.

Christopher M. Frost,
Agency Records Officer, FOIA/Privacy Officer, Information Governance.

[FR Doc. 2015-30220 Filed 11-25-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

National Coal Council

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of renewal.

SUMMARY: Pursuant to section 14(a)(2)(A) of the Federal Advisory Committee Act (Pub. L. 92-463) and in accordance with Title 41 of the Code of Federal Regulations, section 102-3.65, and following consultation with the Committee Management Secretariat of the General Services Administration, notice is hereby given that the National Coal Council has been renewed for a two-year period. The Council will continue to provide advice, information, and recommendations to the Secretary of Energy on a continuing basis regarding general policy matters relating to coal issues.

SUPPLEMENTARY INFORMATION: Council members are chosen to assure a well-balanced representation from all sections of the country, all segments of the coal industry, including large and small companies, and commercial and residential consumers. The Council also has diverse members who represent interests outside the coal industry, including the environment, labor, research, and academia. Membership and representation of all interests will continue to be determined in accordance with the requirements of the Federal Advisory Committee Act, and implementing regulations.

The renewal of the Council has been deemed essential to the conduct of the Department's business and in the public interest in conjunction with the performance of duties imposed upon the Department of Energy by law. The Council will continue to operate in accordance with the provisions of the Federal Advisory Committee Act and implementing regulations.

FOR FURTHER INFORMATION CONTACT: Robert Wright at (202) 586-0429.

Issued at Washington, DC on November 20, 2015.

Amy Bodette,
Committee Management Officer.

[FR Doc. 2015-30163 Filed 11-25-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16-36-000.

Applicants: LWP Lessee, LLC.

Description: Application for Authorization Under Section 203 of the FPA and Request for Waivers, Confidential Treatment, and Expedited Action of LWP Lessee, LLC.

Filed Date: 11/19/15.

Accession Number: 20151119-5242.

Comments Due: 5 p.m. ET 12/10/15.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16-22-000.

Applicants: Shelby County Energy Center, LLC.

Description: Notice of Self-Certification as an Exempt Wholesale Generator or FC of Shelby County Energy Center, LLC.

Filed Date: 11/20/15.

Accession Number: 20151120-5066.

Comments Due: 5 p.m. ET 12/11/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15-1907-001; ER15-1908-001.

Applicants: Joliet Battery Storage LLC, West Chicago Battery Storage LLC.

Description: Notice of Change in Status and Request for Confidential Treatment of Joliet Battery Storage LLC, et. al.

Filed Date: 11/20/15.

Accession Number: 20151120-5067.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16-360-000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Concurrence of Revised WECC Unscheduled Flow Mitigation Plan in ER16-193-000 to be effective 1/1/2016.

Filed Date: 11/19/15.

Accession Number: 20151119-5228.

Comments Due: 5 p.m. ET 12/10/15.

Docket Numbers: ER16-361-000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Distribution Service Agreement Camp Rock Solar Farm, LLC Camp Rock PV Project to be effective 1/21/2016.

Filed Date: 11/20/15.

Accession Number: 20151120-5001.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16-362-000.

Applicants: Pleasant Valley Wind, LLC.

Description: Notice of cancellation of MBR tariff of Pleasant Valley Wind, LLC.

Filed Date: 11/20/15.

Accession Number: 20151120-5053.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16-363-000.

Applicants: Madison Gas and Electric Company.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff to be effective 11/23/2015.

Filed Date: 11/20/15.

Accession Number: 20151120-5083.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16–364–000.

Applicants: PacifiCorp.

Description: Tariff Cancellation:

Termination of Idaho Power MOU to be effective 1/20/2016.

Filed Date: 11/20/15.

Accession Number: 20151120–5106.

Comments Due: 5 p.m. ET 12/11/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30135 Filed 11–25–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–18–000]

Conway Corporation; Notice of Filing

Take notice that on November 19, 2015, Conway Corporation submitted an application for a proposed rate for reactive supply and voltage control from generation or other sources service under Schedule 2 to the Midcontinent Independent Transmission System Operator Tariff.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the

comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 11, 2015.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30138 Filed 11–25–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–17–000]

City of West Memphis, Arkansas; Notice of Filing

Take notice that on November 19, 2015, City of West Memphis, Arkansas submitted an application for a proposed rate for reactive supply and voltage control from generation or other sources service under Schedule 2 to the Midcontinent Independent Transmission System Operator Tariff.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the

comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 11, 2015.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30137 Filed 11–25–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–37–000.

Applicants: NRG Wholesale Generation LP, Shelby County Energy Center, LLC.

Description: Joint Application of NRG Wholesale Generation LP and Shelby County Energy Center, LLC for Authorization Pursuant to Section 203 of the Federal Power Act, Request for Expedited Action and Request for Privileged Treatment.

Filed Date: 11/20/15.

Accession Number: 20151120–5154.

Comments Due: 5 p.m. ET 12/11/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–411–005.

Applicants: Arizona Public Service Company.

Description: Compliance filing: Rate Schedule No. 274—Planning

Participation Agreement to be effective 1/1/2015.

Filed Date: 11/20/15.

Accession Number: 20151120–5128.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16–8–000.

Applicants: Duke Energy Ohio, Inc.

Description: Supplement to October 1, 2015 Duke Energy Ohio, Inc. tariff filing.

Filed Date: 11/19/15.

Accession Number: 20151119–5174.

Comments Due: 5 p.m. ET 12/3/15.

Docket Numbers: ER16–365–000.

Applicants: Meyersdale Windpower LLC.

Description: Baseline eTariff Filing: Meyersdale Windpower LLC Common Facilities Agreement to be effective 11/20/2015.

Filed Date: 11/20/15.

Accession Number: 20151120–5136.

Comments Due: 5 p.m. ET 12/11/15.

Docket Numbers: ER16–366–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: Rate Schedule 81, PGE EIM Implementation Agmt to be effective 1/20/2016.

Filed Date: 11/20/15.

Accession Number: 20151120–5149.

Comments Due: 5 p.m. ET 12/11/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30136 Filed 11–25–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Commission Information Collection Activities (FERC–556, FERC–606, and FERC–607); Consolidated Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the requirements and burden¹ of the information collections described below.

DATES: Comments on the collections of information are due January 26, 2016.

ADDRESSES: You may submit comments (identified by Docket No. IC16–3–000) by either of the following methods:

- eFiling at Commission's Web site:

<http://www.ferc.gov/docs-filing/efiling.asp>.

- Mail/Hand Delivery/Courier:

Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Please reference the specific collection number and/or title in your comments.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Type of Request: Three-year extension of the information collection

¹The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

requirements for all collections described below with no changes to the current reporting requirements. Please note that each collection is distinct from the next.

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FERC–556, Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility

OMB Control No.: 1902–0075.

Abstract: Form No. 556 is required to implement sections 201 and 210 of the Public Utility Regulatory Policies Act of 1978² (PURPA). FERC is authorized, under those sections, to encourage cogeneration and small power production and to prescribe such rules as necessary in order to carry out the statutory directives.

A primary statutory objective is efficient use of energy resources and facilities by electric utilities. One means of achieving this goal is to encourage production of electric power by cogeneration facilities which make use of reject heat associated with commercial or industrial processes, and by small power production facilities which use other wastes and renewable resources. PURPA encourages the development of small power production facilities and cogeneration facilities that meet certain technical and corporate criteria through establishment of various regulatory benefits. Facilities that meet these criteria are called Qualifying Facilities (QFs).

FERC's regulations in 18 CFR part 292, as relevant here, specify: (a) The certification procedures which must be followed by owners or operators of small power production and cogeneration facilities; (b) the criteria which must be met; (c) the information which must be submitted to FERC in order to obtain qualifying status; (d) the PURPA benefits which are available to QFs to encourage small power production and cogeneration.

² 16 U.S.C. 796, 824a–3.

18 CFR part 292 also exempts QFs from certain corporate, accounting, reporting, and rate regulation requirements of the Federal Power Act,³ certain state laws and the Public Utility Holding Company Act of 2005.⁴

Type of Respondent: Facilities that are self-certifying their status as a cogenerator or small power producer or that are submitting an application for FERC certification of their status as a cogenerator or small power producer.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden for the information collection as:

FERC-556: CERTIFICATION OF QUALIFYING FACILITY STATUS FOR A SMALL POWER PRODUCTION OR COGENERATION FACILITY

Facility type	Filing type	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response ⁵	Total annual burden hours & total annual cost	Cost per respondent (\$)
		(1)	(2)	(1)*(2)=(3)	(4)	(3)*(4)=(5)	(5)÷(1)
Cogeneration Facility > 1 MW ⁶ .	Self-certification	54	1.25	67.5	1.5 hrs; \$108	101.25 hrs; \$7,290.	\$135
Cogeneration Facility > 1 MW.	Application for FERC certification.	1	1.25	1.25	50 hrs; 3,600	62.5 hrs; 4,500	4,500
Small Power Production Facility > 1 MW.	Self-certification	1,787	1.25	2,234	1.5 hrs; 108	3,351hrs; 241,272.	135
Small Power Production Facility > 1 MW.	Application for FERC certification.	0	1.25	0	50 hrs; 3,600	0 hrs; 0	0
Cogeneration and Small Power Production Facility ≤ 1 MW (Self-Certification) ⁷ .	Self-certification	312	1.25	390	1.5 hrs; 3,600 ...	585 hrs; 42,120	135
TOTAL	2,154	2,693	4,100 hrs; \$295,182.

FERC-606, Notification of Request for Federal Authorization and Requests for Further Information; FERC-607, Report on Decision or Action on Request for Federal Authorization

OMB Control No.: 1902-0241.

Abstract: FERC-606 requires agencies and officials responsible for issuing, conditioning, or denying requests for federal authorizations necessary for a proposed natural gas project to report to the Commission regarding the status of an authorization request. This reporting requirement is intended to allow agencies to assist the Commission to make better informed decisions in establishing due dates for agencies'

decisions. FERC-607 requires agencies or officials to submit to the Commission a copy of a decision or action on a request for federal authorization and an accompanying index to the documents and materials relied on in reaching a conclusion.

The information collections can neither be discontinued nor collected less frequently because of statutory requirements. The consequences of not collecting this information are that the Commission would be unable to fulfill its statutory mandate under the Energy Policy Act of 2005 to:

- Establish a schedule for agencies to review requests for federal

authorizations required for a project, and

- Compile a record of each agency's decision, together with the record of the Commission's decision, to serve as a consolidated record for the purpose of appeal or review, including judicial review.

Type of Respondent: Agencies with federal authorization responsibilities.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden and cost⁸ (rounded) for the information collection as follows:

FERC-606: (NOTIFICATION OF REQUEST FOR FEDERAL AUTHORIZATION AND REQUESTS FOR FURTHER INFORMATION), AND FERC-607 (REPORT ON DECISION OR ACTION ON REQUEST FOR FEDERAL AUTHORIZATION)

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1)*(2)=(3)	(4)	(3)*(4)=(5)	(5)÷(1)
FERC-606	6	1	6	4 hrs; \$288	24 hrs; \$1,728	\$288
FERC-607	1	1	1	1 hr.; 72	1 hr.; 72	72
TOTAL	7	25 hrs; 1,800

³ 16 U.S.C. 791, *et seq.*

⁴ 42 U.S.C. 16, 451-63.

⁵ The burden costs are based on an FERC's 2015 average annual wage (and benefits) figure for a full-time employee of \$149,489 (\$72/hour). The

Commission staff believes that industry is similarly situated in terms of staff costs and skill sets.

⁶ MW = megawatt.

⁷ Not required to file.

⁸ The cost is based on FERC's average cost (salary plus benefits) of \$72/hour for 2015. The Commission staff believes that the level and skill set (as a reporting agency official, *e.g.*, Environmental Program Manager or Reviewer) is comparable to FERC staff.

Issued: November 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-30139 Filed 11-25-15; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2014-0486; FRL-9933-45-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Lead Training, Certification, Accreditation and Authorization Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA): “Lead Training, Certification, Accreditation and Authorization Activities” and identified by EPA ICR No. 2507.01 and OMB Control No. 2070-NEW. The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized in this document. EPA did not receive any comments in response to the previously provided public review opportunity issued in the **Federal Register** on December 29, 2014 (79 FR 78084). With this submission, EPA is providing an additional 30 days for public review.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0486, to both EPA and OMB as follows:

- To EPA online using <http://www.regulations.gov> (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- To OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA’s policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is

restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Colby Lintner, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket: Supporting documents, including the ICR that explains in detail the information collection activities and the related burden and cost estimates that are summarized in this document, are available in the docket for this ICR. The docket can be viewed online at <http://www.regulations.gov> or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA’s public docket, visit <http://www.epa.gov/dockets>.

ICR status: This is a new ICR. that seeks to consolidate the information collection activities that are currently covered by the following three ICRs that are currently approved by OMB under the separate OMB control numbers identified:

1. OMB Control No. 2070-0155; EPA ICR No. 1715.14; entitled “TSCA Sections 402 and Section 404 Training, Certification, Accreditation and Standards for Lead-Based Paint Activities and Renovation, Repair, and Painting”; approved through August 31, 2018.

2. OMB Control No. 2070-0158; EPA ICR No. 1669.07; entitled “Lead-Based Paint Pre-Renovation Information Dissemination—TSCA Sec. 406(b)”; approved through August 31, 2018.

3. OMB Control No. 2070-0181; EPA ICR No. 2381.03; entitled “ICR for the Final Rule entitled “Lead; Clearance and Clearance Testing Requirements for the Renovation, Repair, and Painting Program”; approved through August 31, 2018.

Under PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for

certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This consolidated ICR will cover the information collection activities imposed on entities conducting lead-based paint related activities currently approved in the ICRs listed above. Following approval of this ICR, the previous ICRs will be discontinued.

Respondents/Affected entities: Private entities and state, territorial or Native American agencies who are engaged in or who administer lead-based paint activities or programs.

Respondent’s obligation to respond: Mandatory (see 40 CFR part 745). Respondents may claim all or part of a document confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Estimated total number of potential respondents: 791,805.

Frequency of response: On occasion.

Estimated total burden: 5,746,565 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: \$283,187,555 (per year), includes no annualized capital investment or maintenance and operational costs.

Changes in the estimates: There is an overall decrease of 282,737 hours in the total estimated combined respondent burden that is currently approved by OMB in the three ICRs consolidated in this request. This decrease reflects changes in EPA’s estimates of the number of respondents and burden-related activities based on economic conditions in the housing market and related industries. Further, the fact that the 2008 Renovation, Repair and Painting (RRP) rule and the 2010 Opt-Out rule have been in place for several years allows this ICR to use estimates based on actual certification data instead of making broader assumptions about industry behavior. Further details about these changes are included in the supporting statement for this ICR. This change is an adjustment.

Authority: 44 U.S.C. 3501 *et seq.*

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015-30114 Filed 11-25-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9024-2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7146 or <http://www2.epa.gov/nepa>.

Weekly receipt of Environmental Impact Statements (EISs)

Filed 11/16/2015 Through 11/20/2015 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxnodengn.epa.gov/cdx-nepa-publication/eis/search>.

EIS No. 20150332, Final, FDA, PRO, PROGRAMMATIC—Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Review Period Ends: 12/28/2015, Contact: Annette McCarthy 240-402-1057.

EIS No. 20150333, Draft, USFWS, CA, Butte Regional Conservation Plan, Comment Period Ends: 02/16/2016, Contact: Dan Cox 916-414-6593.

EIS No. 20150334, Draft, USFS, CA, Rim Fire Reforestation, Comment Period Ends: 01/11/2016, Contact: Maria Benech 209-532-3671.

EIS No. 20150335, Final, NRC, IL, Generic—License Renewal of Nuclear Plants Regarding Braidwood Station Units 1 and 2, Review Period Ends: 12/28/2015, Contact: Richard G. Baum 301-415-0018.

EIS No. 20150336, Draft, USACE, AK, Donlin Gold Project, Comment Period Ends: 04/30/2016, Contact: Keith Gordon 907-753-5710.

Amended Notices

EIS No. 20150302, Draft, NPS, WY, Moose-Wilson Corridor Draft Comprehensive Management Plan, Comment Period Ends: 01/15/2016, Contact: Chris Church 303-969-2276; Revision to FR Notice Published 10/30/2015; Extending Comment Period from 12/29/2015 to 01/15/2016.

Dated: November 23, 2015.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015-30183 Filed 11-25-15; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[AU Docket No. 14-252; DA 15-1252]

Instructions for FCC Form 177 Application To Participate in the Reverse Auction (Auction 1001)

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document provides information on and filing instructions for completing FCC Form 177, the application for licensees of commercial and noncommercial educational full power and Class A television stations to participate in the reverse auction (Auction 1001).

DATES: Reverse Auction FCC Form 177 filing window opens 12 noon Eastern Time (ET) on December 8, 2015, and closes 6:00 p.m. ET on January 12, 2016.

FOR FURTHER INFORMATION CONTACT:

Wireless Telecommunications Bureau, Auctions and Spectrum Access Division: for general reverse auction questions: Erin Griffith or Kathryn Hinton at (202) 418-0660.

SUPPLEMENTARY INFORMATION: This is a summary of the *Reverse Auction 1001 FCC Form 177 Instructions Public Notice (Reverse Auction 1001 FCC Form 177 Instructions PN)*, AU Docket No. 14-252, DA 15-1252, released on November 19, 2015. The complete text of the *Reverse Auction 1001 FCC Form 177 Instructions PN*, including all attachments is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. ET Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY-A257, Washington, DC 20554. The complete text is also available on the Commission's Web site at <http://wireless.fcc.gov>, or by using the search function on the ECFS Web page at <http://www.fcc.gov/cgb/ecfs/>.

Alternative formats are available to persons with disabilities by sending an email to FCC504@fcc.gov or by calling the Consumer & Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

I. General Information

1. The *Reverse Auction 1001 FCC Form 177 Instructions PN* provides the filing instructions for the electronic FCC Form 177, the application for licensees of commercial and noncommercial educational full power and Class A television stations (eligible broadcast licensees) to participate in the reverse auction (Auction 1001). Separate

attachments to the *Reverse Auction 1001 FCC Form 177 Instructions PN* provide the step-by-step filing instructions and templates for the certification by prospective channel sharer(s) that a reverse auction applicant-sharee must provide when submitting a channel sharing agreement in an application.

2. When filling out an FCC Form 177, a reverse auction applicant should follow the instructions in Attachments to the *Reverse Auction FCC Form 177 Instructions PN* along with the guidance provided in the *Auction 1000 Application Procedures PN*, 80 FR 66429, October 29, 2015. Each prospective applicant should also reference other public notices and/or decisions that have been issued in this proceeding, any future public notices and/or decisions that may be issued in this proceeding, and any other relevant public notices and/or decisions issued by the Commission in other proceedings that may relate to the incentive auction. Additional guidance, data, and information related to the broadcast incentive auction is available on the Auction 1000 Web site (<http://www.fcc.gov/auctions/1000>). A pre-auction process tutorial for the reverse auction was made available on the Auction 1001 Web site (<http://www.fcc.gov/auctions/1001>) on November 20, 2015, and the reverse auction application process workshop will be held on December 8, 2015.

Federal Communications Commission.

William Huber,

Associate Chief, Auctions and Spectrum Access Division, WTB.

[FR Doc. 2015-30298 Filed 11-25-15; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[DA 15-1242]

Notice of Intent To Terminate 214 Authorization

AGENCY: Federal Communications Commission

ACTION: Notice.

SUMMARY: This notice serves as final opportunity for Ocean Technology Limited (Ocean) to respond to the July 1, 2015 letter from the Department of Justice, Federal Bureau of Investigation, the Drug Enforcement Agency, and the U.S. Marshals Service (Agencies) requesting that the Federal Communications Commission (FCC) terminate and declare null, void and no longer in effect, and/or revoke the

international 214 authorization issued to Ocean by the FCC. The Agencies state that Ocean has failed to comply with commitments and undertakings in the July 9, 2013 Letter of Assurance entered into with the Agencies to address national security and law enforcement concerns. The FCC now provides final notice to Ocean that it intends to declare Ocean's international 214 authorization terminated for failure to comply with conditions of its authorization. Ocean must respond to this notice no later than 15 days after publication in the **Federal Register**.

DATES: Submit comments on or before December 14, 2015.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington DC, 20554.

FOR FURTHER INFORMATION CONTACT: Cara Grayer, Policy Division, International Bureau, at (202) 418-2960 or Cara.Grayer@fcc.gov.

SUPPLEMENTARY INFORMATION: Compliance with the commitments in the July 9, 2013 Letter of Assurance is a condition to the section 214 authorization granted to Ocean on July 17, 2013, by the FCC under file number ITC-214-20121210-00323. The FCC previously served its Notice of Intent to Terminate Ocean's 214 Authorization, DA 15-1242, to Ocean by mail, return receipt requested, at the last addresses of record which appears in the FCC's records. Ocean should send its response to Denise Coca, Chief, Policy Division, International Bureau via email at Denise.Coca@fcc.gov and file it in File No. ITC-214-20121210-00323 via IBFS at <http://licensing.fcc.gov/myibfs/pleading.do>. Ocean should also email a copy of its response to Cara Grayer, Policy Division, International Bureau at Cara.Grayer@fcc.gov.

Ocean's failure to respond to this notice will be deemed as an admission of the facts alleged by the Agencies.

The proceeding in this notice is treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules.

Federal Communications Commission.

Denise Coca,
Chief, Policy Division, International Bureau.

[FR Doc. 2015-30232 Filed 11-25-15; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank

Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 11, 2015.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *VHS Grantor Retained Annuity Trust #1 and Martha Sigmon Spurlock* as trustee, both of Big Stone Gap, Virginia; to acquire voting shares Commercial Bancgroup, Inc., and thereby indirectly acquire voting shares of Commercial Bank, both in Harrogate, Tennessee.

Board of Governors of the Federal Reserve System, November 23, 2015.

Michael J. Lewandowski,
Associate Secretary of the Board.

[FR Doc. 2015-30146 Filed 11-25-15; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also

includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 21, 2015.

A. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166-2034:

1. *Bank of the Ozarks, Inc.*, Little Rock, Arkansas; to merge with Community & Southern Holdings, Inc., and thereby indirectly acquire Community & Southern Bank, both in Atlanta, Georgia.

Board of Governors of the Federal Reserve System, November 23, 2015.

Michael J. Lewandowski,
Associate Secretary of the Board.

[FR Doc. 2015-30147 Filed 11-25-15; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0055; Docket 2015-0055; Sequence 23]

Information Collection; Freight Classification Description

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning freight classification description.

DATES: Submit comments on or before January 26, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000-0055, Freight Classification Description, by any of the following methods:

• *Regulations.gov*: <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0055, Freight Classification Description". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0055, Freight Classification Description" on your attached document.

• *Mail*: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 First Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0055, Freight Classification Description.

Instructions: Please submit comments only and cite Information Collection 9000–0055, Freight Classification Description, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Acquisition Policy, at 202–501–1448 or via email at curtis.glover@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Government is required to provide, in solicitations, a complete description of the supplies to be acquired and the packing requirements to determine transportation (freight rate) charges for the evaluation of offers. Generally, the freight rate for supplies is based on the ratings applicable to the freight classification description published in the National Motor Freight Classification (for carriers) and the Uniform Freight Classification (for rail) filed with Federal and State regulatory bodies.

When the Government purchases supplies that are new to the supply system, nonstandard, or modifications of previously shipped supplies, and different freight classifications may apply, per FAR clause 52.247–53, offerors are requested to indicate the full Uniform Freight Classification or National Motor Freight Classification

description applicable to the supplies. The Government will use these descriptions as well as other information available to determine the classification description most appropriate and advantageous to the government.

B. Annual Reporting Burden

Respondents: 3,000.
Responses per Respondent: 3.
Annual Responses: 9,000.
Hours per Response: .167.
Total Burden Hours: 1,503.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 First Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0055, Freight Classification Description, in all correspondence.

Edward Loeb,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–30141 Filed 11–25–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16ET; Docket No. CDC–2015–0107]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project entitled "Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color." Seven U.S. health departments will form, lead, and coordinate a collaborative with 37 community-based organizations (CBOs), clinics and other health providers, behavioral health and social health providers in their jurisdictions. The collaborative will report standardized program monitoring and evaluation (M&E) data to the health department and then the health department will report the same M&E data to CDC.

DATES: Written comments must be received on or before January 26, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0107 by any of the following methods:

• *Federal eRulemaking Portal*: *Regulation.gov*. Follow the instructions for submitting comments.

• *Mail*: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of

Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Comprehensive HIV Prevention and Care for Men Who Have Sex With Men of Color—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Approximately 50,000 people in the United States are newly infected with HIV each year. Gay, bisexual, and other men who have sex with men (MSM) remain the US population most heavily affected by HIV infection. Among MSM,

those who are black and Hispanic comprise 58% of all new infections. To address the burden of HIV in this population, high impact HIV prevention approaches should be implemented by state, local, and territorial health departments to reduce new HIV infections among MSM of color, and to improve outcomes along the HIV continuum of care for MSM of color living with HIV.

Antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP) can be used for HIV prevention by MSM at substantial risk for HIV acquisition or by those with a possible HIV exposure in the past 72 hours post-exposure prophylaxis (nPEP). The daily use of co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada) for PrEP has been proven to significantly reduce the risk of HIV acquisition among sexually active MSM. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published clinical practice guidelines for provision of PrEP. Given the high incidence of HIV among MSM of color, those who are sexually active are considered at risk for HIV acquisition and thus could benefit from prevention services such as routine and frequent HIV screening with lab-based 4th generation HIV tests, routine screening for STDs, assessment of PrEP eligibility, provision of PrEP (if at substantial risk for HIV acquisition), provision of nPEP (if a possible HIV exposure occurred in the past 72 hours), and/or other risk reduction interventions.

Among people living with HIV (PLWH), ARV treatment can suppress HIV viral load, which both improves health outcomes of individuals and reduces the risk of HIV transmission. Two studies, one that demonstrated the effectiveness of ARV treatment in preventing HIV transmission, and one that demonstrated improved health outcomes for individuals whose ARV treatment was initiated immediately, have led to increased public health focus on interventions and strategies designed to initiate ARV treatment, link, retain, and re-engage PLWH in HIV care, and to provide support for adherence to ARV medications.

The purpose of this project is to support state and local health departments to develop and implement demonstration projects for provision of comprehensive HIV prevention and care services for MSM of color by creating a collaborative with CBOs, clinics and other health care providers, and behavioral health and social services providers in their jurisdiction.

Behavioral health services include mental health and substance abuse treatment to enable MSM of color to utilize HIV prevention and care services; social services include services that promote access to housing, job counseling, and employment services to enable MSM of color to utilize HIV prevention and care services.

Comprehensive models of HIV prevention and care for MSM of color will be developed and implemented by a collaborative that is led by the jurisdiction's health department and includes the following: Health care providers (e.g., federally qualified health centers (FQHCs), FQHC Look-Alikes, other clinics, or health care providers); HIV care providers (e.g., clinics funded through the Ryan White HIV/AIDS Program (RWHAP clinics), other HIV care clinics, or HIV care providers); behavioral health and social services providers (i.e., mental health and substance abuse services, housing programs, and job training or employment services); and community based organizations (CBOs). Principles of high impact prevention should guide the selection and implementation of activities and strategies to focus on MSM of color at substantial risk for HIV infection (i.e., eligible for prevention with PrEP), and those living with HIV. MSM of color who are at risk for HIV acquisition (i.e., sexually active) but not eligible for or decline PrEP will be provided risk reduction interventions, partner services if diagnosed with an STD, re-testing for HIV and STDs in 3–6 months, and behavioral health and social services. The risk of HIV acquisition should be assessed at every encounter with an individual, and MSM of color at substantial risk of HIV acquisition should be offered PrEP when indicated by the risk assessment.

There are a total of 24 required HIV prevention and care services that must be provided by the health department collaborative for this project. This is to include thirteen HIV prevention services for MSM of color at substantial risk for HIV infection and eleven HIV care services for MSM of color living with HIV infection. The following are the thirteen HIV prevention services: 1. HIV testing services that use lab-based 4th generation HIV tests; 2. Assessment of indications for pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP); 3. Provision of PrEP and nPEP; 4. Adherence interventions for PrEP and nPEP; 5. Immediate linkage to care, ARV treatment, and partner services for those diagnosed with acute HIV infection; 6. Expedient linkage to care, ARV treatment, and partner

services for those diagnosed with established HIV infection; 7. STD screening and treatment; 8. Partner services for patients with STDs; 9. Behavioral risk reduction interventions; 10. Screening for behavioral health and social services' needs; 11. Linkage to behavioral health and social services; 12. Navigators to assist accessing HIV prevention and behavioral health and social services; 13. Navigators to assist enrollment in a health plan. The following are the eleven HIV care services: 1. HIV primary care, including

antiretroviral (ARV) treatment; 2. Retention interventions; 3. Re-engagement interventions; 4. Adherence interventions; 5. STD screening and treatment; 6. Partner services; 7. Behavioral risk reduction interventions; 8. Screening patients for behavioral health and social services' needs; 9. Linkage to behavioral health and social services; 10. Navigators to assist linking to care and accessing behavioral health and social services; 11. Navigators to assist enrollment in a health plan.

CDC HIV program grantees will collect, enter or upload, and report agency-identifying information, budget data, information on the HIV prevention and care services, and client demographic characteristics with an estimate of 2,466 burden hours. It is estimated that the 37 respondents will see approximately 200 patients per year. The respondents will take about 20 minutes to enter the data for each of the 200 patients using the monitoring and evaluation form.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Health jurisdictions	Health Department Collaborative	37	200	20/60	2,466

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015-30130 Filed 11-25-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16FE; Docket No. CDC-2015-0108]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection entitled "Monitoring and Reporting System for Rape Prevention and Education (RPE) Awardees." CDC will use the information collected to monitor cooperative agreement awardees and to identify challenges to

program implementation and achievement of outcomes.

DATES: Written comments must be received on or before January 26, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0108 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each

collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and

maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Monitoring and Reporting System for Rape Prevention and Education (RPE) Awardees—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

According to CDC’s National Intimate Partner and Sexual Violence Survey (NISVS), in the United States, nearly 1 in 5 women and 1 in 71 men have been raped in their lifetime, while 1 in 2 women and 1 in 5 men have experienced severe sexual violence victimization other than rape at some point in their lives. Sexual violence is a major public health problem, but it is preventable. The majority of victimization starts early in life with approximately 80% of female victims experiencing their first rape before the age of 25 and almost half experiencing their first rape before age 18. CDC’s Rape Prevention and Education Initiative is a national program which funds, through a cooperative agreement,

all 50 state health departments, the District of Columbia, Puerto Rico, and territories (e.g., Guam, U.S. Virgin Islands, and the Commonwealth of Northern Mariana Islands) to conduct state- and territorial-wide sexual violence prevention activities.

The current Rape Prevention and Education (RPE) Cooperative Agreement builds on a decade long (2002–2012) investment in the infrastructure and capacity for sexual violence prevention within state health departments, state sexual assault coalitions, rape crisis centers and other community based organizations. Support and guidance for these programs have been provided through cooperative agreement funding and technical assistance administered by CDC’s National Center for Injury Prevention and Control (NCIPC).

The goal of this information collection is to receive the needed data to monitor cooperative agreement programs funded under the Rape Prevention Education program (CDC–RFA–CE14–1401), for program monitoring and improvement among funded state health departments.

Data to be collected will provide crucial information for program performance monitoring and budget tracking, and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources.

Awardees will report progress and activity information to CDC on an annual schedule using an Excel-based fillable electronic templates, pre-populated to the extent possible by CDC staff, to be submitted via Grant Solutions. Each awardee will submit an Annual reporting Progress Report Tool and an Annual reporting Evaluation Plan Tool. In Year 1, each awardee will have additional burden related to initial collection of the reporting tools. Initial population of the tools is a one-time activity, after completing the initial population of the tools, pertinent information only needs to be updated for each annual report. The same instruments will be used for all information collection and reporting.

CDC will use the information to monitor each awardee’s progress and to identify facilitators and challenges to program implementation and achievement of outcomes. Monitoring allows CDC to determine whether an awardee is meeting performance and budget goals and to make adjustments in the type and level of technical assistance provided to them, as needed, to support attainment of their performance measures.

OMB approval is requested for three years. Participation in the information collection is required as a condition of funding. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Territorial Health Departments or Sexual Assault Coalition Designee.	Program Report Tool (initial collection—Year 1).	55	1	7	385
	Work Plan Tool (initial collection—Year 1).	55	1	10	550
	Program Report Tool (annual reporting collection—Years 2–3).	55	2	3	330
	Work Plan Tool (annual reporting collection—Years 2–3).	55	2	3	330
Total	1,595

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

[FR Doc. 2015–30131 Filed 11–25–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16FG; Docket No. CDC–2015–0109]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on *Workplace Health In America*, a nationally representative survey of employer-based workplace health programs to describe the current state of U.S. workplace health promotion and protection programs and practices in employers of all sizes, industries and regions.

DATES: Written comments must be received on or before January 26, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0109 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for

Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Workplace Health In America—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The health of a workplace and its workers are inextricably linked. Ideally, workplaces not only protect the safety and wellbeing of employees but also provide them opportunities for better long-term health and enhanced quality of life. Effective workplace programs, policies, and environments that are health-focused and worker-centered have the potential to significantly benefit employers, employees, their families, and communities. As the nation's premier public health agency, the CDC helps protect the health and safety of all people in our schools, communities, homes and workplaces through prevention. The workplace can specifically protect and promote health through programs, policies, and practices that have the potential of reaching millions of workers, retirees, and their families.

Increasing health care costs and decreasing health-related productivity are leading American businesses to examine strategies to improve employee health and contain health costs that are largely driven by chronic diseases and related lifestyle choices. Employers are recognizing the role they can play in creating a healthy work environment and providing their employees with opportunities to make healthy lifestyle choices. They increasingly look to CDC and other public health experts for guidance and solutions to combat the effects of chronic diseases on their employees and businesses. Workplace health programs not only benefit individual employees but also make good business sense.

Although a number of national and local level studies and surveys have been conducted over the past 25 years examining aspects of workplace health promotion and protection programs, there has not been, to date, a systematic and ongoing effort to document the evidenced-based and best practice strategies and interventions at the individual employee and organizational level that comprise a comprehensive workplace health program from a nationally representative sample of employers. Workplace Health in America is authorized by the Public Health Service Act and funded through the Prevention and Public Health Fund of the Patient Protection and Affordable Care Act (ACA). CDC has developed the Workplace Health in America survey program to describe the current state of U.S. workplace health promotion and protection programs and practices in employers of all sizes, industries and regions. National worksite health promotion experts, employers, and

content experts from the CDC advised on the survey content. Items from existing, validated surveys were used whenever possible. The survey contains yes/no, multiple choice and a small number of open-ended items.

The Workplace Health in America survey is designed to collect information about: Basic organizational characteristics; employer-sponsored health insurance; health risk assessments; staffing and other resources devoted to employee health and safety programming; incentives; work-life policies and benefits; availability of health screenings and disease management programs; occupational safety and health programs. The survey items also cover the presence of evidence-based and other health promotion programs, policies and supports related to physical activity; nutrition; weight; tobacco; excess alcohol use and drug abuse; lactation and prenatal support; musculoskeletal disorders, arthritis and back pain; stress; and sleep.

CDC seeks to request Office of Management and Budget (OMB) approval. The information that is collected is intended to build an infrastructure supporting ongoing surveillance to evaluate national workplace health priorities (e.g., *Healthy People*), monitor trends, and address emerging issues; provide free and accessible benchmarking data for employers and other stakeholders in workplace health promotion and protection; provide a better understanding of employer practices to inform the development of tools and resources to support the design, implementation, and evaluation of employer-based workplace health programs; and advance workplace health promotion and protection research.

To achieve these aims, CDC has developed an infrastructure for this initial effort that can be expanded for future iterations of data collection. CDC has designed a process to select a nationally representative sample of

worksites representing employers in all size categories, industry sectors, and CDC regions. The data collection platform was developed to collect information primarily by online survey or telephone assisted interview, and can be easily modified to accommodate additional survey modules. CDC has also created a dissemination plan to ensure the data and results can be used by employers and other stakeholders beyond the research community. Planned dissemination products include webinars to employer groups, an online dashboard for employers to benchmark their programs against other employers with comparable characteristics, and brief reports tailored to employers of different sizes.

OMB approval is requested for two years. CDC estimates that a total 8,085 employers will complete the Workplace Health in America survey. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Wellness/HR representative ...	Screening and Recruiting call	11,684	1	15/60	2,921
	Workplace Health in America Survey	4,043	1	40/60	2,695
Total	5,616

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

[FR Doc. 2015-30132 Filed 11-25-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Board of Scientific Counselors (BSC), National Institute for Occupational Safety and Health (NIOSH)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the BSC, NIOSH.

The BSC, NIOSH consists of 15 experts in fields related to occupational safety and health. The members are selected by the Secretary of the U.S.

Department of Health and Human Services (HHS). The board advises the NIOSH Director on occupational safety and health research and prevention programs. The board also provides advice on standards of scientific excellence, current needs in the field of occupational safety and health, and the applicability and dissemination of research findings. This advice may take the form of reports or verbal communications to the NIOSH Director during BSC meetings.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the board's mission. More information is available on the NIOSH BSC Web site: <http://www.cdc.gov/niosh/BSC/default.html>.

Nominees will be selected based on expertise in occupational safety and health fields, such as occupational medicine, occupational nursing, industrial hygiene, occupational safety and health engineering, toxicology, chemistry, safety and health education, ergonomics, epidemiology, biostatistics, and psychology. Members may be

invited to serve for terms of two to four years. Selected nominees would begin service on the BSC, NIOSH in January 2017.

The U.S. Department of Health and Human Services policy stipulates that committee membership shall be balanced in terms of professional training and background, points of view represented, and the committee's function. In addition to a broad range of expertise, consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, all ethnic and racial groups, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government or federally registered lobbyists.

Candidates should submit the following items:

- Current *curriculum vitae*, including complete contact information (name, affiliation, mailing address, telephone number, email address)
- A letter of recommendation stating the qualifications of the candidate.

Nomination materials must be postmarked by December 21, 2015, and sent to: John Decker, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E-20, Atlanta, Georgia 30333, telephone (404) 498-2500.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-30124 Filed 11-25-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates to Serve on the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the BSC, OID. This board consists of 17 experts in fields related to infectious diseases who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The board advises the HHS Secretary; the CDC Director; the OID Director; and the Directors of the National Center for Immunization and Respiratory Diseases (NCIRD), the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) concerning strategies, goals, and priorities for the programs and research within the national centers and monitors the overall strategic direction and focus of OID and the national centers.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the board's mission. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable in the fields of infectious diseases and related disciplines, including epidemiology, microbiology, bioinformatics, and

clinical and veterinary medicine, as well as from the general public. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that committee membership shall be balanced in terms of professional training and background, points of view represented, and the committee's function. In addition to a broad range of expertise, consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, all ethnic and racial groups, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government or federally registered lobbyists.

Candidates should submit the following items:

- Current *curriculum vitae*, including complete contact information (name, affiliation, mailing address, telephone number, email address);
- A letter of recommendation stating the qualifications of the candidate.

Nomination materials must be postmarked by December 31, 2015, and sent to: Kim Distel, Office of Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30329, telephone (404) 639-2100.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-30123 Filed 11-25-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10066 and CMS-10596]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 26, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10066 Detailed Notice of Discharge (DND) and Supporting Regulations in 42 CFR 405.1206 and 422.622

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Detailed Notice of Discharge (DND) and Supporting Regulations in 42 CFR 405.1206 and 422.622; *Use:* A beneficiary or enrollee who wishes to appeal a determination by a Medicare health plan (for a managed care enrollee) or hospital (for an original Medicare beneficiary) that inpatient care is no longer necessary may request Quality Improvement Organization (QIO) review of the determination. On the date the QIO receives the beneficiary's/enrollee's request, it must notify the plan and hospital that the beneficiary/enrollee has filed a request for an expedited determination. The plan or hospital, in turn, must deliver a DND to the enrollee/beneficiary. In this iteration the DND has been minimally changed to include language informing beneficiaries of their rights under the Rehabilitation Act of 1973 (section 504), by alerting the beneficiary to CMS's

nondiscrimination practices and the availability of alternate forms of this notice if needed. There are no substantive changes to the DND form and instructions. *Form Number:* CMS-10066 (OMB Control Number: 0938-1019); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 6,164; *Total Annual Responses:* 17,000; *Total Annual Hours:* 17,000. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Reapplication Submission Requirement for Qualified Entities under ACA Section 10332; *Use:* Section 10332 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary to make standardized extracts of Medicare claims data under Parts A, B, and D available to "qualified entities" for the evaluation of the performance of providers of services and suppliers. The statute provides the Secretary with discretion to establish criteria to determine whether an entity is qualified to use claims data to evaluate the performance of providers of services and suppliers. After consideration of comments from a wide variety of stakeholders during the public comment period, CMS established "Medicare Program; Availability of Medicare Data for Performance Measurement" (hereinafter called the Final Rule and referred to as the Medicare Data Sharing Program). It was published in the **Federal Register** on December 7, 2011 (42 CFR, Part 401, Subpart G). To implement the requirements outlined in the legislation, the Centers for Medicare and Medicaid Services (CMS) established the Qualified Entity Certification Program (QECP). The Qualified Entity Certification Program (QECP) was established to implement the Final Rule. One of the requirements in the Final Rule is that QEs must reapply for certification six months prior to the end of their 3-year certification period to remain in good standing. This form is the official reapplication that QEs must complete to reapply to the QECP. *Form Number:* CMS-10596 (OMB Control Number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 1,200. (For policy questions regarding

this collection contact Kari Gaare at 410-786-8612.)

Dated: November 20, 2015.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-30070 Filed 11-25-15; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 14, 2016, from 1 p.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link <https://collaboration.fda.gov/vrbpacsem1/>.

Contact Person: Sujata Vijn or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993-0002, at 240-402-7107 and 240-402-8158 respectively, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On January 14, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of the research program in the Laboratory of Method Development, Division of Viral Products, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On January 14, 2016, from 1 p.m. to 3:35 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 7, 2016. Oral presentations from the public will be scheduled between approximately 2:35 p.m. and 3:35 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 29, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 30, 2015.

Closed Committee Deliberations: On January 14, 2016, from 3:35 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The Committee will discuss the report of the intramural research program and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sujata Vijh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 20, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-30121 Filed 11-25-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: December 15, 2015 (9:30 a.m.—4:00 p.m.).

Place: Conference Call/Webinar Format.

Status: The meeting will be open to the public.

Purpose: The ACICBL provides advice and recommendations to the Secretary of the Department of Health and Human Services (Secretary) concerning policy, program development, and other

matters of significance related to interdisciplinary, community-based training grant programs authorized under sections 750–759, Title VII, Part D of the Public Health Service Act, as amended by the Affordable Care Act. The following sections are included under this Part: 751—Area Health Education Centers; 752—Continuing Education Support for Health Professionals Serving in Underserved Communities; 753—Geriatrics Workforce Enhancement; 754—Quentin N. Burdick Program for Rural Interdisciplinary Training; 755—Allied Health and Other Disciplines; 756—Mental and Behavioral Health Education and Training, and 759—Program for Education and Training in Pain Care.

The members of the ACICBL will select a topic for the legislatively mandated 16th report. They will also finalize their discussion of the legislatively mandated 15th Annual Report to the Secretary of Health and Human Services and Congress. In the 15th Annual Report they will make recommendations for Title VII, Part D programs, performance measures, and appropriation levels.

Agenda: The ACICBL agenda will be available 2 days prior to the meeting on the HRSA Web site at <http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/index.html>.

SUPPLEMENTARY INFORMATION: Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call and webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Advisory Committee on Interdisciplinary, Community-Based Linkages.

- The conference call-in number is 1-800-619-2521. The passcode is: 9271697.

- The webinar link is <https://hrsa.connectsolutions.com/acicbl-meeting/>.

Contact: Anyone requesting information regarding the ACICBL should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of

Health Workforce, Health Resources and Services Administration, Room 12C-05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443-0430; or (3) send an email to jweiss@hrsa.gov.

Jackie Painter,

Director, Division of the Executive Secretariat.
[FR Doc. 2015-30073 Filed 11-25-15; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NIEHS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)

Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, P.O. Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-4668, or email your request, including your address to: sandler@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925-0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013-

2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Estimated annual number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Private and Commercial Applicators and Spouses.	Reminder, Missing, and Damaged Scripts for Buccal Cell.	100	1	5/60	8
Private Applicators	BEEA CATI Eligibility Script	480	1	20/60	160
Private Applicators	Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire.	160	1	20/60	53
Private Applicators	BEEA Home Visit CAPI, Blood, Buccal cell, Urine & Dust.	160	1	90/60	240
Private Applicators	BEEA Pre-Visit Scripts	20	3	5/60	5
Private Applicators	BEEA Home Visit CAPI, Blood, Buccal cell, Urine, & Dust x 3.	20	3	90/60	90
Private Applicators	BEEA Mailed Consents (Home Visit & Farm Visit), Pre-Visit Show Card, and Paper/Pen Dust Questionnaire.	16	1	25/60	7
Private Applicators	BEEA Home Visit CAPI, Blood, Urine, Buccal cell & Dust x 2.	16	2	90/60	16
Controls	BEEA CATI Control Eligibility Script	215	1	20/60	72

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Estimated annual number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Controls	BEEA Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire.	67	1	20/60	22
Controls	BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust.	67	1	90/60	101
Private Applicators	'Life in a Day' Smartphone Application x 25	100	25	10/60	417
Private Applicators	Paper/pen, CAWI or CATI	13,855	1	25/60	5,773
Spouses	Paper/pen, CAWI or CATI	10,201	1	25/60	4,250
Proxy	Paper/pen, CAWI or CATI (Attachment 26)	635	1	15/60	159
Total	25,486	28,608	11,516

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,516.

Dated: November 20, 2015.

Chris Long,

Acting Executive Officer, NIEHS.

[FR Doc. 2015-30219 Filed 11-25-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2015-0078]

Privacy Act of 1974; Department of Homeland Security/United States Coast Guard-029 Notice of Arrival and Departure System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, "Department of Homeland Security/United States Coast Guard-029 Notice of Arrival and Departure System of Records." This system of records allows the United States Coast Guard (Coast Guard) to facilitate the effective and efficient entry and departure of vessels into and from the United States, and assist with assigning priorities for complying with maritime safety and security regulations. As part of the Department's ongoing effort to promote transparency regarding its collection of information, the Coast Guard is updating this system of records notice to update the (1) authority for maintenance of the system, (2) security classification, (3) system location, (4) purpose(s), (5)

categories of individuals, (6) categories of records, (7) routine uses, (8) retention and disposal, (9) notification procedures, and (10) system manager and address. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

The Coast Guard is also issuing a Notice of Proposed Rulemaking (NPRM) to clarify the exemptions for this system concurrently with this notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 28, 2015. This updated system will be effective December 28, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS-2015-0078 by one of the following methods:

- Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: (202) 343-4010.
- Mail: Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Marilyn Scott-Perez, (202) 475-3515, Privacy Officer, Commandant (CG-61), United States Coast Guard, 2703 Martin Luther King Jr. Ave SE., Mail Stop 7710, Washington, DC 20593. For privacy questions, please contact: Karen L. Neuman, (202) 343-1717, Chief Privacy

Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) United States Coast Guard (USCG) proposes to update and reissue a current DHS system of records titled, "DHS/USCG-029 Notice of Arrival and Departure (NOAD) System of Records." The collection and maintenance of this information assists DHS/USCG in meeting its statutory obligation to assign priorities while conducting maritime safety and security missions in accordance with international and U.S. regulations. DHS/USCG is updating this system of records to (1) clarify the authority for the maintenance of the system to align with the recently published *Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System* Final Rule (January 30, 2015, 80 FR 5281); (2) update the security classification; (3) change the system location to clarify that NOAD records may be stored on information technology (IT) systems connected to classified networks; (4) update the purpose(s) to align with the updated authorities for collection, pursuant to the newly issued *Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System* Final Rule and to allow for replication of data for analysis and vetting as part of the DHS Data Framework. DHS/USCG is also updating the categories of individuals and categories of records to clarify that individuals considered "non-crew" for the purposes of this system may include passenger records, as well as organizations; and removing routine use (M) because it is not compatible with the original purpose for collection of the records. Further DHS/USCG is updating the retention period and disposal standards to reflect that

records will follow the same retention schedule despite their storage in a classified environment; and modify the notification procedures to confirm that regardless of record storage on a classified environment, DHS/USCG will review all replicated records; and update the system manager and mailing address to reflect the new mail stop.

Consistent with DHS's information sharing mission, information stored in this system of records may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions and missions. In addition, DHS/USCG may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

The Coast Guard is issuing a new Notice of Proposed Rulemaking (NPRM) to clarify the exemptions for this system concurrently with this notice. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/USCG-029 Notice of Arrival and Departure System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/United States Coast Guard (USCG)-029

System name:

DHS/USCG-029 Notice of Arrival and Departure System of Records

SECURITY CLASSIFICATION:

Unclassified. The data may be retained on classified networks but this does not change the nature and character of the data until it is combined with classified information.

SYSTEM LOCATION:

The United States Coast Guard (USCG) maintains records in the operational system at the USCG Operations Systems Center, Kearneysville, West Virginia (WV), and in disaster recovery backup systems in other USCG field locations. USCG maintains records associated with this function in the Ship Arrival Notification System (SANS) operational information technology (IT) system.

DHS replicates records from the operational IT system and maintains them in other IT systems connected on the DHS unclassified and classified networks.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this notice include:

- Crew members who arrive or depart the United States by sea; and
- Other individuals or organizations associated with a vessel and whose information is submitted as part of a notice of arrival or notice of departure, such as vessel owners, operators, charterers, reporting parties, 24-hour contacts, company security officers, and passengers who arrive and depart the United States by sea.

CATEGORIES OF RECORDS IN THE SYSTEM:

- Records on vessels include: Name of vessel; name of registered owner; country of registry; call sign; International Maritime Organization (IMO) number or, if a vessel does not have an IMO number the official number; name of the operator; name of charterer; and name of classification society.
- Records on arrival information pertaining to the voyage include: Names of last five foreign ports or places the vessel visited; dates of arrival and departure for last five foreign ports or places it visited; for each port or place in the United States the vessel will visit, the name of the receiving facility; for the port or place in the United States the estimated date and time of arrival; for the port or place in the United States the estimated date and time of departure; the location (port or place and country) or position (latitude and longitude or

waterway and mile marker) of the vessel at the time of reporting; and the name and telephone number of a 24-hour point of contact (POC). This individual may be a crew or non-crew member.

- Records on departure information pertaining to the voyage include: The name of the departing port or waterway of the United States; the estimated date and time of departure; next port or place of call (including foreign); the estimated date and time of arrival at the next port or place of call; and the name and telephone number of a 24-hour POC.

- Records about crewmembers includes: Full name; date of birth; nationality; identification type (e.g., passport, U.S. Alien Registration Card, U.S. Merchant Mariner Document, foreign mariner document, government-issued picture identification (ID) (Canada) or (United States)); identification issue and expiration dates; position or duties on the vessel; location where the crewmember embarked (list port or place and country); and location where the crewmember will disembark.

- Records about "other individuals associated with a vessel and whose information is submitted as part of a notice of arrival or notice of departure" (e.g., passenger information) includes: Full name; date of birth; nationality; identification type (e.g., passport, U.S. Alien Registration Card, government-issued picture ID); identification number, issuing country, issue date, expiration date; U.S. address information; and location where the individual embarked (list port or place and country).

- Records related to cargo onboard the vessel include: A general description of cargo other than Certain Dangerous Cargo (CDC) onboard the vessel (e.g., grain, container, oil); name of each CDC carried, including United Nations (UN) number, if applicable; and amount of each CDC carried.

- Records regarding the operational condition of equipment required by 33 Code of Federal Regulations (CFR) part 164 include: The date of issuance for the company's document of compliance certificate; the date of issuance of the vessel's safety management certificate; and the name of the flag administration, or recognized organization(s) representing the vessel flag administration that issued those certificates.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Secretary of the Department of Homeland Security has delegated to the Coast Guard authority from the Ports and Waterways Safety Act (33 U.S.C. 1221 *et se.*). See specifically 33 U.S.C.

1223(a)(5), 1225, and 1231; 46 U.S.C. 3717; 46 U.S.C. 12501; the Maritime Transportation Act of 2002, Pub. L. 107-295; the Homeland Security Act of 2002, Public Law 107-296; 33 CFR part 160; and 36 CFR chapter XII.

PURPOSE(S):

The purpose of this system is to maintain NOAD information to improve navigation safety, enhance the Coast Guard's ability to identify and track vessels, and heighten the Coast Guard's overall situational and maritime domain awareness (MDA), which will enhance mariner's navigation safety and the Coast Guard's ability to address threats to maritime transportation security.

DHS maintains a replica of some or all of the NOAD data in operational IT systems residing on unclassified and classified DHS networks to allow for analysis and vetting consistent with the above stated purposes and this published notice.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by

law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To federal and foreign government intelligence or counterterrorism agencies or components if USCG becomes aware of an indication of a threat or potential threat to national or international security, or if such use is to assist in anti-terrorism efforts and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.

I. To an organization or individual in either the public or private sector, foreign or domestic, if there is a reason to believe that the recipient is or could become the target of a particular

terrorist activity or conspiracy, to the extent the information is relevant to the protection of life, property, or other vital interests of a data subject and disclosure is proper and consistent with the official duties of the person making the disclosure;

J. To appropriate federal, state, local, tribal, territorial, or foreign governmental agencies or multilateral governmental organizations for the purpose of protecting the vital interests of a data subject or other persons, USCG will provide appropriate notice of any identified health threat or risk to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantined disease or for combating other significant public health threats;

K. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, settlement negotiations, response to a subpoena, or in connection with criminal law proceedings;

L. To third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate in the proper performance of the official duties of the officer making the disclosure;

M. To appropriate federal, state, local, tribal, territorial, or foreign governmental agencies or multilateral governmental organizations if USCG is aware of a need to utilize relevant data for purposes of testing new technology and systems designed to enhance border security or identify other violations of law, provided disclosure is appropriate in the proper performance of the official duties of the person making the disclosure;

N. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING**AGENCIES:**

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

Records in this system are stored electronically in the operational IT system as well as on other IT systems residing on the unclassified and classified networks or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD-ROM.

USCG stores NOAD information electronically in the Ship Arrival Notice System (SANS) located at USCG Operations Systems Center in Kearneysville, WV. USCG uses an alternative storage facility for the SANS historical logs and system backups. Derivative NOAD system data may be stored on USCG Standard Workstation computers or USCG unit servers located at USCG Headquarters, headquarters units, area offices, sector offices, sector sub-unit offices, and other locations where USCG authorized personnel may be posted to facilitate DHS's mission.

RETRIEVABILITY:

USCG retrieves records from the SANS by vessel. Information from the retrieved records may then be extracted by name, passport number, or other unique personal identifier. NOAD information maintained in the SANS operational IT system is not directly retrievable by name or other unique personal identifier.

NOAD data that is replicated on the unclassified and classified DHS networks to allow for analysis and vetting consistent with the above stated purposes and this published notice may be retrieved by all core and extended biographic fields (e.g., full name; date of birth; nationality).

SAFEGUARDS:

USCG safeguards NOAD data in accordance with applicable laws, rules, and policies. All records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include role-based access provisions, restricting access to authorized personnel who have a need-to-know, using locks, and password-protection identification features. USCG file areas are locked after normal duty hours and the facilities are protected from the outside by security personnel. In addition, the system manager, in addition, has the capability to maintain

system back-ups for the purpose of supporting continuity of operations and the discrete need to isolate and copy specific data access transactions for the purpose of conducting security incident investigations. All communication links with the USCG datacenter are encrypted. The databases are Certified and Accredited in accordance with the requirements of the Federal Information Security Management Act (FISMA).

RETENTION AND DISPOSAL:

In accordance with NARA Disposition Authority number N1-026-05-11, NOAD information on vessels and individuals maintained in the SANS is destroyed or deleted when no longer needed for reference, or after ten years, whichever is later. Outputs, which include ad-hoc reports generated for local and immediate use to provide a variety of interested parties with necessary information are deleted after five years if they do not constitute a permanent record according to NARA. For example, in accordance with this schedule, USCG shares outputs with the Captain of the Port and marine safety offices, sea marshals, U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement require such information to set up security zones, schedule boarding and inspections activities, take actions for non-compliance with regulations, and other activities in support of USCG's mission to provide for safety and security of U.S. ports. Records replicated to IT systems residing on the unclassified and classified networks will also follow the same retention schedule.

SYSTEM MANAGER AND ADDRESS:

Commandant (CG-26), United States Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Mail Stop 7301, Washington, DC 20593-0001.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and USCG's Freedom of Information Act (FOIA) Officer, whose contact information can be found at <http://www.dhs.gov/foia> under "Contacts." If an individual believes more than one component maintains Privacy Act records concerning him or herself, the individual may submit the request to the Chief Privacy Officer and Chief FOIA Officer, Department of Homeland Security, Washington, DC 20528-0655.

When seeking records about yourself from this system of records or any other

Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer, <http://www.dhs.gov/foia> or 1-866-431-0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records;

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

In processing requests for access to information in this system, the USCG will review not only the records in the operational IT system but also the records replicated on IT systems residing on the unclassified and classified networks; and provide appropriate access to the information based on this notice.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

USCG obtains NOAD records from vessel carriers and operators regarding passengers, crewmembers, and cargo that arrive in, depart from, or transit through the United States on a vessel carrier covered by notice of arrival and departure regulations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemption shall be asserted with respect to information maintained in the

system that is collected from a person if that person, or his or her agent, seeks access or amendment of such information.

The Privacy Act, however, requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agency has sought particular records may affect ongoing law enforcement activities. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), exempted this system from the following provisions of the Privacy Act: Sections (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information. Further, DHS has exempted section (c)(3) of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(k)(2) as is necessary and appropriate to protect this information.

Dated: November 16, 2015.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015-30303 Filed 11-25-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Revision Notice; Student and Exchange Visitor Information System Forms I-20

ACTION: 30-Day notice of Information collection for review; Form No. I-20; Certificate of Eligibility for Nonimmigrant (F-1) Student Status—For Academic and Language Students, and the Form I-20, Certificate of Eligibility for Nonimmigrant (M-1) Student Status—For Vocational Students; OMB Control No. 1653-0038.

The Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** (FR) to obtain comments from the public and affected agencies.

Written comments and suggestions regarding items contained in this notice should be directed to the Department of Homeland Security, Scott Elmore, Forms Management Office, U.S. Immigration and Customs Enforcement,

801 I Street NW., Mailstop 5800, Washington, DC 20536-5800.

SUMMARY: This FR notice pertains to all schools certified to enroll F-1 and/or M-1 nonimmigrant students. DHS's Student and Exchange Visitor Program (SEVP) performs and manages these certifications, as well as oversees the F-1 and M-1 students. SEVP uses the Form I-20, Certificate of Eligibility for Nonimmigrant (F-1) Student Status—For Academic and Language Students, and the Form I-20, Certificate of Eligibility for Nonimmigrant (M-1) Student Status—For Vocational Students, which are issued solely through the Student and Exchange Visitor Information System (SEVIS), as an instrument to facilitate the oversight process and to document student eligibility for nonimmigrant benefits. The Forms I-20 are being modified to reflect current DHS branding, remove obsolete information, and modernize the forms' layout to improve readability. The old Forms I-20 sunset on July 1, 2016; after that date, they will no longer be accepted at ports-of-entry, nor suffice for any other nonimmigrant benefit application by either F-1 and M-1 students or their F-2 and M-2 accompanying dependents.

Authority: The authority for DHS/SEVP to manage the program comes from the following sources:

- Sections 101(a)(15)(F)(i) and (M)(i), of the Immigration and Nationality Act of 1952 (INA), as amended (Pub. L. 82-414, 66 Stat. 163, June 27, 1952), codified under Title 8 of the United States Code (U.S.C.) 1101(a)(15)(F) and (M), under which a foreign national may be admitted to the United States in nonimmigrant status as

- A student to attend an SEVP-certified academic school or language training program (F-1),

- A student to attend an SEVP-certified vocational or other recognized nonacademic institution (M-1), respectively, or

- An accompanying F-2 or M-2 dependent spouse or minor child, respectively.

- Section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104-208, Div. C, 110 Stat. 3009-546, September 30, 1996, codified at 8 U.S.C. 1372, which authorized the following:

- Creation of a program to collect current and ongoing information provided by schools regarding F or M nonimmigrants during the courses of their stay in the United States.

- Use of electronic reporting technology where practicable.

- DHS certification of schools to participate in F-1 or M-1 student enrollment.

- Section 416(b) of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56, 115 Stat. 272, October 26, 2001 (USA PATRIOT Act), as amended, which provides for the collection of alien date of entry and port of entry information of aliens whose information is collected under 8 U.S.C. 1372.

- Homeland Security Presidential Directive No. 2 (HSPD-2), Combating Terrorism Through Immigration Policies, which requires DHS to “conduct periodic reviews of all institutions certified to receive nonimmigrant students.” “These reviews shall include checks for compliance with record keeping and reporting requirements” and authorize the termination of certification for institutions that fail to comply. 37 Weekly Comp. Pres. Docs. 1570, 1571-72 (Oct. 29, 2001).

- Section 502 of the Enhanced Border Security and Visa Entry Reform Act of 2002, Public Law 107-173, 116 Stat. 543, May 14, 2002, codified at 8 U.S.C. 1762, which directs DHS to review compliance with recordkeeping and reporting requirements under 8 U.S.C. 1372 and INA section 101(a)(15)(F) and (M), 8 U.S.C. 1101(a)(15)(F) and (M), of all schools approved to receive F or M nonimmigrants within two years of enactment, and every two years thereafter.

Accordingly, as directed by DHS, SEVP certifies, reviews, recertifies and collects data from schools enrolling F-1 and M-1 students. The specific data collection requirements for SEVP-certified schools associated with these laws are identified comprehensively in the Code of Federal Regulations (CFR) at 8 CFR 214.3.

Under the combined mandates of the USA PATRIOT Act and HSPD-2, the U.S. Immigration and Naturalization Service (INS) received funding and accelerated the development of SEVIS. Soon after, the INS published rules in the FR implementing supporting modifications to 8 CFR 214, Nonimmigrant Classes. 67 FR 60107 (September 25, 2002); and 67 FR 76256, (December 11, 2002).

The Homeland Security Act of 2002, Public Law 107-296, 116 Stat. 2135 (codified at 6 U.S.C. Chapter 1) created DHS, which came into effect on March 1, 2003. DHS encompasses and replaces the INS. Simultaneously, DHS established ICE, now the second largest criminal investigations agency in the

U.S. government. ICE subsequently created SEVP to administer SEVIS.

How does this notice affect SEVP-certified schools?

SEVP-certified schools must replace old Forms I-20 with the new version, produced through SEVIS. All prospective and active F-1 and M-1 students and their accompanying F-2 and M-2 dependents must be issued and use the new Forms I-20 no later than June 30, 2016. SEVP will not approve additional time for schools to comply.

How does this notice affect F-1 and M-1 students and their F-2 and M-2 dependents?

All prospective and active F-1 and M-1 students and their accompanying F-2 and M-2 dependents must be issued and use new Forms I-20 no later than June 30, 2016. The old Forms I-20 will sunset on July 1, 2016. At that time, bearers of the old Forms I-20 will be denied admission at ports-of-entry; old Forms I-20 will not be accepted as supporting documentation with applications for other nonimmigrant benefits.

How is SEVIS used to support F and M nonimmigrant admission into, and oversight while in, the United States?

SEVIS is an internet-based reporting and tracking system that is accessible by U.S. government agencies involved in the admission and oversight of nonimmigrants in the United States, as well as by authorized officials at SEVP-certified schools and Department of State (DOS)-designated exchange visitor programs. Data and information on F and/or M nonimmigrants are maintained in SEVIS, collected during the admission process and throughout the length of their stay in the United States. Foreign students who wish to study in the United States must first apply to an SEVP-certified school. When a foreign student accepts an offer to study, a designated school official at the applicable school will access SEVIS to enter the relevant student and accompanying dependent information electronically prior to issuing a Form I-20 to each individual that will be applying for admission into the United States. Authorized consular officials use SEVIS data through an interface to the DOS Consolidated Consular Database to support the visa issuance process, and to report associated F and/or M visa issuances to DHS. U.S. Customs and Border Protection officials access SEVIS information at ports-of-entry to verify or clarify a prospective F or M nonimmigrant's entry eligibility.

Dated: November 18, 2015.

Scott Elmore,

*Program Manager, Forms Management Office,
Office of the Chief Information Officer, U.S.
Immigration and Customs Enforcement,
Department of Homeland Security.*

[FR Doc. 2015-30127 Filed 11-25-15; 8:45 am]

BILLING CODE 9111-28-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5828-N-48]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT:

Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402-3970; TTY number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the

homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B-17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (This is not a toll free number).

Dated: November 19, 2015.

Brian P. Fitzmaurice,

*Director, Division of Community Assistance,
Office of Special Needs Assistance Programs.*

**TITLE V, FEDERAL SURPLUS PROPERTY
PROGRAM FEDERAL REGISTER REPORT
FOR 11/27/2015**

Suitable/Unavailable Properties

Building

Alabama

SGT Jack Richburg USARCr
107 Kinston Highway
Opp AL 36467
Landholding Agency: GSA
Property Number: 54201520016
Status: Excess
GSA Number: 4-D-AL-0816AA
Directions: GSA—Disposal Agency; US Army
Reserve—Landholding Agency
Comments: 4,316 sq. ft.; administrative
bldg.; office; built: 1967; sits on 4.53 acres;
asbestos; remediation required; contact
GSA for more information.

Alaska

FAA Housing
111 Henrichs Loop Road
Cordova AK 99754
Landholding Agency: GSA
Property Number: 54201440002
Status: Excess
GSA Number: 9-U-AK-0854
Directions: Disposal Agency: GSA; Land
Holding Agency: Transportation
Comments: 25+ yrs. old; 2,688 sq. ft.; 3
months vacant; residential good condition;
may be difficult to move; contact GSA for
more information.

Colorado

6 Bldgs. Grand Junction Complex
500 South 10th Street
Grand Junction CO 81501
Landholding Agency: GSA
Property Number: 54201510002
Status: Excess
GSA Number: 7-I-CO-0698-AA
Directions: Disposal Agency: GSA;
Landholding Agency: Bureau of
Reclamation
Comments: 50+ yrs. old; Brick/Metal
structure; 11,244 sq. ft., total 6 bldgs.; sits
on 1.2 acres; office/storage/warehouse;
repairs needed totaling \$10,000; contact
GSA for more info.

Illinois

Peoria Radio Repeater Site
Between Spring Creek and Caterpillar Lane
Peoria IL
Landholding Agency: GSA

Property Number: 54201420008
Status: Excess
GSA Number: I-D-IL-806
Directions: Landholding Agency: COE;
Disposal agency GSA
Comments: 8x12 equipment storage shed; fair
conditions contact GSA for more
information.

Missouri

Former NMCB15 Richards-Gedaur
RPSUID 212
600 Seabee Drive
Belton MO 64068
Landholding Agency: GSA
Property Number: 54201510004
Status: Surplus
GSA Number: 7-D-MO-0705
Directions: Disposal Agency: GSA;
Landholding Agency: Navy
Comments: 10 bldgs. Ranging from 960 to
4,980 sq. ft.; 12+ months vacant; some
recent use includes: admin./classroom/
warehouse; 14.67 acres; asbestos/lead/
mold may be present; contact GSA for
more information.

Nebraska

Grand Island U.S. Post Office and Courthouse
203 West 2nd Street
Grand Island NE 68801
Landholding Agency: GSA
Property Number: 54201520018
Status: Surplus
GSA Number: 7 G-NE-0519-AA
Directions: (RPUID)NE0018ZZ
Comments: 105+ yrs. old; 5,508 sq. ft.; office;
good condition; asbestos; sits on 0.53 acres;
listed on Nat. Reg. of Historic Place; need
to contact property manager for acs.;
contact GSA for more info.

Nevada

2 Buildings
Military Circle
Tonopah NV
Landholding Agency: GSA
Property Number: 54201240012
Status: Excess
GSA Number: 9-I-NV-514-AK
Directions: Bldg. 102: 2,508 sf.; bldg. 103:
2,880 sf.
Comments: Total sf. for both bldgs. 5,388;
Admin.; vacant since 1998; sits on 0.747
acres; fair conditions; lead/asbestos
present.

New York

Portion of GSA Binghamton
"Hillcrest" Depot- Tract 1
1151 Hoyt Ave.
Fenton NY 13901
Landholding Agency: GSA
Property Number: 54201320017
Status: Surplus
GSA Number: 1-G-NY0760-AC
Directions: Previously reported on March 24,
2006 under 54200610016; this property
includes 40 acres of land w/6 structures;
property is being parcelized
Comments: warehouses range from approx.
16,347 sf.-172,830 sf.; admin. bldg. approx.
5,700 sf; guard house & butler bldg. sf. is
unknown; 10 vacant; fair conditions; bldgs.
locked; entry by appt. w/GSA.

South Dakota

Lemmon Vehicle Storage Building

207 10th Street W.
Lemmon SD 57638
Landholding Agency: GSA
Property Number: 54201510009
Status: Surplus
GSA Number: 7-D-SD-0633-AA
Directions: Disposal Agency: GSA;
Landholding Agency: COE
Comments: 2,000 sq. ft.; vehicle storage barn;
sits on 0.77 acres; contact GSA for more
information.

Washington

Old Oroville Border Patrol Station
1105 Main St.
Oroville WA 98844
Landholding Agency: GSA
Property Number: 54201420010
Status: Excess
GSA Number: 9-Z-WA-1272-AB
Directions: Landholding Agency: Dept. of
Homeland Security; Disposal Agency: GSA
Comments: 5,500 sq. ft.; office; 18+ months
vacant; good to moderate conditions;
contact GSA for more info.

West Virginia

Naval Information Operations Center
133 Hedrick Drive
Sugar Grove WV 26815
Landholding Agency: GSA
Property Number: 54201430015
Status: Excess
GSA Number: 4-N-WV-0560
Directions: Land holding agency—Navy;
Disposal Agency GSA
Comments: 118 Buildings; 445,134 sq. ft.;
Navy base; until 09/15 military checkpoint;
wetlands; contact GSA for more info.

Wisconsin

St. Croix National Scenic
Riverway Residential Structures
401 N. Hamilton St.
St. Croix Falls WI 54204
Landholding Agency: GSA
Property Number: 54201430001
Status: Excess
GSA Number: 1-I-WI-541B
Directions: Landholding Agency: Interior;
Disposal Agency: GSA
Comments: house #1: 1,048 sq. ft.; House #2:
2,376 sq. ft.; House #3: 2,936 sq. ft.; good
to fair conditions; LBP; contact GSA for
more information.

Wyoming

2 Buildings
Cheyenne Naval Reserve Center
4700 Ocean Loop Drive
Cheyenne WY 82009
Landholding Agency: GSA
Property Number: 54201520009
Status: Surplus
GSA Number: 7-G-WY-0542-AC
Directions: Previously reported under HUD
property number 54200510015. The
property was originally conveyed from the
GSA to the Wyoming Coalition of
Homeless as a PBC for homeless use.
Grantee unable to continue to use the
property for homeless purposes. The title
reverted to the Government.
Comments: 36+ yrs. old, building (11,858 sq.
ft.); shed (613 sq. ft.); 12+ mos. vacant;
contact GSA for more information.

Land**Colorado**

Grand Valley Project
39.25326873–108.84370271
Unincorporated CO 81524
Landholding Agency: GSA
Property Number: 54201520001
Status: Excess
GSA Number: 7–I–CO–0699–AA
Directions: Disposal Agency: GSA; Land
Holding Agency: Interior
Comments: 30.12 acres; agricultural; silage
pits; contact Interior for more information.

Illinois

FAA Outer Marker
5549 Elizabeth Place
Rolling Meadows IL
Landholding Agency: GSA
Property Number: 54201430004
Status: Excess
GSA Number: I–U–IL–807
Directions: Landholding Agency: FAA;
Disposal Agency: GSA
Comments: 9,640 sq. ft.; 12+ months vacant;
outer marker to assist planes landing at
O'Hare Airport; contact GSA for more
information.

New York

QTP Radio Comm. Link
Repeater Facility
N. of Tennesanah Rd.
Fremont NY 12736
Landholding Agency: GSA
Property Number: 54201510006
Status: Excess
GSA Number: 1–U–NY–0988–AA
Directions: Disposal Agency: GSA;
Landholding Agency: FAA
Comments: approx. 4.99 acres; deeded access
road to property; adjacent property has
metal gate; ongoing discussions
w/owner to remove gate; contact GSA for
more information.

Former ELM Directional Finder

N. of Halderman Hollow Rd.
Big Flats NY 14903
Landholding Agency: GSA
Property Number: 54201520004
Status: Excess
GSA Number: 1–U–NY–0990–AA
Directions: Disposal Agency: GSA; Land
Holding Agency: Federal Aviation Admin.
Comments: reversed Suitability
Determination: Approx. 0.57 acres; deeded
right of way for access to site; contact GSA
for more information.

Oklahoma

FAA Oklahoma City Outer Marker
NW 3rd. Street
Oklahoma City OK 73127
Landholding Agency: GSA
Property Number: 54201530003
Status: Surplus
GSA Number: 7–U–OK–0582–AA
Directions: Disposal Agency: GSA; Land
Holding Agency: DOT/Federal Aviation
Admin.
Comments: 0.27 fee acres and a 0.08 acre
assess easement.

Pennsylvania

FAA 0.65 Acres Vacant Land
Westminster Rd.
Wilkes-Barre PA 18702

Landholding Agency: GSA
Property Number: 54201520013
Status: Surplus
GSA Number: 4–U–PA–0828AA
Directions: GSA—Disposal Agency; FAA—
Landholding Agency
Comments: cleared area w/gravel; contact
GSA for more information.

Tennessee

Parcel 279.01
Northwest corner of Administration Rd. &
Laboratory Rd
Oak Ridge TN 37830
Landholding Agency: GSA
Property Number: 54201520014
Status: Surplus
GSA Number: 4–B–TN–0664–AD
Directions: Disposal Agency; Energy—
Landholding Agency
Comments: corner lot w/out an est.
driveway/curb; transferee will need to
contact the City of Oak Ridge for ingress/
egress requirements (865–425–3581;
www.oakridgetn.gov); contact GSA for
more information.

Parcel ED–3 E

and W (168.30 +/- acres)
South Side of Oak Ridge Turnpike
Oak Ridge TN 37763
Landholding Agency: GSA
Property Number: 54201520015
Status: Surplus
GSA Number: 4–B–TN–0664–AG
Directions: GSA—Disposal Agency; Energy—
Landholding Agency; (State Rte. 58)
Comments: accessibility/usage subjected to
Federal, state, & local laws including but
not limited to historic preservation,
floodplains, wetlands, endangered species,
Nat'l EPA; contact GSA for more
information.

Parcels ED–13, 3A, 16

Portions of D–8 & ED–4
N. Side of Oak Ridge Turnpike (State Rte. 58)
Oak Ridge TN 37763
Landholding Agency: GSA
Property Number: 54201530001
Status: Surplus
GSA Number: 4–B–TN–0664–AF
Directions: Energy: Landholding Agency;
GSA: Disposal Agency
Comments: 168 +/- acres; legal constraints:
Ingress/egress utility easement;
groundwater constraints; contact GSA for
more information.

West Virginia

Former AL1–RCLR Tower Site
2146 Orleans Rd.,
Great Cacapon WV 25422
Landholding Agency: GSA
Property Number: 54201530002
Status: Surplus
GSA Number: 4–U–WV–0561AA
Directions: Disposal Agency: GSA; Land
Holding Agency: Federal Aviation
Administration
Comments: 9.69 acres; located on ridgetop.
[FR Doc. 2015–29951 Filed 11–25–15; 8:45 am]

BILLING CODE 4210–67–P**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs**

[167A2100DD/AAKC001030/
AOA501010.999900]

Receipt of Documented Petitions for Federal Acknowledgment of American Indian Tribes

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: Under Part 83 of Title 25 of the Code of Federal Regulations (25 CFR part 83), the Department of the Interior (Department) gives notice of three groups that have each filed a documented petition for Federal acknowledgment as an American Indian tribe with the Assistant Secretary—Indian Affairs. The Department seeks comment and evidence from the public on the petitions listed below.

DATES: Comments and evidence must be postmarked March 28, 2016.

ADDRESSES: Copies of the narrative portion of the documented petitions, as submitted by the petitioner (with any redactions appropriate under § 83.21(b)), and other information are available at the Office of Federal Acknowledgment's (OFA) Web site: www.bia.gov/WhoWeAre/AS-IA/OFA. Submit any comments or evidence to: Mr. R. Lee Fleming, Director, Office of Federal Acknowledgment, U.S. Department of the Interior, MS–34B–SIB, 1951 Constitution Avenue NW., Washington, DC 20240 or by email to: lee.fleming@bia.gov.

FOR FURTHER INFORMATION CONTACT: Mr. R. Lee Fleming, OFA Director, Office of the Assistant Secretary—Indian Affairs, (202) 513–7650.

SUPPLEMENTARY INFORMATION: On July 31, 2015, the Department's revisions to 25 CFR part 83 became final and effective (80 FR 37861). A key goal of the revisions was to improve transparency through increased notice of petitions and providing improved public access to petitions. Today the Department informs the public that three documented petitions have been submitted under the current regulations, that portions of those petitions are publically available on the Web site identified below for easy access, and that we are seeking public comment early in the process on these petitions.

Pursuant to the regulations, OFA notified 15 groups that the Department had identified them as having previously submitted complete documented petitions, under the 1994 acknowledgment regulations, which had

not yet received final agency decisions. Section 83.7 of the regulations allow petitioners that have submitted a complete documented petition but have not yet received a final agency decision to choose whether to proceed applying those standards and processes set forth in the current regulations or the standards and processes of the superseded regulations; 25 CFR part 83, revised as of February 25, 1994 (59 FR 9280). This notice informs the public that three petitioners have submitted complete documented petitions and are proceeding under the standards and processes set forth in the current regulations. Two of these petitioners elected not to supplement their petitions, and one elected to supplement its petition and did so immediately.

Under § 83.22(b)(1), OFA publishes notice that the following groups have each filed a documented petition for Federal acknowledgment as American Indian tribes to the Assistant Secretary—Indian Affairs:

- Muscogee Nation of Florida
 - c/o Ms. Ann D. Tucker, 278 Church Road, Bruce, Florida 32455;
 - Piro/Manso/Tiwa Indian Tribe of the Pueblo of San Juan Guadalupe
 - c/o Mr. Edward Roybal, II, 4048 Calle De Estrellas, Las Cruces, New Mexico 88012; and
 - Fernandño Tataviam Band of Mission Indians
 - c/o Mr. Rudy Ortega, Jr., 1019 Second Street, #1, San Fernando, California 91340.

Under § 83.22, OFA also publishes on its Web site the following:

- (i) The name, location, and mailing address of the petitioner and other information to identify the entity;
- (ii) The date of receipt;
- (iii) The narrative portion of the documented petition, as submitted by the petitioner (with any redactions appropriate under § 83.21(b));
- (iv) The opportunity for individuals and entities to submit comments and evidence supporting or opposing the petitioner's request for acknowledgment within 120 days of the date of the Web site posting (postmarked by the date in the **DATES** section of this notice); and
- (v) The opportunity for individuals and entities to request to be kept informed of general actions regarding a specific petitioner.

Additionally, OFA is required under § 83.22(c) to publish on the Web site other portions of the documented petition, to the extent feasible and allowable under Federal law, except documentation and information protectable from disclosure under

Federal law, as identified by Petitioner under § 83.21(b) or otherwise.

The Department publishes this notice and request for comment in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Dated: November 20, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–30228 Filed 11–25–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/
AOA501010.999900]

Gila River Indian Community; Amendments to Alcoholic Beverages Ordinance

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice.

SUMMARY: This notice publishes two comprehensive amendments to the Gila River Indian Community's Title 14 Alcoholic Beverages Ordinance. This Ordinance amends and supersedes the existing Gila River Indian Community Control Ordinance, Ordinance No. GR–03–05, enacted by the Gila River Indian Community Council in 2005.

DATES: This ordinance shall become effective 30 days after November 27, 2015.

FOR FURTHER INFORMATION CONTACT:

Ms. Sharlot Johnson, Tribal Government Services Officer, Western Regional Office, Bureau of Indian Affairs, 2600 North Central Avenue, Phoenix, AZ 85004, Telephone: (602) 379–6786, Fax: (602) 379–4100; or Ms. Laurel Iron Cloud, Chief, Division of Tribal Government Services, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW., MS–4513–MIB, Washington, DC 20240, Telephone: (202) 513–7641.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice v. Rehner*, 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor control ordinances for the purpose of regulating liquor transactions in Indian country. On October 7, 2009, the Gila River Indian Community Council duly adopted the amendments to the Community's Title 14—Alcoholic Beverages Ordinance by Ordinance GR–

15–09. On January 7, 2015, the Gila River Indian Community Council duly adopted additional amendments to the Community's Title 14—Alcoholic Beverages Ordinance by Ordinance GR–01–15. This **Federal Register** Notice comprehensively amends and supersedes the existing Gila River Indian Community Control Ordinance, Ordinance No. GR–03–05, enacted by the Gila River Indian Community Council, which was published in the **Federal Register** on November 9, 2005 (70 FR 68071).

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Gila River Indian Community Council of the Gila River Indian Community duly adopted these amendments to the Community's Title 14—Alcoholic Beverages Ordinance on October 7, 2009 and January 7, 2015.

Dated: November 17, 2015.

Kevin Washburn,

Assistant Secretary—Indian Affairs.

The Gila River Indian Community's Title 14—Alcoholic Beverages Ordinance, as amended, shall read as follows:

TITLE 14

ALCOHOLIC BEVERAGES

Chapter 1. Legalizing Alcoholic Beverages

14.101. Permission to Introduce, Possess, Store and Sell Alcoholic Beverages.

14.102. Definitions.

Chapter 2. Jurisdiction, Licensing, and Exemptions

14.201. Jurisdiction of Community Court.

14.202. Liquor License Applications.

14.203. Scope of Liquor License.

14.204. Transfer of Liquor License.

14.205. Expiration of Liquor License.

14.206. Exemptions from License Requirement.

Chapter 3. License Fees

14.301. Disposition of License Fees and Fines.

14.302. Fees for Liquor License.

Chapter 4. Alcohol Regulation

14.401. Registration of Stills.

14.402. Close of Business.

14.403. Change of Business or Trade Name; Permission Required.

14.404. Liquor Containers.

14.405. Licensee Recordkeeping Requirements.

14.406. Emergency Closing of Premises.

14.407. Disclosure of Interest in Liquor License; Requirements.

14.408. Unlawful Acts.**Chapter 5. Violations, Appeals and License Proceedings****14.501. Violations; Penalties;****Revocation.****14.502. Appeal.****14.503. Effect of Suspension or****Revocation of State License.****14.504. Effective Date.****CHAPTER 1. LEGALIZING ALCOHOLIC BEVERAGES****14.101. Permission to Introduce, Possess, Store and Sell Alcoholic Beverages.**

Members of the Gila River Indian Community and other persons are hereby authorized to introduce, possess, store and sell alcoholic beverages in accordance with all Community ordinances, rules, and regulations, and state and federal law to the extent they apply. Such possession, storage, and sale is permitted in these enumerated situations:

A. Possession of alcoholic beverages is permitted throughout the Gila River Indian Reservation.

B. Locations for Introduction, Storage and Sale of Alcoholic Beverages. The introduction, storage, and sale of alcoholic beverages is permitted upon application to and approval by the Gila River Indian Community Council, as further described in section 14.202 of this title. Such permission shall apply to a corridor extending one-half mile on either side of centerline of Interstate 10, where it crosses the Reservation, and in the following areas: parcels within Township 2 South, Range 4 East of the Gila and Salt River Base and Meridian, a part of the Gila River Indian Reservation located in Arizona.

1. More Particularly: The True Point of Beginning at a point of the North line of said Township 2 South, Range 4 East on the centerline of Interstate 10, thence westerly on said Township line to a Point on a line which is one-half mile westerly and parallel to the Interstate 10 centerline, thence southerly on said one-half mile line to a point on the centerline of the Broad acres Canal, thence southwesterly on said canal centerline to the North-South midsection line of Section 6, Township 2 South, Range 4 East, thence south on the midsection lines of Sections 6, 7 and 18 to the center point of Section 18, Township 2 South, Range 4 East, thence easterly on the East-West midsection lines of Sections 18, 17 and 16 to the centerline of said Interstate 10, thence northwesterly along said centerline to the North line of said Township 2 South, Range 4 East, the true Point of Beginning;

2. Together With: A parcel of which the True Point of Beginning is the Northeast corner of Section 4, of said Township 2 South, Range 4 East, thence westerly on the North line of Township 2 South, Range 4 East, to the Easterly right-of-way line of Interstate 10, thence southeasterly on said right-of-way line to the south section line of Section 9, Township 2 South, Range 4 East, thence east on said Section 9 south section line to the southeast corner of Section 9, thence northerly on the east section lines of Section 9 and Section 4, Township 2 South, Range 4 East to the True Point of Beginning;

3. Also Together With: The property as described within the Memorial Airport lease, all in Township 2 South, Range 4 East of the Gila and Salt River Base and Meridian, to wit:

Section 14

SW1/4

Section 15

S1/2, NE1/4

SE1/4, NW1/4

NE1/4/SW1/4

SE1/4

Section 22

N1/2, NE1/4, NE1/4

Section 23

NE1/4

NW1/4, NW1/4

N1/2, N1/2, SW1/4, NW1/4

E1/2, NW1/4

N1/2, N1/2, NE1/4, SW1/4

NW1/4, SE1/4

N1/2, N1/2, SW1/4, SE1/4

E1/2, SE1/4

Section 24

NE1/4, NE1/4

W1/2, NE1/4

N1/2, N1/2, SE1/4, SE1/4

NW1/4

N1/2, SW1/4

SW1/4, SW1/4

N1/2, N1/2, SE1/4, SW1/4

N1/2, N1/2, NW1/4, SE1/4

4. Also together with: A parcel of land commonly referred to as the "Wild Horse Pass Development Area", situated within the SE1/4 of the SE1/4 of Section 1, the E1/2 of the NE1/4 and SE1/4 of Section 12, NE1/4 of the NE1/4 of Section 13, Township 2 South, Range 3 East, the S1/2 of the SW1/4 of Section 5, the S1/2 of the SW1/4 and SE1/4 of Section 6, all of Section 7, W1/2 of Section 8, N1/2 of the NW1/4 of Section 17, N1/2 of the NW1/4 and NE1/4 of Section 18, Township 2 South, Range 4 East of the Gila and Salt River and Base and Meridian.

C. Introduction, Storage, Sale of Alcoholic Beverages at Other Locations. The introduction, storage, and sale of alcoholic beverages on any part of the Reservation other than in the areas

described in Subsection 14.101.B is permitted upon application to and approval by the Gila River Indian Community Council as further described in section 14.202; provided that the council shall not approve the application until the affected District has voted to recommend approval of the application. The vote described in this paragraph shall occur at a regular meeting of the affected District, and shall require the Community members residing in the affected District, who are present and vote at such regular meeting, to recommend approval of the application by majority vote.

D. The Gila River Indian Community Council may adopt further resolutions as may be necessary to implement this title.

14.102. Definitions.

A. In this title, unless the context otherwise requires:

1. *Beer* means any beverage obtained by the alcoholic fermentation, infusion, or decoction of barley malt, hops, or other ingredients not drinkable, or any combination thereof.

2. *Broken package* means any container of spirituous liquor on which the United States tax seal has been broken or removed, or from which the cap, cork, or seal placed thereupon by the manufacturer has been removed.

3. *Club* includes any of the following organizations where the sale of spirituous liquor for consumption on the premises is made to members only:

a. A post, chapter, camp, or other local unit composed solely of veterans and its duly recognized auxiliary which has been chartered by the Congress of the United States for patriotic, fraternal, or benevolent purposes and which has, as the owner, lessee, or occupant, operated an establishment for that purpose within the Reservation.

b. A chapter, aerie, parlor, lodge, or other local unit of an American national fraternal organization which has as the owner, lessee or occupant operated an establishment for fraternal purposes within the Reservation. An American national fraternal organization as used in this subdivision shall actively operate in not less than 36 states or have been in active continuous existence for not less than 20 years.

c. A hall or building association of a local unit mentioned in subdivisions 1 and 2 of this paragraph, all of the capital stock of which is owned by the local unit or the members, and which operates the clubroom facilities of the local unit.

d. A golf club which has more than 50 bona fide members which owns, maintains, or operates a bona fide golf

links together with a clubhouse. A social club which has more than 50 bona fide members who are actual residents of the county in which it is located, that owns, maintains or operates club quarters, is authorized and incorporated to operate as a non-profit club under the laws of this Community, and has been continuously incorporated and operating for a period of not less than one year. The club shall have had, during this one-year period, a bona fide membership with regular meetings conducted at least once each month and the membership shall be and shall have been actively engaged in carrying out the objectives of the club. The club's membership shall consist of bona fide dues paying members paying at least \$6.00 per year, payable monthly, quarterly, or annually, which have been recorded by the secretary of the club, and the members at the time of application for a club license shall be in good standing having for at least one full year paid dues. At least 51 percent of the members shall have signified their intention to secure a social club license by personally signing a petition, on a form prescribed by the Committee, which shall also include the correct mailing address of each signer. The petition shall not have been signed by a member at a date earlier than 30 days prior to the filing of the petition. It is the intent of this paragraph that a license shall not be granted to a club which is, or has been primarily formed or activated to obtain a license to sell liquor, but solely to a bona fide club, where the sale or liquor is incidental to the main purposes of the club.

4. *Committee* means the Government and Management Standing Committee, a committee of the Gila River Indian Community Council.

5. *Community* means the Gila River Indian Community.

6. *Company* or *association* when used in reference to a corporation includes successors or assigns.

7. *Council* means the Gila River Indian Community Council.

8. *License* means a license or an interim retail permit issued pursuant to the provisions of this title.

9. *Off-sale retailer* means any person operating a bona fide regularly established retail liquor store selling spirituous liquors, wines and beer, and any established retail store selling commodities other than spirituous liquors and engaged in the sale of spirituous liquors only in the original package, to be taken away from the premises of the retail and to be consumed off the premises.

10. *On-sale retailer* means any person operating an establishment where

spirituous liquors are sold in the original container for consumption on or off the premises or in individual portions for consumption on the premises.

11. *Premises* or *licensed premises* means the area from which the licensee is authorized to sell, dispense, or serve spirituous liquors under the provisions of the license.

12. *Person* includes partnership, limited liability company, association, company, or corporation, as well as a natural person.

13. *Reservation* means the Gila River Indian Reservation, located in the counties of Maricopa and Pinal in the State of Arizona.

14. *Sell* includes soliciting and receiving an order for, keeping or exposing for sale, directly or indirectly delivering for value, peddling, or keeping with the intent to sell and trafficking in.

15. *Spirituous liquor* includes alcohol, brandy, whiskey, rum, tequila, mescal, gin, wine, porter, ale, beer, any malt liquor or beverage, absinthe, a compound or mixture of any of them with any vegetable or other substance, alcohol bitters, bitters containing alcohol, any liquid mixture or preparation, whether patented or otherwise, which produces intoxication, fruits preserved in ardent spirits, and beverages containing more than one-half of one percent of alcohol by volume.

16. *Vehicle* means any means of transportation by land, water, or air, and includes everything made up of in any way for such transportation.

17. *Wine* means the product obtained by the fermentation of grapes or other agricultural products containing natural or added sugar or any such alcoholic beverages fortified with grape brandy and containing not more than 24 percent alcohol by volume.

CHAPTER 2. JURISDICTION, LICENSING, AND EXEMPTIONS

14.201. Jurisdiction of Community Court.

The Gila River Indian Community Court is vested with original jurisdiction to hear and decide all matters arising pursuant to his article.

14.202. Liquor License Applications.

Liquor license applications shall be filed with the Government and Management Standing Committee of the Gila River Indian Community Council.

A. The Committee shall review all liquor license applications and provide the Community Council with a recommendation as to the disposition of the application. A spirituous liquor

license shall be issued only after a satisfactory showing of the capability, qualifications and reliability of the applicant and, with the exception of club licenses, that the public convenience requires and that the best interests of the Community will be substantially served by the issuance.

B. All applications shall be referred to the District in which the applicant seeks to do business, except for applications in which the applicant will conduct business within the areas referenced in section 14.101.B., of this title, which do not require District approval.

C. License Issuance Contingent Upon Possession of Gila River Indian Community Business License. Any person or organized business entity that applies for a liquor license to manufacture, sell, or deal in spirituous liquors within the exterior boundaries of the Gila River Indian Reservation shall possess a Community Business License before being issued a liquor license.

D. License Issuance Contingent Upon Possession of Arizona Liquor License. Issuance of a Community Liquor License shall be contingent upon the applicant obtaining a liquor license of the same type from the Department of Liquor Licenses and Control of the State of Arizona.

14.203. Scope of Liquor License.

A license issued under this title shall permit the licensee to manufacture, sell, or deal in spirituous liquors only at the place and in the manner provided therein, and a separate license shall be issued for each specific business. Each license shall specify the:

A. Particular spirituous liquors which the licensee is authorized to manufacture, sell, or deal in.

B. Licensee's mailing and physical address and business or trade name.

C. Purpose for which the spirituous liquors shall be manufactured or sold.

14.204. Transfer of Liquor License.

No Community license shall be transferred without the prior written consent of the Gila River Indian Community Council.

14.205. Expiration of Liquor License.

Every license expires annually, measured from the date of issuance.

A. A licensee who fails to renew the license on or before the due date shall pay a penalty of \$100.00 with their application for renewal.

B. A license renewal application that is deposited, properly addressed, and postage prepaid in an official depository of the United States mail on or before the due date shall be deemed filed and received by the Committee on the date

shown by the postmark or other official mark of the United States Postal Service.

C. If the due date falls on a Saturday, Sunday, or other Community-recognized holiday, the renewal shall be deemed timely if received by the Committee on the next business day.

D. A licensee who fails to renew the license on or before the due date shall not sell, purchase, or otherwise deal in spirituous liquor until the license is renewed.

E. A license not renewed within 20 working days after the due date shall be deemed terminated.

14.206. Exemptions from License Requirement.

This title shall not apply to drugstores selling spirituous liquors only upon prescription or to ethyl alcohol used for the following purposes:

A. Scientific, chemical, mechanical, industrial, and medicinal purposes.

B. Use by those authorized to procure spirituous liquor or ethyl alcohol tax-free, as provided by the acts of Congress and regulations promulgated thereunder.

C. In the manufacture of denatured alcohol produced and used as provided by the acts of Congress and regulations promulgated thereunder.

D. In the manufacture of patented, patent, proprietary, medicinal, pharmaceutical, antiseptic toilet, scientific, chemical, mechanical and industrial preparations or products, unfit and not used for beverage purposes.

E. In the manufacture of flavoring extracts and unfit for beverage purposes.

CHAPTER 3. LICENSE FEES

14.301. Disposition of License Fees and Fines.

All license fees and fines collected under this title shall be paid to the Community Treasurer's Office and deposited in the Gila River Indian Community's general fund, unless otherwise directed by Community Council resolution.

14.302. Fees for Liquor License.

All applications for liquor licenses shall include full payment of the fees described herein. Original license application fees shall be refunded to the applicant if the application is denied.

A. Application Fees For An Original Community License.

1. Distiller's, Brewer's, or Vintner's license: \$100.00.

2. Wholesaler's license to sell spirituous liquors: \$100.00.

3. On-sale retailer's license to sell all spirituous liquors in individual portions and in the original container: \$100.00.

4. Off-sale retailer's license to sell all spirituous liquors: \$100.00.

5. Club license issued in the name of a bona fide club qualified under this title to sell all liquors on-sale: \$1,000.00.

6. Hotel-motel license issued as such to sell and serve spirituous liquors solely for consumption on the licensed premises of the hotel or motel: \$1,000.00.

7. Restaurant license issued to sell and serve spirituous liquors solely for consumption on the licensed premises of the restaurant: \$1,000.00.

B. Renewal Fees.

1. Distiller's, Brewer's, or Vintner's license: \$300.00.

2. Wholesaler's license to sell all spirituous liquors: \$250.00.

3. On-sale retailer's license to sell all spirituous liquors by individual portions and in the original containers: \$150.00.

4. Off-sale retailer's license to sell all spirituous liquors: \$50.00.

5. Hotel-motel license issued as such to sell and serve spirituous liquors solely for consumption on the licensed premises of the hotel or motel: \$250.00.

6. Restaurant license issued to sell and serve spirituous liquors solely for consumption on the licensed premises of the restaurant: \$250.00.

C. Transfer Fees. Licenses may be transferred to another licensee only on approval from the Community Council as stated in section 14.204 of this title.

1. Distiller or Brewer's license: \$500.00.

2. Vintner's license: \$300.00.

3. Wholesaler's license to sell all spirituous liquors: \$200.00.

4. On-sale retailer's license to sell all spirituous liquors by individual portions and in the original containers: \$300.00.

5. Off-sale retailer's license to sell all spirituous liquors: \$100.00.

6. Site Transfer Fee. Persons or business organizations who wish to retain their license but transfer their business to another site may do so after paying a site transfer fee of \$25.00.

D. Seasonal Business. Where the business of an on-sale retail licensee is seasonal, extending for periods of less than six months in a calendar year, the licensee may designate the periods of his operation and be granted a license for a period not to exceed six months. The fees for any license granted pursuant to this subsection shall be one-half of the fee listed in subsection 14.302.A., B., or C.

E. Licenses Issued After July 1. Any application, renewal, or transfer fee levied under this title after July 1 shall be reduced by one-half.

CHAPTER 4. ALCOHOL REGULATION

14.401. Registration of Stills.

A. Every person who possesses or otherwise exercises control of a still or distilling apparatus shall register it with the Committee under the rules and regulations the Committee may prescribe.

B. Every still or distilling apparatus not registered, and any mash, wort, or wash, for distillation or for the production of spirits or alcohol, and all finished products, together with all personal property in the possession or custody of, or under the control of any person which may be used in the manufacture or transportation of spirituous liquors which is found in the building, yard, or enclosure connected with the building in which the unregistered still or distilling apparatus is located, shall be forfeited to the Community.

C. The still, distilling apparatus, mash, wort, wash or finished products shall forthwith be destroyed by an agency of the Committee, or other peace officer, and all personal property forfeited to the Committee shall be sold at public auction to the highest bidder for cash on five days' notice. Notice shall be posted at the Gila River Indian Community Court and at the District Service Center in the District where the still and associated personal property were seized. All publication and sale expenses shall be deducted from the sale proceeds and the balance will be paid into the Gila River Indian Community general fund.

14.402. Close of Business.

No on-sale licensee shall lock, or permit to be locked, any entrance of his licensed establishment until all persons other than the licensee and his employees have left the premises.

14.403. Change of Business or Trade Name; Permission Required.

No licensee shall change the name of his licensed business without first obtaining written permission from the Committee. No licensee shall use a name for his licensed business until that name has been approved in writing by the Committee. The licensee shall submit his license for change within 15 days of the written approval of the business or trade name change.

14.404. Liquor Containers.

A. No liquor bottle or other container authorized by the laws of the United States or any agency thereof shall be reused for the packaging of distilled spirits, nor shall the original contents, or any portion of such original contents,

remaining in a liquor bottle or other such authorized container, be increased by the addition of any substance.

B. No licensee shall reuse, sell, or give away empty spirituous liquor bottles contrary to federal laws or regulations.

14.405. Licensee Recordkeeping Requirements.

All licensees shall retain, for a period of not less than two years, all invoices, records, bills, and other papers and documents relating to the purchase, sale, and delivery of alcoholic beverages. Such records and papers shall be kept in such condition as to be easily accessible to the Committee or authorized Community employee for audit or examination.

14.406. Emergency Closing of Premises.

A licensed place of business may be required to cease its operation and stop all sales of alcoholic beverages or allow any person on the premises, with the exception of peace officers, the licensee and his employees, during the time at which it appears to the Committee or any peace officer that violence might reasonably occur.

14.407. Disclosure of Interest in Liquor License; Requirements.

A. All persons having a legal or equitable interest in a spirituous liquor license shall file with the Committee a statement of such interest on a form prescribed and furnished by the Committee. Notice of termination of such interest shall be filed in writing by the interest holder upon final determination of the interest. Interest holders shall immediately file amended statements presently on file.

B. The Committee may periodically, by notice to the holders of interests filed under this regulation, require those interest holders to verify in writing to the Committee that the statement presently on file is correct and accurate and, if not, such interest holder shall immediately file an amended statement or termination notice. If no response is received by the Committee within 30 days of the mailing of such notice, the interest shall be deemed terminated.

C. All persons having filed statements of interest in accordance with this regulation and the statute shall be given notice of all matters and/or action affecting or regarding the spirituous liquor license in which they have an interest. Notice shall be effected by mailing a copy thereof by registered or certified mail in a sealed envelope with postage prepaid and addressed to such person as his address as shown by the statement on file with the Committee. Service of such notice shall be complete

when deposited in the United States mail.

D. All interest holders who are entitled to receive notice as provided hereinabove shall have the right to appear and participate in person and through counsel in any hearing held before the Committee affecting the subject spirituous liquor license as his interests may appear.

E. The statement of legal or equitable interest shall allow the person filing said statement to participate in the proceedings and shall not in any manner bind the Community concerning the matter under consideration.

14.408. Unlawful Acts.

It is unlawful:

A. For any person, whether as principal or agent, clerk or employee, whether for himself, or for any other person, or for any body corporate, or as officer of any corporation, or as a member of any firm or co-partnership or otherwise to buy for resale, sell or deal in spirituous liquors on and within the exterior boundaries of the Gila River Indian Reservation, Arizona, without first obtaining all necessary federal and state licenses including, but not restricted to a federal license to trade with the Indians issued pursuant to Title 25, Code of Federal Regulations, and a valid license issued by the Gila River Indian Community.

B. For a person to sell or deal in alcohol for beverage purposes without first complying with the provisions of this title.

C. For a distiller, vintner, brewer or wholesaler to sell, dispose of or give spirituous liquor to any persons other than a licensee, except in sampling wares as may be necessary in the ordinary course of business.

D. For a distiller, vintner or brewer to require a wholesaler to offer or grant a discount to a retailer, unless the discount has also been offered and granted to the wholesaler by the distiller, vintner or brewer.

E. For a distiller, vintner or brewer to use a vehicle for trucking or transportation of spirituous liquors unless there is affixed to both sides of the vehicle a sign showing the name and address of the licensee and the type and number of his license in letters not less than three and one-half inches in height.

F. For a person to take or solicit orders for spirituous liquors unless he is a registered salesman or solicitor of a licensed wholesaler or a registered salesman or solicitor of distillery, vintner, brewery, importer or broker.

G. For any retail licensee to purchase spirituous liquor from any person other

than a registered solicitor or salesman of a wholesaler licensed by the State of Arizona and the Community.

H. For a retailer to acquire an interest in property owned, occupied or used by a wholesaler in his business, or in a license with respect to the premises of the wholesaler.

I. Except as provided in subsections 14.408.J. and 14.408.K. of this section, for a licensee or other person to sell, furnish, dispose of or give, or cause to be sold, furnished, disposed of or given, to a person under the legal drinking age or for a person under the legal drinking age to buy, receive, have in the person's possession or consume spirituous liquor. This paragraph shall not prohibit the employment by an off-sale retailer of persons who are at least 16 years of age to check out, if supervised by a person on the premises who is at least 19 years of age, package or carry merchandise, including spirituous liquor, in unbroken packages, for the convenience of the customer of the employer, if the employer sells primarily merchandise other than spirituous liquor.

J. For a licensee to employ a person under the age of 19 years to manufacture, sell or dispose of spirituous liquors. This paragraph shall not prohibit the employment by an off-sale retailer of persons who are at least 16 years of age to check out, if supervised by a person on the premises who is at least 19 years of age, package or carry merchandise, including spirituous liquor, in unbroken packages, for the convenience of the customer of the employer, if the employer sells primarily merchandise other than spirituous liquor.

K. For an on-sale retailer to employ a person under the age of 19 years in any capacity connected with the handling of spirituous liquors. This paragraph does not prohibit the employment by an on-sale retailer of a person under the age of 19 years who cleans up the tables on the premises for reuse, removes dirty dishes, keeps a ready supply of needed items and helps clean up the premises.

L. For a licensee, when engaged in waiting on or serving customers, to consume spirituous liquor or remain on or about the premises while in an intoxicated or disorderly condition.

M. For an employee of a licensee, during that employee's working hours or in connection with such employment, to give to or purchase for any other person, accept a gift of, purchase for himself or consume spirituous liquor.

N. For a licensee or other person to serve, sell or furnish spirituous liquor to an intoxicated or disorderly person, or for a licensee or employee of the

licensee to allow or permit an intoxicated or disorderly person to come into or remain in or about the premises.

O. For an on-sale or off-sale retailer or an employee of such retailer to sell, dispose of, deliver or give spirituous liquor to a person between the hours of 2:00 a.m. and 6:00 a.m.

P. For a licensee or employee to knowingly permit any person on or about the licensed premises to give or furnish any spirituous liquor to any person under the age of 21 or knowingly permit any person under the age of 21 to have in the person's possession spirituous liquor on the licensed premises.

Q. For an on-sale retailer or an employee of such retailer to allow a person to consume or possess spirituous liquors on the premises between the hours of 2:30 a.m. and 6:00 a.m.

R. For an on-sale retail licensee to employ a person for the purpose of soliciting the purchase of spirituous liquors by patrons of the establishment for themselves, on a percentage basis or otherwise, and no licensee shall serve employees or allow a patron of the establishment to give spirituous liquor to, or to purchase liquor for or drink liquor with, any employee.

S. For an off-sale retailer to sell spirituous liquors except in the original container, to permit spirituous liquor to be consumed on the premises, or to sell spirituous liquor in a container having a capacity of less than eight ounces, or for an on-sale retailer to sell spirituous liquor for consumption off the premises in the container having a capacity of less than eight ounces.

T. For a person to consume spirituous liquor from a broken package in a public place, thoroughfare or gathering, and the license of a licensee permitting a violation of this paragraph on the premises shall be subject to revocation. This paragraph shall not apply to sale of spirituous liquors on the premises of and by an on-sale retail licensee.

U. For a person to have possession of or to transact spirituous liquor which is manufactured in a distillery, winery, brewery, or rectifying plant contrary to the laws of the United States and any property used in transporting such spirituous liquor shall be forfeited to the Community and shall be seized and disposed of by the Gila River Indian Community Police Department.

V. For a licensee or employee to fail or refuse to make the premises or records available for inspection and examination as provided in this title or to comply with a lawful subpoena issued either by the State of Arizona or the Gila River Indian Community under state or Community law.

CHAPTER 5. VIOLATIONS, APPEALS AND LICENSE PROCEEDINGS

14.501. Violations; Penalties; Revocation.

Any person or licensee who is fined under this title or who has had their license suspended or revoked may appeal such action to the Committee. Upon receipt of said appeal, the Committee shall set a date to hear the appeal. The Committee shall hear such evidence as the appellant, Community, and other interested parties may offer, and render its decision at the conclusion of such hearing.

A. Unlawful Acts. Any person or licensee who violates any enumerated provision of section 14.408 shall be fined \$500.00. In the event of multiple violations, the Committee may levy one fine per violation or may levy a single \$500.00 fine.

B. Licensees. The Committee may revoke the license of any licensee who violates any provision of this title.

14.502. Appeal.

The Committee's decision may be appealed to the Gila River Indian Community Court, provided that the appeal is duly filed within 20 working days of the Committee's decision.

14.503. Effect of Suspension or Revocation of State License.

A. All licensees shall comply with the laws of the United States and the State of Arizona governing the manufacture and sale of spirituous liquor.

B. Any suspension or revocation of an Arizona-issued liquor license shall automatically take effect against a licensee's Gila River Indian Community-issued license.

C. Notwithstanding the appeal process described in sections 14.501 and 14.502, no appeal shall be permitted for any Community-issued license suspended or revoked under subsection 14.503.2.

14.504. Effective Date.

In accordance with 18 U.S.C. 1161 (2005), this title shall be effective on the date upon which, after having been certified by the Secretary of the Interior, it is published in the **Federal Register**.

[FR Doc. 2015-30001 Filed 11-25-15; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO210000.16X.L11100000.PH0000 LXSIGST0000]

Cancellation of Bureau of Land Management Public Meeting for the Sagebrush Focal Areas Proposed Withdrawal, Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice cancels the public meeting scheduled for December 14, 2015 at the Harney County Chamber of Commerce building located at 484 North Broadway, Burns, Oregon, as published in the **Federal Register** on November 13, 2015, (80 FR 70252). Parties interested in participating in the public process are encouraged to attend the meetings scheduled at the Bureau of Land Management District Office in Lakeview, Oregon on December 14th from 5 p.m. to 7 p.m., or the Best Western Vista Inn & Conference Center, at 2645 Airport Way, Boise, Idaho on December 15th from 4 p.m. to 6 p.m.

Michael Stiewig,

Chief, Division of Lands, Realty, and Cadastral Survey.

[FR Doc. 2015-30222 Filed 11-25-15; 8:45 am]

BILLING CODE 4310-84-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-PWR-PWRO-17266;PX.P0169628B.00.1]

Notice of Intent To Prepare Environmental Impact Statement for Wilderness Stewardship Plan, Yosemite National Park, Madera, Mariposa, and Tuolumne, California

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent.

SUMMARY: Yosemite National Park is initiating the conservation planning and environmental impact analysis process needed to inform consideration of alternative strategies for the future management of Yosemite Wilderness. The Yosemite Wilderness encompasses 704,638 acres that were designated by the California Wilderness Act of 1984 (an additional 927 acres were designated as potential wilderness additions). Through the preparation of the Wilderness Stewardship Plan/ Environmental Impact Statement (WSP/ EIS), Yosemite National Park (YOSE) proposes to update the park's current

1989 Wilderness Management Plan to achieve enhanced wilderness stewardship objectives, which include preserving wilderness character, providing appropriate types and levels of access for visitors and authorized users, protecting natural and cultural resources, and adhering to legally-mandated management and preservation requirements. YOSE intends to coordinate the steps of Section 106 of the National Historic Preservation Act with reviews under the NEPA process.

DATES: All written comments must be postmarked or transmitted not later than January 26, 2016.

ADDRESSES: Requests to be added to the WSP/EIS mailing list may be submitted to: Superintendent, Yosemite National Park, Attn: Wilderness Stewardship Plan, P.O. Box 577, Yosemite, CA 95389.

FOR FURTHER INFORMATION CONTACT: Please contact the Yosemite Planning and Compliance Office by telephone at (209) 379-1365 or by email at yose_planning@nps.gov.

SUPPLEMENTARY INFORMATION: Over 94% of Yosemite National Park is designated Wilderness. The Wilderness encompasses the upper watersheds of the Tuolumne and Merced Rivers, ranging in elevation from less than 3,000 feet to more than 13,000 feet. This large elevation range supports a wide diversity of plant and animal communities including threatened and endangered species. The Yosemite Wilderness is rich in cultural resources including tribal ancestral homelands and historic and archeological features. It is known for its granite peaks, alpine and subalpine lakes, and dramatic waterfalls. It is a popular Wilderness, with visitors enjoying over 100,000 use nights and approximately 400,000 to 500,000 use days. Visitors engage in activities such as backpacking, rockclimbing, stock trips, fishing, and dayhiking. The WSP/EIS will address a variety of issues including, but not limited to trails, minimum requirements analysis for administrative use and facilities, wilderness restoration, cultural resources management, potential wilderness additions, commercial use, visitor use and capacity, stock use and meadow management. The plan will provide detailed management direction consistent with the National Park Service's Management Policies (2006) and other agency guidelines regarding the preservation of wilderness character.

How To Comment: Public comments regarding the range of issues that should be addressed, alternative approaches to managing YOSE wilderness, and other

concerns regarding YOSE Wilderness or the planning process may be submitted online through the Planning, Environment, and Public Comment (PEPC) Web site at <http://parkplanning.nps.gov/yosewild> (electronic comment submittal saves resources and allows for direct entry into the National Park Service's comment analysis system). You may also submit written comments mailing to the address noted above; written comments will also be accepted during public scoping meetings.

Before including your address, phone number, email address, or other personal identifying information in your comment, please be advised that your entire comment including your personal identifying information may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

At this time several public scoping meetings are expected to be hosted during the Winter of 2015. Scoping materials including WSP planning process information and confirmed details regarding public meetings will be posted on the park planning Web site <http://www.nps.gov/yose/parkmgmt/yosewild.htm> and on the PEPC Web site (noted above). The status of the Draft WSP/EIS will be updated periodically at both Web sites listed above. To be added to the WSP/EIS mailing list, email your request to yose_planning@nps.gov or mail your request to the address noted above. Please note in your request if you would like to receive an electronic copy of the document (*i.e.*, CD-ROM) or a printed copy of the Draft WSP/EIS when it is released (limited copies will be available). To reduce printing costs and conserve resources, the public is strongly encouraged to download materials from the Web site.

Decision Process: Following consideration of all comments obtained through this scoping effort, YOSE will prepare the Draft WSP/EIS. This document will state the purpose and need for federal action, describe and analyze a range of alternatives (including a "no action" baseline alternative), assess potential environmental consequences and provide appropriate impact mitigation strategies for each alternative, and identify the "agency-preferred" alternative. Public release of the Draft WSP/EIS will be formally announced by publication of a Notice of Availability in the **Federal Register** and via Web site postings and announcements in local and regional news media. Notifications

will also be sent to the WSP/EIS mailing list and YOSE planning electronic mailing list, as well as to local, state, federal, and tribal organizations and groups.

Following careful analysis of all responses received concerning the Draft WSP/EIS, a Final WSP/EIS will be prepared and its availability similarly announced in the **Federal Register**. Thereafter, but not sooner than 30 days after release of the Final WSP/EIS, a Record of Decision will be prepared. As a delegated EIS, the official responsible for final approval of the WSP/EIS is the Regional Director, Pacific West Region. Subsequently the official responsible for implementation of the approved WSP is the Superintendent, Yosemite National Park.

Dated: November 12, 2015.

Martha J. Lee,

Acting Regional Director, Pacific West Region.

[FR Doc. 2015-30160 Filed 11-25-15; 8:45 am]

BILLING CODE 4312-FF-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNL-19677;
PPWOCRADIO, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before October 24, 2015, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by December 14, 2015.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202-371-6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 24, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties

under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

CALIFORNIA

Madera County

Devils Postpile National Monument Ranger Cabin, Minaret Summit Rd., Mammoth Lakes, 15000859

Solano County

Harrier, Daniel Webster, House, 739 Ohio St., Vallejo, 15000860

FLORIDA

Franklin County

Marshall House, N. bay side shore, Little St. George Island, Little St. George Island, 15000861

Osceola County

Monument of States, E. Monument Ave. & Lakeview Dr., Kissimmee, 15000862

IOWA

Dallas County

Minburn Railroad Depot, 210 4th St., Minburn, 15000863

NORTH CAROLINA

Dare County

U-576 and BLUEFIELDS (shipwrecks and remains), (World War II Shipwrecks along the East Coast and Gulf of Mexico MPS) Address Restricted, Hatteras, 15000864

OKLAHOMA

Beckham County

Vannerson Homestead, Address Restricted, Erick, 15000865

Cleveland County

University of Oklahoma Armory, 103 W. Brooks St., Norman, 15000866

Garfield County

Fuksa, John and Mary, Farm, 1228 E0580 Rd., Bison, 15000867

Kisner, Robert R. and Minnie L., House, 1111 Wynona Ave., Enid, 15000870

Marshall Hall, 100 S. University Ave., Enid, 15000868

Public Library of Enid and Garfield County, 120 W. Maine St., Enid, 15000869

Santa Fe Freight Depot, 702 N. Washington Ave., Enid, 15000871

Kay County

Lake Ponca Duck Pond Historic District, L.A. Cann Dr. & Edam Rd., Ponca City, 15000872

Oklahoma County

Fairview Community Center, 206 E. Broadway, Fairview, 15000873
Santa Fe Depot, 146 S. E.K. Gaylord Blvd., Oklahoma City, 15000874

Rogers County

Foyil Filling Station, (Route 66 in Oklahoma MPS) 12243 S. Andy Payne Blvd., Claremore, 15000875

Tulsa County

Belmont Apartments, 1314 S. Denver Ave., W., Tulsa, 15000876

TEXAS

Dallas County

Sharrock, Everard Jr., Farm, 6900 Grady Niblo Rd., Dallas, 15000877

VIRGINIA

Loudoun County

Stoke, 23587 Stoke Farm Ln., Aldie, 15000878

Page County

Locust Grove, 6601 Ida Rd., Stanley, 15000879

WASHINGTON

King County

Woolworth, F.W., Company Store, 724 S. 3rd St., Renton, 15000880

Spokane County

Christiansen, George and Blanche, House, 1329 E. Overbluff Rd., Spokane, 15000881

Authority: 60.13 of 36 CFR part 60.

Dated: October 29, 2015.

J. Paul Loether,

Chief, National Register of Historic Places/
National Historic Landmarks Program.

[FR Doc. 2015-30104 Filed 11-25-15; 8:45 am]

BILLING CODE 4312-51-P

DEPARTMENT OF THE INTERIOR

National Park Service

**[NPS-IMR-GRCA-16825;
PX.P0133318B.00.1]**

Draft Environmental Impact Statement for Backcountry Management Plan, Grand Canyon National Park, Arizona

AGENCY: National Park Service, Interior.
ACTION: Notice of availability.

SUMMARY: The National Park Service (NPS) announces the availability of the Draft Environmental Impact Statement for the Backcountry Management Plan (Plan/DEIS), Grand Canyon National Park, Arizona. The Plan/DEIS evaluates

the impacts of three action alternatives that address backcountry and wilderness management.

DATES: The NPS will accept comments from the public on the Plan/DEIS for 90 days following publication by the U.S. Environmental Protection Agency (EPA) of the Notice of Availability of the Draft Environmental Impact Statement. After the EPA Notice of Availability is published, the NPS will schedule public meetings to be held during the comment period. Dates, times, and locations of these meetings will be announced in press releases and on the NPS Planning, Environment, and Public Comment (PEPC) for the project at <http://parkplanning.nps.gov/GRCA>.

ADDRESSES: Information will be available for public review and comment online at <http://parkplanning.nps.gov/GRCA>. Copies of the Plan/DEIS will also be available at the park library located in the Park Headquarters Building, 20 South Entrance Road, Grand Canyon, AZ.

FOR FURTHER INFORMATION CONTACT: Linda Jalbert, Wilderness Coordinator, PO Box 129, Grand Canyon, AZ 86023, (928) 638-7909, Linda_Jalbert@nps.gov or Rachel Bennett, Environmental Protection Specialist, 1824 S Thompson Street, Flagstaff, AZ 86001, (928) 638-7326, Rachel_Bennett@nps.gov.

SUPPLEMENTARY INFORMATION: The purpose of the Backcountry Management Plan is to establish an up-to-date plan that addresses immediate backcountry issues and provides an adaptive management framework to preserve, while allowing the public to experience, Grand Canyon's unique backcountry and wilderness resources and values. The park's backcountry encompasses over 1.1 million acres, most of which are proposed for wilderness designation. The Plan/DEIS evaluates four alternatives—the no-action alternative (A) and three action alternatives (B, C, and D)—all of which are summarized below. Alternative B is the NPS preferred alternative. Alternative D is the environmentally preferable alternative.

Alternative A, the no-action alternative, would continue existing management practices. Under this alternative user conflicts and concerns and resource impacts would continue to occur because extended day hiking and running (*i.e.* rim-to-rim day trips) would not be comprehensively managed. An interim process was developed in 2014 that requires organized groups participating in extended day hiking and running to apply for a special use permit and limits group size to 30. The interim policy is expected to remain in

place until the completion of the Backcountry Management Plan Final EIS and Record of Decision. Commercial overnight backpacking would not be capped, would continue to occur in all backcountry management zones, and would be managed by commercial use authorizations. Commercial backpacking operators would continue to compete with the non-commercial public for backcountry permits which are limited by use area. River-assisted backcountry travel would continue to be managed with a rule that allows up to five miles of river travel on one backcountry permit. Under the no-action alternative, no additional campsites would be added to the corridor-zone campgrounds to address the bottleneck for overnight users. Under this alternative, overnight backpacking would continue at the level that occurred in 2012, which was 94,277 user nights (one user night is one person in the backcountry for one night). The no-action alternative is required by NEPA as a baseline against which action alternatives can be compared and evaluated.

Common to all action alternatives, NPS proposes an adaptive management process for extended day hiking and running (*i.e.* rim-to-rim day trips), human waste management, use area management, day use at Tuweep, and management of canyoneering and climbing. For example, seasonal day use permits are proposed for rim-to-rim and extended day hiking and running in the cross-canyon corridor in order to collect data and educate visitors. Future adaptive management actions could include limiting group size (*e.g.* 30), limiting overall number of people per day (*e.g.* 250), year-round day use permits, or designating specific days for these activities. Also common to all action alternatives, NPS proposes to authorize the majority of commercial overnight backpacking through longer-term concessions contracts (estimated at 3–5 contracts) instead of the commercial use authorization permits currently used. Commercial use authorizations would continue to be issued for commercial groups conducting three or less trips per year.

Alternative B, the NPS preferred alternative, focuses on providing a variety of recreational activities and a high level of protection for natural and cultural resources and wilderness character. Changes would include a reduction in group size for overnight backpacking, from a maximum of 11 to a maximum of 6, in two of the most remote wilderness zones. Alternative B would manage river-assisted backcountry travel using 31 route-based

river sections and would include development of four additional campsites at Cottonwood Campground in the cross-canyon corridor. Commercially guided services would be limited by zone and would be allowed only in less remote backcountry areas, while the most remote wilderness areas would remain free of guided activities. Commercial overnight backpacking use would be capped, and commercial guides would no longer compete with the non-commercial public for backcountry permits. Overnight use in the popular cross-canyon corridor would increase by approximately 3% (from 53,821 to a projected 55,531 user nights). Overall, overnight use in the backcountry is expected to decrease by 1% (93,116 user nights), primarily as a result of the reduction in group size in two of the wilderness zones.

Alternative C focuses on recreational activities and expanded opportunities for these activities. Group sizes for overnight backpacking would be the same as at present. Alternative C proposes to manage river-assisted backcountry travel using 11 river sections. Up to eight additional campsites would be developed at Indian Garden, Cottonwood Campground and Roaring Springs. Commercially guided services would be allowed in more use areas throughout the backcountry when compared with Alternatives B and D. Commercial overnight backpacking use would be capped. Overnight use in the cross-canyon corridor would increase by approximately 10% (from 53,821 to a projected 59,421 user nights). Overall, overnight use in the backcountry is expected to increase by 5% (99,273 user nights), primarily as a result of the increase in campsites in the corridor zone and designated campsites along backcountry road corridors.

Alternative D, the environmentally preferable alternative, would focus on resource protection and opportunities for solitude. Recreational use would be concentrated in non-wilderness areas and facility improvement would be limited. Group size for overnight backpacking would be reduced, from a maximum of 11 to a maximum of 6, in all backcountry zones except the corridor zone. Commercially guided activities would be focused in non-wilderness zones. Commercial overnight backpacking use would be capped and only allowed in the corridor zone. These actions would allow for self-exploration and increased opportunities for solitude in all wilderness zones. Overnight use in the popular cross-canyon corridor would increase by approximately 2% (from 53,821 to a projected 54,846 user nights). Overall, overnight use in the

backcountry is expected to decrease by 3% (91,405 user nights) primarily from the decrease in group size outside the corridor.

If you wish to comment, you may submit your comments by any one of several methods. You may submit comments online at <http://parkplanning.nps.gov/grca>. You may also mail comments to Superintendent, Grand Canyon National Park, PO Box 129, Grand Canyon, AZ 86023. Finally, you may hand-deliver comments to Grand Canyon National Park Headquarters, 20 South Entrance Rd, Grand Canyon, AZ.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will make all submission from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: November 3, 2015.

Sue E. Masica,

*Regional Director, Intermountain Region,
National Park Service.*

[FR Doc. 2015–30162 Filed 11–25–15; 8:45 am]

BILLING CODE 4312–CB–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02054000, 15XR0687NA,
RX.18527901.3000000]

Central Valley Project Improvement Act Water Management Plans

AGENCY: Bureau of Reclamation,
Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Reclamation has made available to the public the Water Management Plans for seven entities. For the purpose of this announcement, Water Management Plans (Plans) are considered the same as Water Conservation Plans. Reclamation is publishing this notice in order to allow the public an opportunity to review the Plans and comment on the preliminary determinations.

DATES: Submit written comments on the preliminary determinations on or before December 28, 2015.

ADDRESSES: Send written comments to Ms. Shanna Hines, Bureau of Reclamation, 2800 Cottage Way, MP-410, Sacramento, CA 95825; or via email at shines@usbr.gov.

FOR FURTHER INFORMATION CONTACT: To be placed on a mailing list for any subsequent information, please contact Ms. Shanna Hines at the email address above or at 916-978-5281 (TDD 978-5608).

SUPPLEMENTARY INFORMATION: To meet the requirements of the Central Valley Project Improvement Act of 1992 and the Reclamation Reform Act of 1982, the Bureau of Reclamation developed and published the Criteria for Evaluating Water Management Plans (Criteria). Each of the eight entities listed below has developed a Plan that has been evaluated and preliminarily determined to meet the requirements of these Criteria. The following Plans are available for review:

- Bella Vista Water District
- Clear Creek Community Services District
- City of Shasta Lake
- Fresno Irrigation District
- Orland Artois Water District
- Santa Barbara County Water Agency
- Santa Ynez River Community District, Improvement District No. 1

We are inviting the public to comment on our preliminary (*i.e.*, draft) determination of Plan adequacy. Section 3405(e) of the Central Valley Project Improvement Act (Title 34 Pub. L. 102-575), requires the Secretary of the Interior to establish and administer an office on Central Valley Project water conservation best management practices that shall “develop criteria for evaluating the adequacy of all water conservation plans developed by project contractors, including those plans required by Section 210 of the Reclamation Reform Act of 1982.” Also, according to Section 3405(e)(1), these criteria must be developed “with the purpose of promoting the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices.” These criteria state that all parties (Contractors) that contract with Reclamation for water supplies (municipal and industrial contracts over 2,000 acre-feet and agricultural contracts over 2,000 irrigable acres) must prepare a Plan that contains the following information:

1. Description of the District;
2. Inventory of Water Resources;
3. Best Management Practices (BMPs) for Agricultural Contractors;
4. BMPs for Urban Contractors;

5. Plan Implementation;
6. Exemption Process;
7. Regional Criteria; and
8. Five-Year Revisions

Reclamation evaluates Plans based on these criteria. A copy of these Plans will be available for review at Reclamation’s Mid-Pacific Regional Office, 2800 Cottage Way, MP-410, Sacramento, CA 95825. Our practice is to make comments, including names and home addresses of respondents, available for public review. If you wish to review a copy of these Plans, please contact Ms. Hines.

Public Disclosure

Before including your name, address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: November 2, 2015.

Richard J. Woodley,

Regional Resources Manager, Mid-Pacific Region, Bureau of Reclamation.

[FR Doc. 2015-30227 Filed 11-25-15; 8:45 am]

BILLING CODE 4332-90-P-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-525 and 731-TA-1260-1261 (Final)]

Certain Welded Line Pipe From Korea and Turkey

Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that an industry in the United States is materially injured by reason of imports of certain welded line pipe from Korea and Turkey, provided for in subheadings 7305.11, 7305.12, 7305.19, and 7306.19, that have been found by the Department of Commerce (“Commerce”) to be sold in the United States at less than fair value (“LTFV”), and that have been found by Commerce to be subsidized by the government of Turkey.

¹ The record is defined in sec. 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

Background

The Commission, pursuant to sections 705(b) and 735(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)), instituted these investigations effective October 16, 2014, following receipt of a petition filed with the Commission and Commerce by American Cast Iron Pipe Company, Birmingham, Alabama; EnergeX, a division of JMC Steel Group, Chicago, Illinois; Maverick Tube Corporation, Houston, Texas; Northwest Pipe Company, Vancouver, Washington; Stupp Corporation, Baton Rouge, Louisiana; Tex-Tube Company, Houston, Texas; TMK IPSCO, Houston, Texas; and Welspun Tubular LLC USA, Little Rock, Arkansas. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of certain welded line pipe from Korea and Turkey were dumped within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)) and preliminary determination by Commerce that imports of certain welded line pipe from Turkey were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)). Notice of the scheduling of the final phase of the Commission’s investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 12, 2015 (80 FR 33554). The hearing was held in Washington, DC, on October 6, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 20, 2015. The views of the Commission are contained in USITC Publication 4580 (November 2015), entitled *Certain Welded Line Pipe from Korea and Turkey: Investigation Nos. 701-TA-525 and 731-TA-1260-1261 (Final)*.

By order of the Commission.

Issued: November 20, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015-30113 Filed 11-25-15; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-15-040]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: December 2, 2015 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701-TA-526-527 and 731-TA-1262-1263 (Final)(Melamine from China and Trinidad and Tobago). The Commission is currently scheduled to complete and file its determinations and views of the Commission on December 16, 2015.

5. Outstanding action jackets: none. In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: November 23, 2015.

William R. Bishop,
Supervisory Hearings and Information Officer.

[FR Doc. 2015-30275 Filed 11-24-15; 11:15 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Stipulation and Agreed Judgment Under the System Unit Resource Protection Act

On November 19, 2015, the Department of Justice lodged a Proposed Stipulation and Agreed Judgment with the United States District Court for the Northern District of Indiana in the lawsuit entitled *United States v. Indiana Harbor Belt Railroad Co., et al.*, Civil Action No. 2:15-cv-0087.

The Stipulation and Agreed Judgment resolves the United States' claims against the Indiana Harbor Belt Railroad Co., et al. ("Defendants") for alleged violation of the System Unit Resource Protection Act, 54 U.S.C. 100721-100725, as set forth in the United States' Verified Complaint filed on March 9, 2015. In this action, the United States seeks recovery of system unit resource damages and response costs that

resulted from fires at the Indiana Dunes National Lakeshore on March 10, 2012, and March 11, 2012. The Verified Complaint alleges that Defendants destroyed, caused the loss of, or injured, System unit resources, including experimental data and property owned by the National Park Service, and that Defendants are liable for response costs and damages resulting from the destruction, loss, and/or injury.

Under the Stipulation and Agreed Judgment, Defendants will pay to the United States \$72,500 for response costs and damages described in the Complaint. There is no injunctive relief under this Judgment.

The publication of this notice opens a period for public comment on the proposed Stipulation and Agreed Judgment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Indiana Harbor Belt Railroad Co., et al.*, D.J. Ref. No. 90-5-1-1-11105. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the proposed Stipulation and Agreed Judgment may be examined and downloaded at this Justice Department Web site: <http://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the proposed Stipulation and Agreed Judgment upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$2.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is \$2.25.

Randall M. Stone,

Acting Assistant Section Chief,
Environmental Enforcement Section,
Environment and Natural Resources Division.

[FR Doc. 2015-30161 Filed 11-25-15; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On November 17, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Columbia in the lawsuit entitled *United States v. HollyFrontier Refining & Marketing LLC, Frontier El Dorado Refining LLC, Holly Refining & Marketing Company—Woods Cross LLC, and Navajo Refining Company, LLC*, Civil Action No. 1:15-cv-02024.

The United States alleges in its Complaint that HollyFrontier Refining & Marketing LLC, Frontier El Dorado Refining LLC, Holly Refining & Marketing Company—Woods Cross LLC, and Navajo Refining Company, LLC (collectively HollyFrontier) are liable for civil penalties and injunctive relief arising from alleged violations of the Clean Air Act, Section 211(h), 42 U.S.C. 7545(h), and the fuels regulations promulgated thereunder and published at 40 CFR part 80. This Complaint addresses HollyFrontier's self-reported violations of the Reid Vapor Pressure (RVP) standard for certain batches of gasoline produced at their respective refineries and introduced into commerce with a RVP in excess of the respective standard. The Complaint also addresses alleged self-reported fuel testing violations at their respective refineries.

The proposed Consent Decree resolves all claims alleged in the Complaint, provides for payment of a \$1.2 million civil penalty, and requires HollyFrontier to implement mitigation projects that are anticipated to reduce emissions of volatile organic compounds, including toxics, by an estimated 96 tons over the lifetime of the Consent Decree.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Environmental Enforcement Section, and should refer to *United States v. HollyFrontier Refining & Marketing LLC, Frontier El Dorado Refining LLC, Holly Refining & Marketing Company—Woods Cross LLC, and Navajo Refining Company, L.L.C.*, D.J. Ref. No. 90-5-2-1-1113. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Director, Office of Trade Adjustment Assistance, at the address shown below, no later than December 7, 2015.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 7, 2015.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC this 27th day of October 2015.

Jessica R. Webster,

Certifying Officer, Office of Trade Adjustment Assistance.

Appendix

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department Web site: <http://www.justice.gov/enrd/consent-decrees>.

We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$ 7.75 (25 cents per page reproduction cost) for the proposed Consent Decree without attachments, \$ 8.75 with attachments, payable to the United States Treasury.

Bob Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–30099 Filed 11–25–15; 8:45 am]

BILLING CODE 4410–15–P

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (“the Act”) and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the

32 TAA PETITIONS INSTITUTED BETWEEN 10/9/15 AND 10/23/15

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
91039	Foxconn Assembly (Workers)	Houston, TX	10/09/15	10/08/15
91040	Verizon Business (Workers)	Cary, NC	10/09/15	10/09/15
91041	Nike, Inc. (State/One-Stop)	Beaverton, OR	10/09/15	10/08/15
91042	Airboss Defense Inc. (Workers)	Milton, VT	10/09/15	10/08/15
91043	Q.E.P. Resources (State/One-Stop)	Tulsa, OK	10/09/15	10/08/15
91044	Thermal Engineering International (a subsidiary of Babcock Power Inc.) (State/One-Stop)	Joplin, MO	10/09/15	10/08/15
91045	Higher One (State/One-Stop)	New Haven, CT	10/13/15	10/09/15
91046	Cimarron Energy (Workers)	Norman, OK	10/13/15	10/10/15
91047	Big Strike U.S.A. (State/One-Stop)	Gardena, CA	10/13/15	10/12/15
91048	Seventy-Seven Energy (Company)	Oklahoma City, OK	10/13/15	10/09/15
91049	Gannett Company, Inc. (Workers)	El Paso, TX	10/13/15	10/12/15
91050	Concentrix (State/One-Stop)	Greenville, SC	10/13/15	10/09/15
91051	Carter Fuel Systems (Company)	Logansport, IN	10/14/15	10/01/15
91052	EnerSys Power/Full Solutions, Inc. (State/One-Stop)	Warrensburg, MO	10/14/15	10/13/15
91053	Sorenson Lighted Controls (State/One-Stop)	Hartford, CT	10/14/15	10/14/15
91054	McDavid Inc. (Workers)	Woodridge, IL	10/15/15	10/14/15
91055	Emerson Tool Company (Company)	St. Louis, MO	10/15/15	10/15/15
91056	Visual Citi, Inc. (State/One-Stop)	Lindenhurst, NY	10/16/15	10/15/15
91057	Voya Retirement and Insurance Annuity Company (State/One-Stop)	Windsor, CT	10/16/15	10/16/15
91058	Nuance Communications (State/One-Stop)	Atlanta, GA	10/19/15	10/16/15
91059	Gordon Bros. Supply, Inc. (Company)	Stroud, OK	10/19/15	10/16/15
91060	Service King Manufacturing, Inc. (Company)	Stroud, OK	10/19/15	10/16/15
91061	Johnson Metall (Union)	Lorain, OH	10/19/15	10/16/15
91062	Unipower LLC (Company)	Dunlap, TN	10/19/15	10/16/15
91063	Unipower LLC (Company)	Coral Springs, FL	10/19/15	10/16/15
91064	General Cable (Company)	Franklin, MA	10/20/15	10/19/15
91065	Monsanto (State/One-Stop)	St. Louis, MO	10/20/15	10/19/15
91066	Sony Electronics (Workers)	Park Ridge, NJ	10/21/15	10/21/15
91067	Mitel (State/One-Stop)	Mount Laurel, NJ	10/22/15	10/21/15
91068	Bombardier (State/One-Stop)	Colchester, VT	10/22/15	10/22/15
91069	Supervalu (Workers)	Boise, ID	10/23/15	10/22/15

32 TAA PETITIONS INSTITUTED BETWEEN 10/9/15 AND 10/23/15—Continued

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
91070	LPL Financial (Workers)	San Diego, CA	10/23/15	10/22/15

[FR Doc. 2015-30173 Filed 11-25-15; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221 (a) of the Trade Act of 1974 (“the Act”) and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has

instituted investigations pursuant to section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, no later than December 7, 2015.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 7, 2015.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N-5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC this 10th day of November 2015.

Jessica R. Webster,
Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[45 TAA petitions instituted between 10/26/15 and 11/6/15]

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
91071	SKF USA Inc (Company)	Hobart, OK	10/26/15	10/23/15
91072	Patriot Special Metals (Union)	Canton, OH	10/26/15	10/23/15
91073	Imperial Sugar Gramercy Packaging Facility (State/One-Stop)	Gramercy, LA	10/26/15	10/23/15
91074	Day & Zimmerman, Inc. (State/One-Stop)	Camden, AR	10/27/15	10/26/15
91075	Stant Inc. (State/One-Stop)	Romeo, MI	10/28/15	10/27/15
91076	Eaton Corporation (Workers)	Pittsburgh, PA	10/28/15	10/22/15
91077	Lee C. Moore (State/One-Stop)	Tulsa, OK	10/28/15	10/27/15
91078	Atlas Medical (State/One-Stop)	Calabasas, CA	10/28/15	10/27/15
91079	HBW Leeds LLC (State/One-Stop)	Salem, OR	10/28/15	10/27/15
91080	Allegany Technologies—Millersburg location (State/One-Stop)	Albany, OR	10/29/15	10/23/15
91081	YP Holdings LLC (Workers)	Tucker, GA	10/29/15	10/23/15
91082	Anodex Anodizing, Inc. (State/One-Stop)	Medford, OR	10/29/15	10/26/15
91083	Voith Paper (Union)	Neenah, WI	10/29/15	10/27/15
91084	EMD Millipore Corp. (Company)	Bedford, MA	10/29/15	10/28/15
91085	YP Holdings (Workers)	Maryland Heights, MO	10/29/15	10/29/15
91086	NSC Global (Workers)	Mason, OH	10/29/15	10/28/15
91087	Cameron (Workers)	Houston, TX	10/29/15	10/28/15
91088	TerraSource Global (Company)	Cuyahoga Falls, OH	10/29/15	10/28/15
91089	On Site Tools, LLC. (Workers)	Yukon, OK	10/29/15	10/29/15
91090	AK Steel Corporation (Union)	Ashland, KY	10/30/15	10/26/15
91091	Caterpillar Precision (Workers)	Franklin, NC	10/30/15	10/30/15
91092	One Call Care Management (State/One-Stop)	Tampa, FL	10/30/15	10/29/15
91093	S&Y Industries (State/One-Stop)	Winfield, KS	11/02/15	10/30/15
91094	Apex Engineering (State/One-Stop)	Wichita, KS	11/02/15	10/30/15
91095	WestRock (Union)	Newberg, OR	11/02/15	10/30/15
91096	E.C. Manufacturing LLC (State/One-Stop)	Shawnee, KS	11/02/15	10/30/15
91097	TABC, Inc. (State/One-Stop)	Long Beach, CA	11/02/15	10/30/15
91098	Motorola Solutions Inc. (Workers)	Schaumburg, IL	11/02/15	10/30/15
91099	Frontier Airlines Milwaukee Reservations Department (State/One-Stop)	Milwaukee, WI	11/03/15	11/02/15
91100	CSX Transportation (Workers)	Corbin, KY	11/03/15	11/03/15
91101	Becton Dickinson & Company (State/One-Stop)	Carlsbad, CA	11/03/15	11/02/15
91102	Direct Power and Water (State/One-Stop)	Albuquerque, NM	11/03/15	11/02/15
91103	Avery Dennison (State/One-Stop)	Covina, CA	11/04/15	11/03/15
91104	Pfizer (State/One-Stop)	Pearl River, NY	11/04/15	11/04/15
91105	Startek, Inc, USA (State/One-Stop)	Grand Junction, CO	11/04/15	10/20/15
91106	Woodgrain Millwork (State/One-Stop)	Prineville, OR	11/04/15	11/03/15
91107	Hartzell Veneer Products LLC (State/One-Stop)	Hillsdale, MI	11/05/15	11/04/15

APPENDIX—Continued

[45 TAA petitions instituted between 10/26/15 and 11/6/15]

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
91108	Volcano Corporation (Company)	Rancho Cordova, CA	11/05/15	11/04/15
91109	Pentair, Inc. (Company)	Mt. Sterling, KY	11/05/15	11/04/15
91110	Trimco (Company)	Los Angeles, CA	11/05/15	11/04/15
91111	Parker Hannifin Corporation (Union)	Youngstown, OH	11/06/15	10/30/15
91112	ATSCO Division of BBB Industries, LLC (Company)	Phoenix, AZ	11/06/15	11/05/15
91113	MC Electronics Inc. (State/One-Stop)	Hollister, CA	11/06/15	11/06/15
91114	Pickard Inc. (State/One-Stop)	Antioch, IL	11/06/15	11/05/15
91115	SCFM Compression Systems (State/One-Stop)	Tulsa, OK	11/06/15	11/05/15

[FR Doc. 2015-30179 Filed 11-25-15; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR**Employment and Training Administration****Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance**

In accordance with section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA-W) number issued during the period of *October 9, 2015 through October 23, 2015*.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(a) of the Act must be met.

I. Under section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly

competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that

employed a group of workers who received a certification of eligibility under section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(e) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1- year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each

determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
85,842	Sypris Technologies, Inc., Manpower	Morganton, NC	January 20, 2014.
85,852	Saint-Gobain Ceramics and Plastics, Inc., DBA Saint-Gobain Proppants, Procon-WFPC, Ltd.	Fort Smith, AR	February 14, 2014.
85,981	Stein Steel Mill Services, Inc., United State Steel Corporation, Granite City Works.	Granite City, IL	May 1, 2014.

The following certifications have been issued. The requirements of section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
85,019	Saliency Insight, Inc., F/K/A KD Paine & Partners, News Group International, DUBAI UAE.	Berlin, NH	January 16, 2013.
85,137	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Miamisburg, OH	March 11, 2013.
85,137A	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Albany, NY	March 11, 2013.
85,137B	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Charlottesville, VA	March 11, 2013.
85,137C	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Colorado Springs, CO	March 11, 2013.
85,137D	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Dayton, OH	March 11, 2013.
85,137E	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Springfield, OH	March 11, 2013.
85,137F	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	New Providence, NJ	March 11, 2013.
85,137G	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	New York, NY	March 11, 2013.
85,137H	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	San Francisco, CA	March 11, 2013.
85,137I	LexisNexis, Reed Elsevier, PLC., AELPO Team, Matthew Bender, Populus Group and Linium.	Orem, UT	March 11, 2013.
85,339	Freescale Semiconductor, Inc., Auto MCU PE/TE C90 Business Unit	Austin, TX	May 28, 2013.
85,871	Multiband Corporation, Goodman Networks, Inc.	Richmond, KY	March 10, 2014.
85,943	Robertshaw Controls Company, CDI Corporation	Corona, CA	April 15, 2014.
85,960	Advanced Lab Concepts, Roundrock 092012 LLC, Opengate Capital Group LLC.	Round Rock, TX	April 23, 2014.
85,960A	Hamilton Scientific LLC, Technical Employment Services, Roundrock 092012 LLC, Opengate Capital Group.	De Pere, WI	April 23, 2014.
85,960B	Laboratory Solutions of America, Roundrock 092012 LLC, Opengate Capital Group LLC.	Branchburg, NJ	April 23, 2014.
85,990	Maxim Integrated, HBO Test Floor Group, Kelly Services	Hillsboro, OR	May 5, 2014.
86,016	Rexnord Industries, LLC, Mill Products Division	Milwaukee, WI	May 7, 2014.
86,040	ATOS IT Solutions and Services, Inc., F/K/A Siemens IT Solutions & Services, Inc. etc..	Mason, OH	May 28, 2014.
86,043	UBM, LLC, Shared Services Division, Robert Half, Aerotek, Accounting Principals, etc..	Manhasset, NY	May 28, 2014.
86,046	International Lease Finance Company, AerCap, Robert Half, Elite Placement, Roth Staffing, Resources Global.	Los Angeles, CA	May 28, 2014.
86,066	Worldwide Digital Company, LLC, Contec, LLC, Select Staff	Brownsville, TX	June 4, 2014.
86,091	Frontier Airlines, Inc., Frontier Airlines Holdings, Sitel and Swiss Port, Etc.	Denver, CO	June 12, 2014.
86,121	Sandvik Coromant, Sandvik, Inc., Uniforce and Snelling Staffing	Pontiac, MI	June 22, 2014.
90,004	Citizens Bank, National Association, Business Services—Operations	Bridgeport, CT	January 1, 2014.
90,009	Bechtel Business Services, A Business Unit Within Bechtel	Glendale, AZ	January 1, 2014.
90,013	National Oilwell Varco, Industrial Products Division, Techstaff, Express Employment, etc..	Springfield, OH	January 1, 2014.
90,024	QBE Americas, Inc., Home Owners Insurance Processing Department	Irvine, CA	January 1, 2014.
90,027	Kongsberg Power Products Systems, Inc., Light Duty Cables, Etcon Employment Solutions.	Swainsboro, GA	January 1, 2014.

TA-W No.	Subject firm	Location	Impact date
90,030	SimplexGrinnell LP, Also known as Tyco Fire Protection Products, Tyco Internation PLC, etc..	Westminster, MA	January 1, 2014.
90,042	SECO/WARWICK Corporation	Meadville, PA	January 1, 2014.
90,047	Athenahealth, Inc.	Birmingham, AL	February 8, 2015.
90,058	ICON Health & Fitness Inc., Your Employment Solutions, Intermountain Staffing, Kelly Services and Nexeo.	Logan, UT	January 1, 2014.
90,058A	ICON Health & Fitness Inc., Your Employment Solutions	Ogden, UT	January 1, 2014.
90,061	Sentry Safe—Schwab Corporation, Advantage Resourcing	Cannelton, IN	January 1, 2014.
90,061A	Sentry Safe—Schwab Corporation, Rochester Business Alliance (RBA Staffing) and AP Professionals.	Rochester, NY	January 1, 2014.
90,062	Hutchinson Technology Incorporated	Eau Claire, WI	December 12, 2014.
90,071	RR Donnelley, Lancaster Premedia	Lancaster, PA	January 1, 2014.
90,080	Conifer Revenue Cycle Solutions, LLC, Mercy Medical Center, Conifer HIM, Revenue Integrity Services, LLC.	Des Moines, IA	January 1, 2014.
90,162	NCO Financial Systems, Inc., Expert Global Solutions, Inc.	Lenexa, KS	January 1, 2014.
90,214	Concurrent Manufacturing Solutions, LLC, Hialeah Division, Oasis Outsourcing, Kelly Services, etc..	Hialeah, FL	January 1, 2014.
91,001	Palmer Johnson Yachts, LLC, Aerotek, Calibre Coatings Unlimited LLC, etc..	Sturgeon Bay, WI	September 17, 2014.

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
85,799	Comprehensive Logistics, Inc	Lansing, MI	January 28, 2014.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and

on the Department's Web site, as required by section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA-W No.	Subject firm	Location	Impact date
85,964	IPSCO Koppel Tubulars, LLC	Ambridge, PA	
85,993	IPSCO Tubulars (KY) Inc.	Wilder, KY	
86,017	IPSCO Tubulars Inc., D/B/A TMK-IPSCO	Houston, TX	
86,067	Guardian Life Insurance Company	Appleton, WA.	

The following determinations terminating investigations were issued in cases where these petitions were not filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed

by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to the date of the petition cannot be covered under a certification of a petition under section 223(b), and

therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA-W No.	Subject firm	Location	Impact date
86,092	National Electronic Warranty/Asurion	Sterling, VA.	

The following determinations terminating investigations were issued because the petitioning groups of

workers are covered by active certifications. Consequently, further investigation in these cases would serve

no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA-W No.	Subject firm	Location	Impact date
90,017	MoneyGram Payment Systems, Inc., MoneyGram International, Inc.	Brooklyn Center, MN.	
90,192	Frontier Airlines, Inc., Frontier Airlines Holdings, Inc., Customer Service Department.	Denver, CO.	
90,225	Ipsco Koppel Tubulars, LLC	Ambridge, PA.	

The following determinations terminating investigations were issued

because the petitions are the subject of ongoing investigations under petitions

filed earlier covering the same petitioners.

TA-W No.	Subject firm	Location	Impact date
90,121	Symantec Corporation	Springfield, OR..	

I hereby certify that the aforementioned determinations were issued during the period of *October 9, 2015 through October 23, 2015*. These determinations are available on the Department's Web site *www.tradeact/taa/taa_search_form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888-365-6822.

Signed at Washington DC this 27th day of October 2015.

Jessica R. Webster

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015-30174 Filed 11-25-15; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for Reporting and Performance Standards System for Migrant and Seasonal Farmworker Programs, Extension With Revision

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506(c)(2)(A)] (PRA). The PRA helps ensure that respondents can provide requested data in the desired format with minimal reporting burden (time and financial resources), collection instruments are clearly understood and the impact of collection requirements on respondents can be properly assessed. Currently, ETA is soliciting comments concerning the information collection request (ICR) to collect data about The National Farmworker Jobs Program (NFJP), which provides employment and training services as well as housing assistance to disadvantaged migrant and seasonal

farmworkers (MSFWs) and their dependents.

Interested parties are encouraged to provide comments to the contact shown in the ADDRESS section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control No. 1205-0425.

DATES: Submit written comments to Gregory Scheib at the office listed in the address section below on or before January 26, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Gregory Scheib, Workforce Analyst for the National Farmworker Jobs Program, at *NFJP@dol.gov*, or by mail to Gregory Scheib, Room C-4510, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202-693-2791 (this is not a toll-free number). Fax: 202-693-3015. Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1-877-889-5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Background

This grant program seeks to counter the impact of the chronic unemployment and underemployment experienced by MSFWs who depend primarily on jobs in agricultural labor. NFJP grant funds are awarded to community-based organizations and public agencies through a biennial grant competition.

NFJP grantees are required to submit a Program Planning Summary report (ETA Form 9094), a Program Status Summary report (ETA Form 9095), a Housing Assistance report (ETA Form 9164), a quarterly file of individual records on all participants who exit the program (Workforce Investment Act Standardized Participant Record (WIASPR), and a grant plan narrative. These reporting requirements

encompass a minimum level of information collection that is necessary to hold grantees appropriately accountable for the Federal funds they receive, assess progress against a set of common performance measures, and allows the Department to fulfill its oversight and management responsibilities. ETA proposes eliminating the Budget Information Summary Form, ETA 9093, currently submitted by grantees as part of annual program plan updates. ETA believes the information collected on this form is not essential to monitor grantee expenditures; moreover, information on prior year funds exists on ETA 9130 (OMB Control No. 1205-0461), a form already required for grantees. Discontinuation of this form will reduce the total estimated annual reporting burden on each NFJP grantees by 15 hours per year.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of response.

III. Current Actions

- *Agency:* DOL-ETA.
- *Type of Review:* extension with change.
- *Title of Collection:* Reporting and Performance Standards System for Migrant and Seasonal Farmworker Programs.
- *Forms:* ETA 9094, 9095, and 9165 (housing assistance).

- OMB Control Number: 1205–0425.
- Affected Public: State, local, and tribal governments.
- Estimated Number of Respondents: 69.
- Frequency: quarterly.
- Total Estimated Annual Responses: 29,897.
- Estimated Total Annual Burden Hours: 73,279 hours.
- Total Estimated Annual Other Cost Burden: \$0.

We will summarize and/or include in the request for OMB approval of the ICR, the comments received in response to this comment request; they will also become a matter of public record.

Portia Wu,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2015–30175 Filed 11–25–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *October 26, 2015 through November 6, 2015*.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under section 222(a)(2)(A), the following must be satisfied:

- (1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;
- (2) the sales or production, or both, of such firm have decreased absolutely; and
- (3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) the increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) there has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) the shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(b) of the Act must be met.

(1) a significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the

production or sales of the workers' firm; or

(B) a loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(e) of the Act must be met.

(1) the workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) the workers have become totally or partially separated from the workers' firm within—

(A) the 1-year period described in paragraph (2); or

(B) not withstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations For Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
85,122	Bimbo Bakeries, USA, Inc., BBU, Inc., Earthgrains Baking Companies, Inc..	Wichita, KS	March 5, 2013.
85,197	Bimbo Bakeries, USA, Inc., BBU, Inc., Orograin Bakeries Manufacturing, Inc..	Bay Shore, NY	April 1, 2013.
85,864	Derwich Industries, Inc.	Grayling, MI	March 6, 2014.
86,047	Republic Steel, Cold-Finished Division	Gary, IN	May 29, 2014.
90,059	Radiant Thermal Products Inc.	Roselle, NJ	January 1, 2014.
90,212	Verso Corporation, Androscoggin Mill, Verso Paper, LLC, Elite Staffing	Jay, ME	January 1, 2014.

The following certifications have been issued. The requirements of section 222(a)(2)(B) (shift in production or

services) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
85,003	Warner Brothers Home Entertainment Inc., Warner Home Video Division, Randstad US, Pacific Tech, DLC.	Burbank, CA	January 3, 2013.
85,048	British Telecommunications, British Telecommunications Voice Telecommunications, Voice and Change Mgt..	Princeton, NJ	January 31, 2013.
85,182	M*Modal Services, Ltd., Medquist	Franklin, TN	March 30, 2014.
85,744	Kroll Factual Data, Inc., Kroll Inc., Manpower, Aerotek, Appleone	Loveland, CO	December 19, 2013.
85,858	Transcend Services, Inc., Nuance Communications, Inc.	Atlanta, GA	February 25, 2014.
85,858A	Transcend Services, Inc., Nuance Communications, Inc.	Burlington, MA	February 25, 2014.
85,999	Carlson Craft, The Occasions Group, Volt Workforce Solutions, and Spherion.	North Mankato, MN	May 7, 2014.
86,058	Merkle Inc., Merkle Group Inc.	Montvale, NJ	June 2, 2014.
90,018	Eaton Corporation, Barteck Group	Watertown, WI	January 1, 2014.
90,019	East Wind Code, Ltd., East Wind Code, Ltd., Vivienne Tam	New York, NY	January 1, 2014.
90,034	Agfa Corporation	City of Industry, CA	January 1, 2014.
90,035	Airtex Products L.P., Airtex Industries, LLC, UCI-Airtex Holdings, Inc., Manpower.	Fairfield, IL	December 25, 2015.
90,067	Frutarom USA Inc.	North Bergen, NJ	January 1, 2014.
90,077	DENTSPLY International Inc., Corporate Division, Addeco, JFC Global, Accountemps.	York, PA	January 1, 2014.
90,086	American Express Travel Related Services Company, Inc., Global Credit Administration (GCA), Global Fraud Protection Services, etc..	Salt Lake City, UT	January 1, 2014.
90,102	Apex Tool Group, LLC, Kelly Services, Inc., CPS Professionals	Cortland, NY	January 1, 2014.
90,109	Echo Bay Minerals Company, Kinross Gold Corporation, Spring Clean, Stotts Construction, Inc., etc..	Republic, WA	January 1, 2014.
90,112	Mondelez Global LLC, Integrated Supply Chain Division, Mondelez International, Fayette Industrial.	Chicago, IL	January 1, 2014.
90,120	Kelly-Smith Printing & Paper	Newport, ME	January 1, 2014.
90,133	Eastland Shoe Corporation, Labor Ready and Bonney Staffing	Freeport, ME	January 1, 2014.
90,137	CyOptics, Inc., Avago Technologies Limited, Laser Package Department, Aerotek, etc..	Breinigsville, PA	January 1, 2014.
90,152	Micro Pneumatic Logic, Inc., MFG., Affinity Resources, LLC	Pompano Beach, FL	January 1, 2014.
90,173	Diamond Power International, Inc., Diamond Power Specialty Company, Babcock; Wilcox Company.	Lancaster, OH	January 1, 2014.
90,176	National Captioning Institute, Inc., Spanish Real-Time Captioning	Dallas, TX	January 1, 2014.
90,218	Legend3D, Inc.	Carlsbad, CA	January 1, 2014.
90,235	Parker Hannifin Corporation (Fontana Location), Medical Systems Division, Workforce Solutions, Office Team.	Fontana, CA	January 1, 2014.
90,243	Gildan Garments, Inc., Gildan Activewear, Inc., Comfort Colors by Chouinard, Kelly Services, Inc..	Northfield, VT	January 1, 2014.
90,251	Caterpillar, Inc., Large Power Systems Division, A to Z Sheet Metal, Inc., etc..	Lafayette, IN	January 1, 2014.
90,258	Rexton, Sivantos, Inc.	Plymouth, MN	January 1, 2014.
90,334	Cummins Filtration, Cummins Inc., Apollo Security	Lake Mills, IA	October 25, 2015.
91,000	TitanX Engine Cooling	Jamestown, NY	September 21, 2014.
91,002	Newell Rubbermaid, Inc., Na-Newekk Rubbermaid, Human American Data Center, Huges Resources.	Freeport, IL	September 28, 2014.

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers

are certified eligible to apply for TAA) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
90,095	Green Diamond Resource Company, Manpower	Shelton, WA	January 1, 2014.

Negative Determinations For Worker Adjustment Assistance

criteria for worker adjustment assistance have not been met for the reasons specified.

(b)(1) (employment decline or threat of separation) of section 222 has not been met.

In the following cases, the investigation revealed that the eligibility

The investigation revealed that the criterion under paragraph (a)(1) and

TA-W No.	Subject firm	Location	Impact date
85,089	Bank of America, Global Technology Trading Support	San Jose, CA.	
86,007	Goldwin America, Inc., Goldwin, Inc., Sales and Marketing Unit	Manhattan Beach, CA.	
90,091	Industrial Television Services, Inc., General Edward Lawrence Logan International Airport.	Boston, MA.	
90,301	Kennedy Consulting, Inc	Eagle River, AK.	

The investigation revealed that the criteria under paragraphs (a)(2)(A)

(increased imports) and (a)(2)(B) (shift in production or services to a foreign

country) of section 222 have not been met.

TA-W No.	Subject firm	Location	Impact date
85,208	Lockheed Martin Ship and Aviation Systems, Lockheed Martin Mission Systems and Training, DCR Workforce.	Akron, OH.	
85,513	Heartland Footwear, Inc.	Pocahontas, AR.	
85,737	Quantum Foods, LLC, Rosa Mystica Enterprises, LLC	Bolingbrook, IL.	
85,982	Bosch Security Systems, Inc., Security Technology North America, Aerotek.	Lancaster, PA.	
86,009	Desta Drilling LP	Odessa, TX.	
86,078	Best Well Services, LLC	Tulsa, OK.	
86,078A	Best Well Services, LLC	Guthrie, OK.	
90,044	First Manufacturing Company, Inc., Labor Ready and Essex Temp	Oceanside, NY.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

on the Department's Web site, as required by section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

After notice of the petitions was published in the **Federal Register** and

TA-W No.	Subject firm	Location	Impact date
85,929	International Business Machines (IBM), GTS Mobility Services (Desk Side Support), 07 (GTS).	Endicott, NY.	
90,126	Sealed Air Corporation	Greenville, SC.	
90,222	Telesource Services, LLC	Bensenville, IL.	
90,223	Telesource Services, LLC	Pontiac, MI.	
91,020	East Wind Code LTD	New York, NY.	

The following determinations terminating investigations were issued in cases where these petitions were not filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed

by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to the date of the petition cannot be covered under a certification of a petition under section 223(b), and

therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA-W No.	Subject firm	Location	Impact date
86,079	Airboss Defense Inc.	Milton, VT.	
90,144	Arvato Digital Services	Reno, NV.	

The following determinations terminating investigations were issued because the petitioning groups of

workers are covered by active certifications. Consequently, further investigation in these cases would serve

no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA-W No.	Subject firm	Location	Impact date
85,617	Day&Zimmermann, Inc., Kansas Division	Parsons, KS.	
91,058	Transcend Services, Inc., Nuance Communications, Inc	Atlanta, GA.	

The following determinations terminating investigations were issued because the petitions are the subject of ongoing investigations under petitions filed earlier covering the same petitioners.

TA-W No.	Subject firm	Location	Impact date
90,205	Lenovo	Morrisville, NC.	
90,274	Legacy Measurement Solutions, Inc., Express Employment Professionals	Bristow, OK.	
91,035	Mitsubishi Motors North America, Inc	Normal, IL.	

I hereby certify that the aforementioned determinations were issued during the period of *October 26, 2015 through November 6, 2015*. These determinations are available on the Department's Web site www.tradeact/taa/taa_search_form.cfm under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888-365-6822.

Signed at Washington, DC this 10th day of November 2015.

Jessica R. Webster,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015-30180 Filed 11-25-15; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Decisions on States' Applications for Relief From Tax Credit Reductions Provided Under Section 3302 of the Federal Unemployment Tax Act (FUTA) Applicable in 2015

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: Sections 3302(c)(2)(A) and 3302(d)(3) of the FUTA provide that employers in a State that has an outstanding balance of advances under Title XII of the Social Security Act at the beginning of January 1 of two or more consecutive years are subject to a reduction in credits otherwise available against the FUTA tax for the calendar year in which the most recent such January 1 occurs, if a balance of advances remains at the beginning of November 10 of that year. Further, section 3302(c)(2)(C) of FUTA provides for an additional credit reduction for a year if a State has outstanding advances on five or more consecutive January firsts and has a balance at the beginning of November 10 for such years. Section 3302(c)(2)(C) also provides for waiver of this additional credit reduction and substitution of the credit reduction provided in section 3302(c)(2)(B) if a state meets certain conditions.

The States of California, Connecticut, Indiana, Kentucky, New York, North Carolina, Ohio, South Carolina, and the Virgin Islands passed January 1, 2015, with outstanding Title XII advances and were potentially subject to FUTA credit reductions.

California, Indiana, Kentucky, Ohio, and the Virgin Islands applied for a waiver of the 2015 additional credit reduction under section 3302(c)(2)(C) of FUTA and it has been determined that each of these States met all of the criteria of that section necessary to qualify for the waiver of the additional credit reduction. Further, the additional credit reduction of section 3302(c)(2)(B) is zero for these States for 2015. Therefore, employers in these States will have no additional credit reduction applied for calendar year 2015.

Also, Section 3302(f) of FUTA provides that a State may apply for a cap in the reduction in credit for a year by meeting certain criteria. Kentucky applied for the cap of the 2015 credit reduction under this section. It has been determined that Kentucky met all of the criteria of section 3302(f) and thus qualifies for a cap on the credit reduction. Therefore, Kentucky employers would not be subject to an increase in FUTA credit reductions for calendar year 2015.

The States of Indiana, Kentucky, New York, North Carolina, and South Carolina repaid all of their outstanding advance balances before the beginning of November 10, 2015. Therefore, employers in those States will have no reduction in FUTA offset credit for calendar year 2015.

California, Ohio, and the Virgin Islands will have a credit reduction of 1.5%, and Connecticut will have a credit reduction of 2.1%, which is the 1.5% plus a 0.6% fifth year add-on amount for calendar year 2015.

Portia Wu,

Assistant Secretary for Employment and Training.

[FR Doc. 2015-30177 Filed 11-25-15; 8:45 am]

BILLING CODE 4510-FW-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2010-0046]

QPS Evaluation Services, Inc.: Request for Renewal of Recognition and Applications for Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of QPS Evaluation Services, Inc. (QPS), for renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL). Additionally, this notice announces QPS's applications for expansion of its recognition as an NRTL and presents the Agency's preliminary finding to grant the application.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before December 14, 2015.

ADDRESSES: Submit comments by any of the following methods:

1. *Electronically:* Submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

2. *Facsimile:* If submissions, including attachments, are not longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693-1648.

3. *Regular or express mail, hand delivery, or messenger (courier) service:* Submit comments, requests, and any attachments to the OSHA Docket Office, Docket No. OSHA-2010-0046, Technical Data Center, U.S. Department of Labor, 200 Constitution Avenue NW., Room N-2625, Washington, DC 20210; telephone: (202) 693-2350 (TTY number: (877) 889-5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery

of materials by express mail, hand delivery, or messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. *Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2010–0046). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the Agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

5. *Docket:* To read or download submissions or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

6. *Extension of comment period:* Submit requests for an extension of the comment period on or before December 14, 2015 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director,

Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; phone: (202) 693–2110, or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of an NRTL signifies that the organization meets the requirements specified in Section 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition. Each NRTL’s scope of recognition includes (1) the type of products the NRTL may test, with each type specified by its applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL’s scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification. OSHA maintains an informational Web site for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The Agency processes applications by an NRTL for renewals and expansions of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, App. II.C. OSHA processes applications for modifying the scope of recognition in accordance with 29 CFR 1910.7, App. IB4. In accordance with these procedures, NRTLs may submit an application to modify its scope of recognition at any time within its recognition period. For renewals, NRTLs must submit a request to OSHA, between nine months and one year before the expiration date of its current recognition. A renewal request includes an application for renewal and any additional information demonstrating its continued compliance with the terms of its recognition and 29 CFR 1910.7. If

OSHA did not conduct an on-site assessment of the NRTL’s headquarters and key sites within the past 18 to 24 months, the Agency will schedule the necessary on-site assessments prior to the expiration date of the NRTL’s recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal and QPS’s requested scope expansion in the **Federal Register** and solicits comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and announcing the Agency’s Final Decision on modifying an NRTL’s scope of recognition and on the renewal of the NRTL’s recognition.

II. Notice of Application for Expansion

The Occupational Safety and Health Administration is providing notice that QPS is applying for expansion of its current recognition as an NRTL. QPS requests the addition of seven test standards to its NRTL scope of recognition.

QPS currently has one facility (site) recognized by OSHA for product testing and certification, with its headquarters located at: QPS Evaluation Services, Inc., 81 Kelfield Street, Unit 8, Toronto, Ontario, M9W 5A3.

III. General Background on the Application for Expansion

QPS submitted two applications, one dated July 16, 2014, and one dated June 9, 2015 (QPS Exhibit 14–1—Expansion Application for Six Standards OSHA–2010–0046 and QPS Exhibit 15–1—Amended Expansion Application to Add an Additional Standard OSHA–2010–0046), to expand its recognition to include seven additional test standards. These two applications were combined. OSHA staff performed a comparability analysis and reviewed other pertinent information. OSHA performed an on-site review in relation to these applications (as well as the application for renewal) on July 16–17, 2015.

Table 1 below lists the appropriate test standards found in QPS’s applications for expansion for testing and certification of products under the NRTL Program.

TABLE 1—PROPOSED APPROPRIATE TEST STANDARDS FOR INCLUSION IN QPS’S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 48	Standard for Electric Signs.
UL 8750	Standard for Light Emitting Diode (LED) Equipment for Use in Lighting Products.
UL 73	Standard for Motor-Operated Appliances.

TABLE 1—PROPOSED APPROPRIATE TEST STANDARDS FOR INCLUSION IN QPS’S NRTL SCOPE OF RECOGNITION—Continued

Test standard	Test standard title
UL 1310	Standard for Class 2 Power Units.
UL 1598	Luminaries.
UL 1741	Standard for Inverters, Converters, Controllers and Interconnection System Equipment for Use with Distributed Energy Resources.
ANSI/ISA 12.12.01	Nonincendive Electrical Equipment for Use in Class I and II, Division 2 and Class III, Divisions 1 and 2 Hazardous (Classified) Locations.

IV. General Background on Application for Renewal

OSHA is additionally providing notice that QPS is applying for renewal of its current recognition as an NRTL. QPS initially received OSHA recognition as an NRTL on March 2, 2011 (76 FR 11518) for a five-year period expiring on March 2, 2016. QPS submitted a timely request for renewal, dated April 21, 2015 (Exhibit 2—Renewal Application, OSHA–2010–0046) and retains its recognition pending OSHA’s final decision in this renewal process. The current address of QPS facilities recognized by OSHA and included as part of the renewal request are:

1. QPS Evaluation Services, Inc., 81 Kelfield Street, Unit 8, Toronto, Ontario, M9W 5A3 Canada.

V. Notice of Preliminary Findings of the Applications

QPS submitted acceptable applications for expansion of its scope of recognition. OSHA’s review of the application file and on-site review indicate that QPS can meet the requirements prescribed by 29 CFR 1910.7 for expanding its recognition to include the addition of the test standards for NRTL testing and certification noted in Table 1 above. This preliminary finding does not constitute an interim or temporary approval of QPS’s applications.

This requested renewal covers QPS’s existing NRTL scope of recognition. OSHA evaluated QPS’s application for renewal, conducted an on-site review of QPS’s facilities and preliminarily determined that QPS can continue to meet the requirements prescribed by 20 CFR 1910.7 for recognition. This information includes OSHA’s most recent on-site assessment of QPS’s facilities conducted on July 16–17, 2015 (Toronto, Canada). The assessors found some nonconformances with the requirements of 29 CFR 1910.7. QPS addressed these issues sufficiently to meet the applicable NRTL requirements. This preliminary finding does not constitute an interim or temporary approval of the application.

OSHA welcomes public comment as to whether QPS meets the requirements of 29 CFR 1910.7 for expansion and renewal of its recognition as an NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. Commenters must submit the written request for an extension by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office, Room N–2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. These materials also are available online at <http://www.regulations.gov> under Docket No. OSHA–2010–0046.

OSHA staff will review all comments submitted to the docket in a timely manner and, after addressing the issues raised by these comments, will recommend whether to grant QPS’s application for renewal and for expansion of its scope of recognition. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor’s Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on November 23, 2015.

David Michaels,
Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–30168 Filed 11–25–15; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL SCIENCE FOUNDATION

National Science Board

Sunshine Act Meetings; Notice

The National Science Board’s *ad hoc* Committee on Nominations for the NSB Class of 2016–2022, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business, as follows:

DATE AND TIME: Monday, December 7, 2015 at 1:30–2:30 p.m. EST

SUBJECT MATTER: Committee chair’s remarks, and discussion of the nomination submissions and preparation of a proposed list of names.

STATUS: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (www.nsf.gov/nsb) for information or schedule updates, or contact: Brandon Powell (bjpowell@nsf.gov), National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Kyscha Slater-Williams,
Program Specialist.

[FR Doc. 2015–30335 Filed 11–24–15; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION**Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978**

AGENCY: National Science Foundation.

ACTION: Notice of Permit Modification Request Received and Permit Issued under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated and permits issued under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at title 45 part 670 of the Code of Federal Regulations. This is the required notice of a requested permit modification and permit issued.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Division of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Or by email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: The Foundation issued a permit (ACA 2014–003) to Jennifer Burns on July 18, 2013. The issued permit allows the applicant to study the interaction of Weddell seal condition and the timing of molting and reproduction via capture, restraint, and sedation of adult female seals to conduct health assessments and attach tags.

A recent modification to this permit, dated December 2, 2014, permitted several handling modifications for animals.

Now the applicant proposes a permit modification to attach 2 new types of tags, to conduct nasal swabs, and to keep on some of the tags over winter to collect more data. Both new proposed tags are less than 100g. The seals are already sedated for other permitted procedures, and these new tag attachments and procedures would not increase handling time, since they can be simultaneously conducted during ultrasounds.

The Environmental Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

November 20, 2015 to February 28, 2017.

The permit modification was issued on November 20, 2015.

Nadene G. Kennedy,
Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2015–30149 Filed 11–25–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION**Notice of Permits Issued Under the Antarctic Conservation Act of 1978**

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Division of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Or by email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: On October 8, 2015 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on November 19, 2015 to:

Permit No. 2016–016

Philip R. Kyle

Nadene G. Kennedy,
Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2015–30148 Filed 11–25–15; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–21; Order No. 2830]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Reseller Expedited Package Contracts 4 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 30, 2015.

ADDRESSES: Submit comments electronically via the Commission's

Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:**Table of Contents**

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- III. Ordering Paragraphs

I. Introduction

On November 19, 2015, the Postal Service filed notice that it has entered into an additional Global Reseller Expedited Package Contracts 4 (GREP 4) negotiated service agreement (Agreement).¹

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–21 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than November 30, 2015. The public portions of the filing can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Christopher C. Mohr to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–21 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Christopher C. Mohr is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than November 30, 2015.

¹ Notice of United States Postal Service of Filing a Functionally Equivalent Global Reseller Expedited Package Contracts 4 Negotiated Service Agreement, November 19, 2015 (Notice).

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary, Commissioner Goldway,
abstaining.

[FR Doc. 2015-30094 Filed 11-25-15; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016-16 and CP2016-22;
Order No. 2831]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express Contract 29 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 1, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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- I. Introduction
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I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 29 to the competitive product list.¹

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a

copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016-16 and CP2016-22 to consider the Request pertaining to the proposed Priority Mail Express Contract 29 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than December 1, 2015. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints James F. Callow to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016-16 and CP2016-22 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than December 1, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2015-30150 Filed 11-25-15; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service

Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* November 27, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202-268-3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 20, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 153 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2016-17, CP2016-23.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2015-30106 Filed 11-25-15; 8:45 am]

BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service.™

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* November 27, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202-268-3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 20, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 29 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2016-16, CP2016-22.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2015-30107 Filed 11-25-15; 8:45 am]

BILLING CODE 7710-12-P

¹ Request of the United States Postal Service to Add Priority Mail Express Contract 29 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, November 20, 2015 (Request).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76489; File No. SR-CBOE-2015-103]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Technical Disconnect Mechanism

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 9, 2015, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.23C related to the Exchange's Technical Disconnect Mechanism. The text of the proposed rule change is provided below. (additions are *italicized*; deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated

Rules

* * * * *

Rule 6.23C Technical Disconnect

(a) When a CBOE Application Server ("CAS") loses communication with a Client Application such that a CAS does not receive an appropriate response to a Heartbeat Request within "x" period of time, the Technical Disconnect Mechanism will automatically logoff the Trading Permit Holder's affected Client Application and[, if applicable, will] automatically cancel all the Trading Permit Holder's Market-Maker quotes, *if applicable, and open orders with a time-in-force of "day" ("day orders"), if the Trading Permit Holder enables that optional service*, posted through the affected Client Application. The following describes how the Technical Disconnect Mechanism works for each of the Exchange's application programming interfaces ("APIs"):

(i) *CBOE Market Interface ("CMi") API*. A CAS shall generate a Heartbeat Request to a Client Application every "n" period of time. The value of "n" shall be set by the Exchange at two (2) seconds. The value of "x" shall be set either by the Exchange or a Trading Permit Holder, depending upon the version of CMi being used. If the value of "x" is determined by the Exchange, "x" shall be set at twenty (20) seconds. If the value of "x" is determined by a Trading Permit Holder, "x" shall in no event be less than three (3) seconds or exceed twenty (20) seconds.]

(i[i]) *CBOE Market Interface 2.0 ("CMi 2") API*. A CAS shall generate a Heartbeat Request to a Client Application (i) after the CAS does not receive any messages from a particular Client Application for "n" period of time or (ii) after every "n" period of time. A Trading Permit Holder shall determine the value of "n." In no event shall "n" be less than three (3) seconds or exceed twenty (20) seconds. If a CAS generates a Heartbeat Request only after it does not receive any messages from a particular Client Application for "n" period of time, the value of "x" shall be set at a half (.5) second. If a CAS generates a Heartbeat Request every "n" period of time, the value of "x" shall be equal to the value of "n."

(ii[i]) *Financial Information eXchange ("FIX") Protocol API*. A CAS shall generate a Heartbeat Message to a Client Application after the CAS does not receive any messages from a particular Client Application for "n" period of time. If the CAS does not receive a response to the Heartbeat Message from the Client Application for "n" period of time, the CAS shall generate a Heartbeat Request to the Client Application. A Trading Permit Holder shall determine the value of "n" at logon. In no event shall "n" be less than five (5) seconds. The value of "x" shall be equal to the value of "n."

(b) The Technical Disconnect Mechanism is enabled for all Trading Permit Holders and may not be disabled by Trading Permit Holders, *except the automatic cancellation of a Trading Permit Holder's day orders is an optional service that the Trading Permit Holder may enable or disable through the API*.

(c) The trigger of the Technical Disconnect Mechanism is event- and Client Application-specific. The automatic cancellation of a Market-Maker's quotes (*if applicable*) or a Trading Permit Holder's day orders (*if enabled by the Trading Permit Holder*) entered into a CAS via a particular Client Application will neither impact nor determine the treatment of the

quotes of the same or other Market-Makers or orders of the same Trading Permit Holder entered into the CAS via a separate and distinct Client Application. *Except for day orders the Technical Disconnect Mechanism automatically cancels if a Trading Permit Holder enables that optional service*, [T]he Technical Disconnect Mechanism will not impact or determine the treatment of orders a Trading Permit Holder previously entered into the CAS.

. . . *Interpretations and Policies:*
.01 No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.23C related to the Exchange's Technical Disconnect Mechanism. Rule 6.23C(a) provides that when a CBOE Application Server ("CAS")³ loses communication with a Client Application⁴ such that a CAS does not receive an appropriate response to a Heartbeat Request⁵ within "x" period of

³ CBOE currently has numerous CASs serving TPHs.

⁴ For relevant purposes, a "Client Application" is the system component, such as a CBOE-supported workstation or a TPH's custom trading application, through which a TPH communicates its quotes and/or orders to a CAS. Messages are passed between a Client Application and a CAS. A Market-Maker may send quotes to the Exchange from one or more Client Applications, and a TPH may send orders to the Exchange from one or more Client Applications.

⁵ A "Heartbeat Request" refers to a message from a CAS to a Client Application to check connectivity and which requires a response from the Client

Continued

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

time, the Technical Disconnect Mechanism will automatically logoff the Trading Permit Holder's ("TPH") affected Client Application. If that occurs, the current rule provides that the Technical Disconnect Mechanism, if applicable, will automatically cancel all the TPH's Market-Maker quotes posted through the affected Client Application.⁶ The Technical Disconnect Mechanism is intended to help mitigate the potential risks associated with a loss of communication with a Client Application, such as erroneous or unintended executions for stale quotes that are resting in the CBOE book. This mechanism serves to assist a TPH when a technical or system issue occurs, as well as assist the Exchange in maintaining a fair and orderly market.

The proposed rule change provides TPHs with an optional service that, if enabled by a TPH, will cause the Technical Disconnect Mechanism to also automatically cancel all the TPH's open orders with a time-in-force of "day" ("day orders") posted through the affected Client Application if the CAS loses communication with the Client Application. The proposed rule change amends Rule 6.23C(b) to provide that the TPH may enable or disable this optional service through its application programming interface ("API") (all other aspects of the Technical Disconnect Mechanism continue to otherwise be enabled for all TPHs and may not be disabled by TPHs).⁷ The proposed rule change makes corresponding changes to Rule 6.23C(c) that indicate the Technical Disconnect Mechanism will automatically cancel a TPH's day orders (in addition to a Market-Maker's quotes), if the TPH enables the proposed optional service.⁸ As is the case in the event the Technical Disconnect

Mechanism automatically logs a TPH off and cancels its Market-Maker quotes (if applicable), if a TPH enables this proposed optional service, and the Technical Disconnect Mechanism automatically logs a TPH off and cancels the TPH's day orders due to lost communication with TPH's Client Application, the TPH may send messages to the CAS to enter new orders once it reestablishes connectivity to the Client Application. In addition, any nonconnectivity will continue to be event- and Client Application-specific. In other words, any cancellation of day orders entered into a CAS via a particular Client Application will neither impact nor determine the treatment of the quotes of the same TPH entered into a CAS via a separate and distinct Client Application. The Technical Disconnect Mechanism will not impact or determine the treatment of orders previously entered into a CAS if the TPH does not enable this optional service, nor will it impact or determine the treatment of non-day orders previously entered into a CAS by the TPH. The Exchange notes use of this service will be voluntary and within the sole discretion of each TPH.

The proposed optional service is an additional preventative risk control measure that CBOE is making available to TPHs. It is intended to help further mitigate the potential risks associated with a loss of communication with a Client Application. While orders may be static in nature and rest in the book, TPHs often enter day orders more frequently in response to then-current market conditions. Therefore, if a TPH's Client Application is disconnected for any period of time, it is possible that market conditions upon which it based its day orders may change during that time and make those orders stale. Consequently, any resulting executions of those orders may be erroneous or unintended. The Exchange believes it is appropriate to limit this optional service to day orders and exclude good-til-cancelled orders,⁹ as those orders are intended to rest in the book for a period of time and thus have lower risk of erroneous or unintended executions during and after the Technical Disconnect Mechanism logs off a TPH.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange

and, in particular, the requirements of Section 6(b) of the Act.¹⁰ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹² requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change helps maintain a fair and orderly market and protects investors and the public interest. The Technical Disconnect Mechanism is a valuable tool that is designed to help maintain a fair and orderly market. The Exchange believes that providing TPHs with the option to have the Technical Disconnect Mechanism cancel its day orders, in addition to Market-Maker quotes (if applicable), further mitigates the potential risks associated with a loss in communication with a Client Application. The Exchange believes it is reasonable to offer to cancel only day orders. Unlike non-day orders, day orders are more likely to be reflective of then-current market conditions and are intended to rest in the book for a limited period of time. As a result, in the event that a CAS loses connectivity with a Client Application, execution of day orders during that time are more likely to result in erroneous or unintended executions, while risk of such executions is lower for non-day orders. The proposed optional service protects TPHs from these potential erroneous or unintended executions, as well as protects investors and the efficiency and fairness of the markets in general. The Exchange believes this functionality enhances the overall market quality for options traded on CBOE. The Exchange notes that other exchanges offer their members similar services that cancels a member's orders if it disconnects from the exchange.¹³

Application in order to avoid logoff. The Heartbeat Request acts as a virtual pulse between a CAS and a Client Application and allows a CAS to continually monitor its connection with a Client Application. Failure to receive a response to a Heartbeat Request within the Heartbeat Response Time is indicative of a technical or system issue.

⁶ See Rule 6.23C and Securities Exchange Act Release No. 34-70039 (July 25, 2013), 78 FR 46395 (July 31, 2013) (SR-CBOE-2013-071) for further information regarding the Technical Disconnect Mechanism.

⁷ CBOE currently makes available two APIs: CBOE Market Interface 2.0 ("CMI 2") and Financial Information eXchange Protocol ("FIX"). The proposed rule change deletes Rule 6.23A(a)(i) [sic] regarding the CBOE Market Interface ("CMI") API, as that has been phased out and is no longer available to TPHs. The proposed rule change also renumbers subparagraphs (ii) and (iii) to become subparagraphs (i) and (ii), respectively.

⁸ In addition, the proposed rule change makes nonsubstantive changes to Rule 6.23C(a), including moving the phrase "if applicable" to ensure that phrase clearly applies to the cancellation of a Market-Maker's quotes (as that functionality only applies to TPHs that are Market-Makers).

⁹ Currently, the Exchange offers two time-in-force order types: Day and good-til-cancelled. The proposed optional service will apply to orders that include the "day" marking.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹² *Id.*

¹³ See, e.g., BZX Exchange US Equities FIX Specification, Version 1.33.5 (October 8, 2014).

The Exchange also believes that the proposed rule change is designed to not permit unfair discrimination among market participants. Use of the optional service will be voluntary and within the sole discretion of each TPH. The proposed optional service is available to all TPHs and will apply to the same order types of all TPHs.

The proposed rule change to delete language related to CMi benefits investors, as that API is no longer available to TPHs and thus deletion of that language helps eliminate confusion. CMi2 and FIX continue to be available to TPHs.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe the proposed rule change will cause any burden on intramarket competition because the optional service will be available to all TPHs. Use of this optional service will be within the sole discretion of each TPH. The proposed rule change will have no impact on TPHs that do not enable the proposed optional service. For TPHs that elect to enable the proposed optional service, the only impact on those TPHs will be cancellation of day orders (in addition to Market-Maker quotes) upon loss of connectivity. The Technical Disconnect Mechanism will otherwise continue to function in the same manner as it does today. Further, the Exchange does not believe that such change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change modifies a mechanism available on CBOE's system and applies only to orders entered on CBOE. The Exchange notes that, should the proposed change make CBOE a more attractive place for trading, market participants trading on other exchanges are welcome to become TPHs and trade at CBOE if they determine that this proposed change has made CBOE more

available at http://www.batstrading.com/resources/membership/BATS_FIX_Specification.pdf (see Section 5.1 for description of automatic cancel on disconnection or malfunction); MIAX Options Market Protections Handout (March 2015), available at https://www.miaxoptions.com/sites/default/files/MIAX_Market_Protections_March_2015.pdf (see page 5 for description of auto cancel on disconnect order protection); and NYSE UTPDirect (CGC Binary) API Specification, V1.4 (February 26, 2015), available at https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSEUTPDirect_Specification.pdf (see Section 3.8 for description of cancel on disconnect service).

attractive or favorable. Additionally, as discussed above, other options exchanges offer their members similar functionality.¹⁴

The proposed rule change to delete language regarding CMi has no impact on competition, as it merely deletes a provision regarding an API that is no longer used by, and is no longer available to, TPHs. CMi 2 ultimately replaced CMi, and FIX continues to be available to TPHs as well.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and paragraph (f) of Rule 19b-4¹⁶ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2015-103 on the subject line.

Paper comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2015-103. This file

¹⁴ *Id.*

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f).

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-2015-103 and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-30075 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76498; File No. SR-CBOE-2015-105]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 16, 2015, Chicago Board Options Exchange, Incorporated (the "Exchange")

¹⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

or “CBOE”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange’s Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule, effective November 16, 2015. Specifically, the Exchange proposes to amend the Fees Schedule with respect to Qualified Contingent Cross (“QCC”) ³ orders. Currently, the Fees Schedule provides for a transaction fee for all non-customer QCC orders of \$0.15 per contract side (customer orders are not assessed a charge) and a \$0.10 per contract credit for the initiating order side, regardless of origin code.⁴ The Exchange first proposes to increase the fee for QCC transactions from \$0.15 per contract to \$0.17 per contract for all

³ A QCC order is comprised of an order to buy or sell at least 1,000 contracts (or 10,000 mini-option contracts) that is identified as being part of a qualified contingent trade, coupled with a contra-side order or orders totaling an equal number of contracts.

⁴ The Exchange notes that the \$0.10 per contract credit is not be available for customer-to-customer transactions.

non-customer orders. The Exchange notes that the proposed increase is in line with other exchanges.⁵

Next, the Exchange proposes to provide that the maximum credit paid shall not exceed \$350,000 per month per Trading Permit Holder (“TPH”). The Exchange notes that it will aggregate the credits of affiliated TPHs (TPHs with at least 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A) for purposes of determining whether a TPH has met the QCC credit cap. The Exchange believes that, while limiting the amount of rebate that a market participant can receive, the current QCC rebate will continue to incentivize market participants to seek to obtain the highest rebate possible. The Exchange also notes that other Exchanges have similar caps on rebates offered for QCC transactions.⁶

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act. Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes the proposed increase to the transaction fee for QCC orders is reasonable because the proposed amount is in line with the amount assessed at other Exchanges for

⁵ See e.g., NASDAQ OMX PHLX LLC (“PHLX”) Pricing Schedule, Section II, QCC Transaction Fees.

⁶ See e.g., PHLX Pricing Schedule, Section II, QCC Transaction Fees and NSYE Amex Options Fees Schedule (“Amex”), Section IE, Qualified Contingent Cross (“QCC”) Fees and Credits for Standard Options and Mini Options.

similar transactions.⁷ Additionally, the proposed fee increase would be charged to all non-customers alike. Assessing QCC rates to all market participants except customers is equitable and not unfairly discriminatory because Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market-Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. By exempting customer orders, the QCC transaction fees will not discourage the sending of customer orders.

The Exchange believes the proposed QCC credit cap is reasonable, equitable and not unfairly discriminatory because it is in line with similar caps on rebates paid for QCC transactions at other exchanges⁸ and because all TPHs would be uniformly capped at \$350,000 per month. The Exchange also believes it’s reasonable, equitable and not unfairly discriminatory to provide that it will aggregate the credits of affiliated TPHs to determine whether the credit cap has been met, as the Exchange believes this should prevent TPHs from dividing up their orders to different affiliates in order to avoid meeting the cap and it would apply to all TPHs.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition that are not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed [sic] rule changes apply uniformly to all Trading Permit Holders. The Exchange believes this proposal will not cause an unnecessary burden on intermarket competition because it only affects trading on CBOE. To the extent that the proposed changes make CBOE a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become CBOE market participants. Additionally,

⁷ See e.g., PHLX Pricing Schedule, Section II, QCC Transaction Fees and NSYE Amex Options Fees Schedule, Section I.E, Qualified Contingent Cross (“QCC”) Fees and Credits for Standard Options and Mini Options.

⁸ *Id.*

the Exchange notes that it operates in a highly competitive market, comprised of thirteen options exchanges, in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or rebates to be inadequate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁹ and paragraph (f) of Rule 19b-4¹⁰ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2015-105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2015-105. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-2015-105, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-30087 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76492; File No. SR-NYSEArca-2015-92]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Adopting a Rule Relating to Fingerprint-Based Background Checks of Directors, Officers, Employees, and Others

November 20, 2015.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on November 12, 2015, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "SEC" or

"Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule to [sic] relating to fingerprint-based background checks of directors, officers, employees and others. The proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and its wholly owned subsidiary NYSE Arca Equities proposes a new Rule 3.11⁴ codifying the current practice of conducting fingerprint-based background checks of prospective and current employees, temporary personnel, independent contractors, service providers and others. The proposed rule is substantially similar to Rule 28 of the Exchange's affiliates, New York Stock Exchange LLC and NYSE MKT LLC.⁵ A number of other securities markets have also adopted a similar rule, permitting them to obtain fingerprints from certain enumerated

⁴ NYSE Arca and NYSE Arca Equities Rule 3 govern organization and administration. The text of proposed Rule 3.11 would be identical for both NYSE Arca and NYSE Arca Equities.

⁵ See NYSE Rule 28; NYSE MKT Rule 28. There are no substantive differences between the proposed Rule and NYSE Rule 28 and NYSE MKT Rule 28.

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f).

¹¹ 17 CFR 200.30-3(a)(12).

¹⁵ U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

parties.⁶ The proposed rule is also consistent with those rules.

Background and Proposed Rule Change

Section 17(f)(2) of the Securities Exchange Act of 1934 (the “Act”), as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”),⁷ provides that every member of a national securities exchange, broker, dealer, registered transfer agent, registered clearing agency, registered securities information processors, national securities exchanges and national securities associations shall require each of its partners, directors, officers and employees of [sic] to be fingerprinted and submit those fingerprints (or cause the fingerprints to be submitted) to the Attorney General of the United States (“Attorney General”) for identification. Section 17(f)(2) explicitly directs the Attorney General to provide self-regulatory organizations (“SROs”) designated by the Commission with access to criminal history record information. Further, SEC Rule 17f-2 authorizes SROs to store criminal record information received from the Federal Bureau of Investigation (“FBI”), which maintains on behalf of the Attorney General a database of fingerprint-based criminal history records.

Consistent with these requirements, proposed Rule 3.11 would permit the Exchange to obtain fingerprints of prospective and current employees, temporary personnel, independent contractors and service providers of the Exchange and its principal subsidiaries; submit those fingerprints to the Attorney General or his or her designee for identification and processing; and receive criminal history record information from the Attorney General for evaluation and use, in accordance with applicable law, in enhancing the security of the facilities, systems, data, and/or records of the Exchange and its principal subsidiaries.

The Exchange would utilize a Live-Scan⁸ electronic system to capture and transmit fingerprints directly to the FBI. The capture and transmittal function, and corresponding receipt of criminal history information from the FBI, would be handled directly by Exchange

⁶ See, e.g., International Securities Exchange (“ISE”) Rule 1408; Nasdaq Stock Market (“Nasdaq”) Rule 0140; Chicago Board Options Exchange (“CBOE”) Rule 15.10.

⁷ See 15 U.S.C. 78q(f)(2); Dodd-Frank Act Sect. 929S.

⁸ Live-Scan refers to the process of capturing fingerprints directly into a digitized format as opposed to traditional ink and paper methods. Live-Scan technology captures and transfers images to a central location and/or interface for identification processing.

personnel and/or an FBI-approved “Channel Partner”⁹ who would maintain and operate, on behalf of the Exchange, a Live-Scan and/or other electronic system(s) for the submission of fingerprints to the FBI; receive and maintain criminal history record information from the FBI; and disseminate such information, through secure systems, to a limited set of approved reviewing officials within the Exchange and its affiliates.

Fingerprint-based background checks would enhance the ability to screen adequately employees and non-employees¹⁰ to determine better, in accordance with applicable law, whether there are unacceptable risks associated with granting such persons access to facilities and records. Through access to state-of-the-art information systems administered and maintained by the FBI, the Exchange would receive centrally-maintained “criminal history record information,” which includes arrest-based data and derivative information, and may include personal descriptive data; FBI number; conviction status; sentencing, probation and parole information; and such other information as the FBI may make available. This information is supplied to the FBI by various local, state, federal and/or international criminal justice agencies. The information obtained through fingerprint-based background checks would thus provide a more exhaustive and reliable profile of a candidate’s criminal record, and thereby better facilitate risk assessment, than a physical review of court records based on information provided by the candidate.

⁹ FBI-approved Channel Partners receive the fingerprint submission and relevant data, collect the associated fee(s), electronically forward the fingerprint submission with the necessary information to the FBI Criminal Justice Information Services Division (“CJIS”) for a national Criminal History Summary check, and receive the electronic summary check result for dissemination to the authorized employer entity. See Securities Exchange Act Release No. 71066 (December 12, 2013), 78 FR 76667 (December 18, 2013) (SR-ISE-2013-66) (“Release No. 71066”). The Exchange would retain ultimate legal responsibility for the fulfillment of its statutory and self-regulatory obligations under the Act, including compliance with Section 17(f)(2) of the Act as amended by the Dodd-Frank Act.

¹⁰ Under the proposed Rule, the Exchange would also obtain fingerprints from service providers, including employees of affiliates of the Exchange. See CBOE Rule 15.10; Securities Exchange Act Release No. 69496 (May 2, 2013), 78 FR 26671, 26671 (May 7, 2013) (SR-CBOE-2013-044) (CBOE conducts fingerprint-based criminal record checks of directors, officers and employees as well as, without limitation, “temporary personnel, independent contractors, consultants, vendors and service providers . . . who have or are anticipated to have access to facilities and records.”).

The proposed access to criminal history information is consistent with federal law. As noted, Section 17(f)(2) was amended by the Dodd-Frank Act to also require partners, directors, officers and employees of registered securities information processors, national securities exchanges and national securities associations to be fingerprinted. Although Section 17(f)(2) does not require the fingerprinting of contractors, the statute specifically permits SROs designated by the SEC to have access to “all criminal history record information.”

The Exchange accordingly believes that fingerprint-based background checks of employees and non-employees would promote the objectives of investor protection, business continuity and workplace safety by providing the Exchange with an effective tool for identifying and excluding persons with felony or misdemeanor conviction records that may pose a threat to the safety of Exchange personnel or the security of facilities and records.

The Exchange will comply with all applicable laws relating to the use and dissemination of criminal history record information obtained from the FBI.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹² in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. In particular, the Exchange believes fingerprint-based background checks of directors, officers, employees and contractors is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest in that they would help identify and exclude persons with felony or misdemeanor conviction records that may pose a threat to the safety of Exchange personnel or the security of facilities and records, thereby enhancing business

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

continuity, workplace safety and the security of the Exchange's operations and helping to protect investors and the public interest. The proposed rule is substantially similar to the rules of the Exchange's affiliates NYSE and NYSE MKT and the fingerprinting rules of other SROs.¹³ The proposed amendment would also conform the Exchange's fingerprinting practices with Section 17(f)(2) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather to enhance the security and continuity of the Exchange's facilities and records by adopting a fingerprinting rule that codifies the Exchange's current practice in compliance with Section 17(f)(2) of the Act as amended by the Dodd-Frank Act.¹⁴ As discussed below, the Exchange notes that the proposed rule change is based on the fingerprinting rules of other SROs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and Rule 19b-4(f)(6) thereunder.¹⁶

¹³ See, e.g., International Securities Exchange Rule 1408. See generally Release No. 71066, 78 FR at 76668, n. 12 (noting that "[a]n FBI-approved Channel Partner simply helps expedite the delivery of Criminal History Summary information on behalf of the FBI", and that the "process for making a request through an FBI-approved Channel Partner is consistent with FBI submission procedures").

¹⁴ See Section 929S of the Dodd-Frank Act.

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁷ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2015-92 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSEArca-2015-92. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official

the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹⁷ 15 U.S.C. 78s(b)(2)(B).

business days between 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at www.nyse.com. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2015-92 and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Robert W. Errett

Deputy Secretary.

[FR Doc. 2015-30082 Filed 11-25-15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76497; File No. SR-NSX-2015-06]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Rule 2.13, Mandatory Participation in Testing of Backup Systems

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Exchange Act" or "Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 10, 2015, National Stock Exchange, Inc. ("NSX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change, as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6)(iii)⁴ thereunder, which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(6)(iii).

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is proposing to adopt Rule 2.13, Mandatory Participation in Testing of Backup Systems, establishing business continuity and disaster recovery plans ("BC/DR plans") testing requirements for certain ETP Holders in connection with Regulation Systems Compliance and Integrity ("Regulation SCI"), as further described below.⁵

The text of the proposed rule change is available at the Exchange's Web site at www.nsx.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As adopted by the Commission, Regulation SCI applies to certain self-regulatory organizations (including the Exchange), alternative trading systems ("ATs"), plan processors, and exempt clearing agencies (collectively, "SCI entities"), and will require these SCI entities to comply with requirements with respect to the automated systems central to the performance of their regulated activities.⁶ Among the requirements of Regulation SCI is Rule 1001(a)(2)(v), which requires the Exchange and other SCI entities to maintain "[b]usiness continuity and disaster recovery plans that include

maintaining backup and recovery capabilities sufficiently resilient and geographically diverse and that are reasonably designed to achieve next business day resumption of trading and two-hour resumption of critical SCI systems following a wide-scale disruption."⁷

Pursuant to Regulation SCI, the Exchange is proposing to require certain ETP Holders to participate in testing of the operation of the Exchange's BC/DR plans. Paragraph (a) of Rule 1004 of Regulation SCI requires each SCI entity to: "[e]stablish standards for the designation of those members or participants that the SCI entity reasonably determines are, taken as a whole, the minimum necessary for the maintenance of fair and orderly markets in the event of the activation of such plans."⁸ Paragraph (b) of Rule 1004 further requires each SCI entity to "[d]esignate members or participants pursuant to the standards established in paragraph (a) of [Rule 1004] and require participation by such designated members or participants in scheduled functional and performance testing of the operation of such plans, in the manner and frequency specified by the SCI entity, provided that such frequency shall not be less than once every 12 months."⁹

To comply with the provisions of Rule 1004 of Regulation SCI, the Exchange is proposing to adopt new Rule 2.13 governing mandatory testing of the Exchange's backup systems. First, in paragraph (a) of Rule 2.13, the Exchange proposes to include language from paragraph (a) of Rule 1004 of Regulation SCI to summarize the Exchange's obligation pursuant to such rule. Specifically, the Exchange proposes to state that "[p]ursuant to Regulation SCI and with respect to the Exchange's business continuity and disaster recovery plans, including its backup systems, the Exchange is required to establish standards for the designation of ETP Holders that the Exchange reasonably determines are, taken as a whole, the minimum necessary for the maintenance of fair and orderly markets in the event of the activation of such plans." The Exchange further proposes that paragraph (a) state that the "Exchange has established standards and will designate ETP Holders according to those standards" as set forth in the proposed Rule. In addition, the Exchange proposes to make clear that all ETP Holders are permitted to connect to the Exchange's

backup systems as well as to participate in testing of such systems. Proposed paragraph (a) is consistent with the Commission's adoption of Regulation SCI, which encouraged "SCI entities to permit non-designated members or participants to participate in the testing of the SCI entity's BC/DR plans if they request to do so."¹⁰

Second, in paragraph (b) of Rule 2.13, the Exchange proposes to specify the criteria that the Exchange will employ to determine whether an ETP Holder will be required to connect to the Exchange's backup systems and to participate in scheduled functional and performance testing as announced by the Exchange, which shall occur at least once every 12 months. Specifically, proposed paragraph (b) would require all ETP Holders that account for a meaningful percentage of the Exchange's volume to connect to the Exchange's backup systems and to participate in functional and performance testing.

In adopting the requirements of Rule 2.13(b) to participate in mandatory testing of such systems, the Exchange intends to subject to the Rule only those ETP Holders that the Exchange believes are necessary to maintain fair and orderly markets at the Exchange. Designating ETP Holders to participate in mandatory testing because they account for a meaningful percentage of the Exchange's overall volume is a reasonable means to ensure the maintenance of a fair and orderly market on the Exchange.

In addition to paragraphs (a) and (b) described above, the Exchange also proposes to adopt Interpretation and Policy .01, which would provide additional detail regarding the notice that will be provided to ETP Holders that have been designated pursuant to subparagraph (b) of the Rule as well as the Exchange's method for measuring the volume threshold. As proposed, Interpretation and Policy .01 would state that for purposes of identifying ETP Holders that account for a meaningful percentage of the Exchange's overall volume, the Exchange will measure volume executed on the Exchange on a quarterly basis. The percentage of volume that the Exchange considers to be meaningful for purposes of this Interpretation and Policy .01 will be determined by the Exchange and will be published in a circular distributed to ETP Holders. The Exchange will publish its first Information Circular consistent with

⁵ See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72252 (December 5, 2014) ("SCI Adopting Release").

⁶ The Exchange ceased trading operations as of the close of business on May 30, 2014. See Securities Exchange Act Release No. 72107 (May 6, 2014), 79 FR 27017 (May 12, 2014) (SR-NSX-2014-14). However, the Exchange has retained its status as a registered national securities exchange under Section 6 of the Act, 15 U.S.C. 78f and a self-regulatory organization as defined in Section 3(a)(26) of the Act, 15 U.S.C. 78c(a)(26). NSX is planning to resume trading operations, subject to receiving Commission approval to do so.

⁷ 17 CFR 242.1001(a)(2)(v).

⁸ 17 CFR 242.1004(a).

⁹ 17 CFR 242.1004(b).

¹⁰ See SCI Adopting Release, *supra* note 5 at 72350.

Rule 2.13 upon a resumption of trading on the System.

The proposed Interpretation and Policy would also require the Exchange to notify, on a quarterly basis, individual ETP Holders that are subject to proposed paragraph (b) based on the prior calendar quarter's volume. Finally, as proposed, if an ETP Holder has not previously been subject to the requirements of proposed paragraph (b), then such ETP Holder would have until the next calendar quarter before such requirements are applicable. The Exchange believes the proposed notice requirements are necessary to provide ETP Holders with proper advance notice in the event they become subject to proposed Rule 2.13(b). The proposed timeframes would also provide ETP Holders with adequate time to become compliant with such Rule due to the necessary infrastructure changes that may be needed to connect to the Exchange's backup systems for an ETP Holder that is not already connected.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(5) of the Act¹² in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposal will ensure that the minimum number of ETP Holders necessary for the maintenance of a fair and orderly market are properly designated consistent with Rule 1004 of Regulation SCI.

Specifically, the proposal will adopt criteria with respect to the designation of ETP Holders that are required to participate in the testing of the Exchange's BC/DR plans, as well as appropriate notification regarding such designation. As set forth in the SCI Adopting Release, "SROs have the authority, and legal responsibility, under Section 6 of the Exchange Act, to adopt and enforce rules (including rules to comply with Regulation SCI's requirements relating to BC/DR testing) applicable to their members or participants that are designed to, among other things, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the

mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest."¹³ The proposal is consistent with such authority and legal responsibility.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the proposal is not a competitive proposal but rather is necessary for the Exchange's compliance with Regulation SCI.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change from market participants or others.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹⁴ and Rule 19b-4(f)(6)(iii) thereunder.¹⁵ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹⁶ A proposed rule change filed under Rule 19b-4(f)(6)(iii)¹⁷ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),¹⁸ the Commission may designate a shorter time if such action

is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow the Exchange to immediately incorporate changes required under Regulation SCI, such as establishing standards for designating BC/DR participants, and help ensure that the Exchange will be able to satisfy the requirements of Regulation SCI once the Exchange commences operations. Accordingly, the Commission designates the proposed rule change to be operative upon filing.¹⁹

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)²⁰ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NSX-2015-06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File No. SR-NSX-2015-06. This file number should be included in the subject line if email is used. To help the

¹³ See SCI Adopting Release, *supra* note 5 at 72350.

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁸ 17 CFR 240.19b-4(f)(6)(iii).

¹⁹ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁰ 15 U.S.C. 78s(b)(2)(B).

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

Commission process and review comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549-1090. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. Interested persons should submit only information that they wish to make available publicly. All submissions should refer to file number SR-NSX-2015-06 and should be submitted on or before December 18, 2015.

For the Commission by the Division of Trading and Markets, pursuant to the delegated authority.²¹

Robert W. Errett,
Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76485; File No. SR-NYSE-2015-57]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Establishing Fees for the NYSE Integrated Feed

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 5, 2015, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items

have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for the NYSE Integrated Feed. The proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish the fees for the NYSE Integrated Feed in the NYSE Proprietary Market Data Fee Schedule ("Fee Schedule").³ The Exchange proposes to make the NYSE Integrated Feed available without charge starting on November 16, 2015. The Exchange proposes to establish the following fees for the NYSE Integrated Feed operative on January 1, 2016:

1. *Access Fee.* For the receipt of access to the NYSE Integrated Feed, the Exchange proposes to charge \$7,500 per month.

2. *User Fees.* The Exchange proposes to charge a Professional User Fee (Per User) of \$70 per month and a Non-Professional User Fee (Per User) of \$16 per month. These user fees would apply to each display device that has access to the NYSE Integrated Feed.

3. *Non-Display Use Fees.* The Exchange proposes to establish non-display fees for the NYSE Integrated

Feed using the same non-display use fee structure established for the Exchange's other market data products.⁴ Non-display use would mean accessing, processing, or consuming the NYSE Integrated Feed delivered via direct and/or Redistributor⁵ data feeds for a purpose other than in support of a data recipient's display or further internal or external redistribution ("Non-Display Use"). Non-Display Use would include any trading use, such as high frequency or algorithmic trading, and would also include any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for algorithmic trading or smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

Under the proposal, for Non-Display Use of NYSE Integrated Feed, there would be three categories of, and fees applicable to, data recipients. One, two or three categories of Non-Display Use may apply to a data recipient.

- Under the proposal, the Category 1 Fee would be \$20,000 per month and would apply when a data recipient's Non-Display Use of the NYSE Integrated Feed is on its own behalf, not on behalf of its clients.

- Under the proposal, Category 2 Fees would be \$20,000 per month and would apply to a data recipient's Non-Display Use of the NYSE Integrated Feed on behalf of its clients.

- Under the proposal, Category 3 Fees would be \$20,000 and would apply to a data recipient's Non-Display Use of the NYSE Integrated Feed for the purpose of internally matching buy and sell orders within an organization, including matching customer orders for data recipient's own behalf and/or on behalf of its clients. This category would apply to Non-Display Use in trading platforms, such as, but not restricted to, alternative trading systems ("ATs"), broker crossing networks, broker crossing systems not filed as ATs, dark pools, multilateral trading facilities, exchanges and systematic internalization systems. Category 3 Fees would be capped at \$60,000 per month for each data recipient for the NYSE Integrated Feed.

⁴ See Securities Exchange Act Release Nos. 69278 (April 2, 2013), 78 FR 20973 (April 8, 2013) (SR-NYSE-2013-25) and 72923 (Aug. 26, 2014), 79 FR 52079 (Sept. 2, 2014) (SR-NYSE-2014-43).

⁵ "Redistributor" means a vendor or any person that provides a real-time NYSE data product to a data recipient or to any system that a data recipient uses, irrespective of the means of transmission or access.

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The proposed rule change establishing the NYSE Integrated Feed was immediately effective on January 23, 2015. See Securities Exchange Act Release No. 74128 (Jan. 23, 2015), 80 FR 4951 (Jan. 29, 2015) (SR-NYSE-2015-03).

Non-Display Use fees for NYSE Integrated Feed include, for customers also paying access fees for NYSE BBO, NYSE Trades, NYSE OpenBook and NYSE Order Imbalances, the Non-Display Use for such products when declared within the same category of use.

The description of the three non-display use categories is set forth in the Fee Schedule in endnote 1 and that endnote would be referenced in the NYSE Integrated Feed fees on the Fee Schedule. The text in the endnote would remain unchanged.

Data recipients that receive the NYSE Integrated Feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed.⁶ A firm subject to Category 3 Fees would be required to identify each platform that uses the NYSE Integrated Feed on a Non-Display Use basis, such as ATSS and broker crossing systems not registered as ATSS, as part of the Non-Display Use Declaration.

4. *Non-Display Declaration Late Fee.* Data recipients that receive the NYSE Integrated Feed for Non-Display Use would be required to complete and submit a Non-Display Use Declaration before they would be authorized to receive the feed. Beginning in 2017, NYSE Integrated Feed data recipients would be required to submit, by January 31st of each year, the Non-Display Use Declaration that applies to all real-time NYSE market data products that include Non-Display Use fees.⁷ The Exchange proposes to charge a Non-Display Declaration Late Fee of \$1,000 per month to any data recipient that pays an Access Fee for NYSE Integrated Feed that has failed to complete and submit a Non-Display Use Declaration. Specifically, with respect to the Non-Display Use Declaration due by January 31st of each year beginning in 2017, the Non-Display Declaration Late Fee would apply to data recipients that fail to complete and submit the Non-Display Use Declaration by the January 31st due date, and would apply beginning February 1st and for each month thereafter until the data recipient has completed and submitted the annual

⁶Data recipients are required to complete and submit the Non-Display Declaration with respect to each market data product on the Fee Schedule that includes Non-Display Fees. See Securities Exchange Act Release Nos. 74870 (May 5, 2015), 80 FR 26962 (May 11, 2015) (SR-NYSE-2015-20) (NYSE OpenBook) and 74872 (May 5, 2015), 80 FR 26975 (May 11, 2015) (SR-NYSE-2015-21) (NYSE Order Imbalances) and 74861 (May 4, 2015), 80 FR 26599 (May 8, 2015) (SR-NYSE-2015-22) (NYSE Trades and NYSE BBO).

⁷ *Id.*

Non-Display Use Declaration. The Exchange also proposes to apply current endnote 2 on the Fee Schedule to the Non-Display Declaration Late Fee for NYSE Integrated Feed, but proposes to modify endnote 2 to the Fee Schedule so that it is clear that the Non-Display Declaration Late Fee applies to the NYSE Integrated Feed beginning February 1st of 2017 and each year thereafter with respect to the Non-Display Use Declaration due by January 31st each year.⁸

In addition, if a data recipient's use of the NYSE Integrated Feed data changes at any time after the data recipient submits a Non-Display Use Declaration, the data recipient must inform the Exchange of the change by completing and submitting at the time of the change an updated declaration reflecting the change of use.

5. *Redistribution Fee.* For redistribution of the NYSE Integrated Feed, the Exchange proposes to establish a fee of \$4,000 per month.

The Exchange notes that the three existing data feed products—NYSE OpenBook, NYSE Trades, and NYSE Order Imbalances—would continue to be available to vendors and subscribers separately, in each case at the same prices at which they are currently available.⁹

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹⁰ in general, and Sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

The Exchange believes it is equitable and not unfairly discriminatory to make the NYSE Integrated Feed available free of charge through December 31, 2015

⁸The second sentence of endnote 2 to the Fee Schedule refers to a late fee for the Non-Display Use Declarations due September 1, 2014 that have not been submitted by July 1, 2015. This sentence is not applicable to the NYSE Integrated Feed because NYSE Integrated Feed was not available as of the September 1, 2014 due date and because data recipients of the NYSE Integrated Feed will have to complete and submit a Non-Display Declaration before they can receive the feed. The Exchange proposes to modify the second sentence so that it applies only to NYSE OpenBook, NYSE BBO, NYSE Trades and NYSE Order Imbalances and not to the NYSE Integrated Feed. The Exchange proposes to modify the third sentence so that it is clear that it applies to all market data products, including the NYSE Integrated Feed, to which Non-Display Use fees apply.

⁹ See Fee Schedule.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4), (5).

because providing it at no charge would provide an opportunity for vendors and subscribers to determine whether the NYSE Integrated Feed suits their needs without incurring fees. Other exchanges provide or have provided market data products free for a certain period of time.¹²

The fees for the NYSE Integrated Feed are reasonable because they represent not only the value of the data available from three existing data feeds but also the value of receiving the data on an integrated basis. Receiving the data on an integrated basis provides greater efficiencies and reduced errors for vendors and subscribers that currently choose to integrate the data themselves after receiving it from the Exchange. Some vendors and subscribers may not have the technology or resources to integrate the separate data feeds in a timely and/or efficient manner, and thus the integration feature of the product may be valuable to them.

Moreover, the fees are equitably allocated and not unfairly discriminatory because vendors and subscribers may choose to continue to receive some or all of the data through the existing separate feeds at current prices, or they can choose to pay for the NYSE Integrated Feed in order to receive integrated data, or they can choose a combination of the two approaches, thereby allowing each vendor or subscriber to choose the best business solution for itself.

The Exchange believes the proposed monthly Access Fee of \$7,500 and monthly Redistribution Fee of \$4,000 for NYSE Integrated Feed are reasonable because they are comparable to the total of the same types of fees for NYSE OpenBook, NYSE Trades, and NYSE Order Imbalances. The monthly Access Fee for NYSE OpenBook is \$5,000, for NYSE Trades is \$1,500 and for NYSE Order Imbalances is \$500.¹³ The monthly Redistribution Fee for NYSE

¹² For example, NYSE Arca, Inc. ("NYSE Arca"), an affiliate of the Exchange, offered ArcaBook for Arca Options-Complex, and NYSE MKT LLC ("NYSE MKT"), an affiliate of the Exchange, offered ArcaBook for Amex Options-Complex, without charge between May 1, 2014 and October 31, 2014. See Securities Exchange Act Release Nos. 72074 (May 1, 2014), 79 FR 26277 (May 7, 2014) (NYSEArca 2014-51) and 72075 (May 1, 2014), 79 FR 26290 (May 7, 2014) (NYSEMKT 2014-40). The NASDAQ Stock Market, Inc. ("NASDAQ") provides a 30-day free trial related to NASDAQ TotalView. See NASDAQ Rule 7023(e).

¹³ The Access Fee for Managed Non-Display Services only for NYSE OpenBook is \$2,500 per month, for NYSE Trades is \$750 per month and for NYSE Order Imbalances is \$250 per month. Managed Non-Display Services will not be offered for NYSE Integrated Feed.

OpenBook is \$3,000 and for NYSE Trades is \$1,000.¹⁴

The Exchange believes that it is reasonable to charge redistribution fees because vendors receive value from redistributing the data in their business products for their customers. The redistribution fees also are equitable and not unfairly discriminatory because they will be charged on an equal basis to those vendors that choose to redistribute the data. Also, the proposed redistribution fee for NYSE Integrated Feed is reasonable because it is comparable to the redistribution fees that are currently charged by other exchanges.¹⁵

The proposed monthly Professional User Fee (Per User) of \$70 and monthly Non-Professional User Fee (Per User) of \$16 are reasonable because they are comparable to the total of the per user fees for NYSE OpenBook and NYSE Trades. The monthly Professional User Fee (Per User) for NYSE OpenBook is \$60 and for NYSE Trades, it is \$4. The monthly Non-Professional User Fee (Per User) for NYSE OpenBook is \$15 and for NYSE Trades, it is \$0.20.

The Exchange believes that having separate Professional and Non-Professional User fees for the NYSE Integrated Feed is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the NYSE Integrated Feed by providing the same data that is available to Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. The fee structure of differentiated Professional and Non-Professional fees applies to the user fees applicable to NYSE OpenBook and NYSE Trades and has long been used by the Exchange in order to reduce the price of data to Non-Professional Users and make it more broadly available.¹⁶

¹⁴ There are no Redistribution or User fees charged for NYSE Order Imbalances.

¹⁵ NYSE Arca charges a \$3,000 per month redistribution fee for the NYSE Arca Integrated Feed. See Securities Exchange Act Release No. 66128 (Jan. 10, 2012), 77 FR 2331 (Jan. 17, 2012) (SR-NYSEArca-2011-96). Distributors of NASDAQ-listed security depth entitlements pay a Monthly External Distributor Fee of \$2,500. See NASDAQ Rule 7019(b).

¹⁶ See e.g., Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR-NYSE-2008-131) (establishing the \$15 Non-Professional User Fee (Per User) for NYSE OpenBook). See e.g., Securities Exchange Act

Offering the NYSE Integrated Feed to Non-Professional Users with the same data available to Professional Users results in greater equity among data recipients.

The Exchange believes the proposed Non-Display Use fees are reasonable, equitable and not unfairly discriminatory because they reflect the value of the data to the data recipients in their profit-generating activities and do not impose the burden of counting non-display devices. After gaining further experience with the non-display fee structure, the Exchange believes that the proposed Non-Display Use fees reflect the significant value of the non-display data to data recipients, which purchase such data on an entirely voluntary basis. Non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. While some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that they can be performed more quickly and accurately and less expensively than if they were performed manually.

Data can be processed much faster by a non-display device than it can be by a human being processing information that he or she views on a data terminal. Non-display devices also can dispense data to multiple computer applications as compared with the restriction of data to one display terminal. While non-display data has become increasingly valuable to data recipients who can use it to generate substantial profits, it has become increasingly difficult for them and the Exchange to accurately count non-display devices. The number and type of non-display devices, as well as their complexity and interconnectedness, have grown in recent years, creating

Release No. 20002, File No. S7-433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing nonprofessional fees for CTA data); NASDAQ Rules 7023(b), 7047.

administrative challenges for vendors, data recipients, and the Exchange to accurately count such devices and audit such counts. Unlike a display device, such as a Bloomberg terminal, it is not possible to simply walk through a trading floor or areas of a data recipient's premises to identify non-display devices. During an audit, an auditor must review a firm's entitlement report to determine usage. While display use is generally associated with an individual end user and/or unique user ID, a non-display use is more difficult to account for because the entitlement report may show a server name or Internet protocol ("IP") address or it may not. The auditor must review each IP or server and further inquire about downstream use and quantity of servers with access to data; this type of counting is very labor-intensive and prone to inaccuracies.

Market data technology and usage has evolved to the point where it is no longer practical, nor fair and equitable, to simply count non-display devices. The administrative costs and difficulties of establishing reliable counts and conducting an effective audit of non-display devices have become too burdensome, impractical, and non-economic for the Exchange, vendors, and data recipients. Indeed, some data recipients dislike the burden of having to comply with count-based audit processes, and the Exchange's non-display pricing policies are a direct response to such complaints as well as a further competitive distinction between the Exchange and other markets. The Exchange believes that the proposed fee structure for non-display use is reasonable, equitable, and not unfairly discriminatory in light of these developments.

The Non-Display Use fees for the NYSE Integrated Feed are reasonable because they represent the extra value of receiving the data for Non-Display Use on an integrated basis. The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using NYSE Integrated Feed on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.¹⁷

¹⁷ See also Exchange Act Release No. 69157, March 18, 2013, 78 FR 17946, 17949 (March 25, 2013) (SR-CTA/CQ-2013-01) ("[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that

The Exchange believes that it is reasonable to require annual submissions of the Non-Display Use Declaration so that the Exchange will have current and accurate information about the use of the NYSE Integrated Feed and can correctly assess fees for the uses of the NYSE Integrated Feed. The annual submission requirement is equitable and not unfairly discriminatory because it will apply to all users.

The Exchange believes that it is reasonable to impose a late fee in connection with the submission of the Non-Display Use Declaration. In order to correctly assess fees for the non-display use of NYSE Integrated Feed, the Exchange needs to have current and accurate information about the use of NYSE Integrated Feed. The failure of data recipients to submit the Non-Display Use Declaration on time leads to potentially incorrect billing and administrative burdens, including tracking and obtaining late Non-Display Use Declarations and correcting and following up on payments owed in connection with late Non-Display Use Declarations. The purpose of the late fee is to incent data recipients to submit the Non-Display Use Declaration promptly to avoid the administrative burdens associated with the late submission of Non-Display Use Declarations. The Non-Display Declaration Late Fee is equitable and not unfairly discriminatory because it will apply to all data recipients that choose to subscribe to the NYSE Integrated Feed.

In addition, the proposed fees are reasonable when compared to fees for comparable products, including the NYSE Arca Integrated Feed,¹⁸ offered by NYSE Arca and Nasdaq TotalView-Itch,¹⁹ offered by NASDAQ. Specifically, the fees for NYSE Arca Integrated Feed, which like NYSE Integrated Feed, includes depth of book, trades, and order imbalances data for the NYSE Arca market, and a security status message, consist of an Access Fee

of \$3,000 per month, a Professional User Fee (Per User) of \$40 per month a Non-Professional User Fee (Per User) of \$20 per month, Non-Display Fees of \$7,000 per month for each of Categories 1, 2 and 3, and a Redistribution Fee of \$3,000 per month. The fees are also equitable and not unfairly discriminatory because they will apply to all data recipients that choose to subscribe to the NYSE Integrated Feed.

The Exchange also notes that the NYSE Integrated Feed is entirely optional. The Exchange is not required to make the NYSE Integrated Feed available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase the NYSE Integrated Feed. Firms that purchase the NYSE Integrated Feed would do so for the primary goals of using it to increase revenues, reduce expenses, and in some instances compete directly with the Exchange (including for order flow); those firms are able to determine for themselves whether the NYSE Integrated Feed or any other similar products are attractively priced or not.

Firms that do not wish to purchase the NYSE Integrated Feed at the new prices have a variety of alternative market data products from which to choose,²⁰ or if the NYSE Integrated Feed does not provide sufficient value to firms as offered based on the uses those firms have or planned to make of it, such firms may simply choose to conduct their business operations in ways that do not use the NYSE Integrated Feed. The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations.²¹ Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSS have chosen not to do so.²²

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010), upheld reliance by the Securities and

Exchange Commission (“Commission”) upon the existence of competitive market mechanisms to set reasonable and equitably allocated fees for proprietary market data:

In fact, the legislative history indicates that the Congress intended that the market system ‘evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed’ and that the SEC wield its regulatory power ‘in those situations where competition may not be sufficient,’ such as in the creation of a ‘consolidated transactional reporting system.’

Id. at 535 (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323). The court agreed with the Commission’s conclusion that “Congress intended that ‘competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.’”²³

As explained below in the Exchange’s Statement on Burden on Competition, the Exchange believes that there is substantial evidence of competition in the marketplace for proprietary market data and that the Commission can rely upon such evidence in concluding that the fees established in this filing are the product of competition and therefore satisfy the relevant statutory standards. In addition, the existence of alternatives to these data products, such as consolidated data and proprietary data from other sources, as described below, further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can select such alternatives.

As the *NetCoalition* decision noted, the Commission is not required to undertake a cost-of-service or ratemaking approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically or offer any significant benefits.²⁴

²³ *NetCoalition*, 615 F.3d at 535.

²⁴ The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties and the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, and as described below, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even

apply trading algorithms to the data, but that do not require widespread data access by the firm’s employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.”)

¹⁸ See NYSE Arca Integrated Feed, <http://www.nyse.com/page/1084> (last visited June 8, 2015) (data feed that provides a unified view of events, in sequence as they appear on the NYSE Arca matching engine, including depth of book, trades, order imbalance data, and security status messages).

¹⁹ See NASDAQ TotalView-ITCH, <http://www.nasdaqtrader.com/Trader.aspx?id=Totalview2> (last visited June 8, 2015) (displays the full order book depth for NASDAQ market participants and also disseminates the Net Order Imbalance Indicator (NOI) for the NASDAQ Opening and Closing Crosses and NASDAQ IPO/Halt Cross).

²⁰ See *supra* notes 19–20.

²¹ See In the Matter of the Application of Securities Industry And Financial Markets Association For Review of Actions Taken by Self-Regulatory Organizations, Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014).

²² For example, Goldman Sachs Execution and Clearing, L.P. disclosed in 2014 that it was not using proprietary market data in connection with Sigma X, its ATS. See response to Question E3, available at <http://www.goldmansachs.com/media-relations/in-the-news/current/pdf-media/gsec-order-handling-practices-ats-specific.pdf>. By way of comparison, IEX has disclosed that it uses proprietary market data feeds from all registered stock exchanges. See <http://www.iextrading.com/about/>.

For these reasons, the Exchange believes that the proposed fees are reasonable, equitable, and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. An exchange's ability to price its proprietary market data feed products is constrained by actual competition for the sale of proprietary market data products, the joint product nature of exchange platforms, and the existence of alternatives to the Exchange's proprietary data.

The Existence of Actual Competition.

The market for proprietary data products is currently competitive and inherently contestable because there is fierce competition for the inputs necessary for the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with one another for listings and order flow and sales of market data itself, providing ample opportunities for entrepreneurs who wish to compete in any or all of those areas, including producing and distributing their own market data. Proprietary data products are produced and distributed by each individual exchange, as well as other entities, in a vigorously competitive market. Indeed, the U.S. Department of Justice ("DOJ") (the primary antitrust regulator) has expressly acknowledged the aggressive actual competition among exchanges, including for the sale of proprietary market data. In 2011, the DOJ stated that exchanges "compete head to head to offer real-time equity data products. These data products include the best bid and offer of every exchange and information on each equity trade, including the last sale."²⁵

in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. See Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at <http://www.sec.gov/rules/concept/s72899/buck1.htm>.

²⁵ Press Release, U.S. Department of Justice, Assistant Attorney General Christine Varney Holds Conference Call Regarding NASDAQ OMX Group Inc. and IntercontinentalExchange Inc. Abandoning

Moreover, competitive markets for listings, order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products and therefore constrain markets from overpricing proprietary market data. Broker-dealers send their order flow and transaction reports to multiple venues, rather than providing them all to a single venue, which in turn reinforces this competitive constraint. As a 2010 Commission Concept Release noted, the "current market structure can be described as dispersed and complex" with "trading volume . . . dispersed among many highly automated trading centers that compete for order flow in the same stocks" and "trading centers offer[ing] a wide range of services that are designed to attract different types of market participants with varying trading needs."²⁶ More recently, SEC Chair Mary Jo White has noted that competition for order flow in exchange-listed equities is "intense" and divided among many trading venues, including exchanges, more than 40 alternative trading systems, and more than 250 broker-dealers.²⁷

If an exchange succeeds in its competition for quotations, order flow, and trade executions, then it earns trading revenues and increases the value of its proprietary market data products because they will contain greater quote and trade information. Conversely, if an exchange is less successful in attracting quotes, order flow, and trade executions, then its market data products may be less desirable to customers using them in support of order routing and trading decisions in light of the diminished content; data

Their Bid for NYSE Euronext (May 16, 2011), available at <http://www.justice.gov/iso/opa/atr/speeches/2011/at-speech-110516.html>; see also Complaint in *U.S. v. Deutsche Borse AG and NYSE Euronext*, Case No. 11-cv-2280 (D.C. Dist.) ¶ 24 ("NYSE and Direct Edge compete head-to-head . . . in the provision of real-time proprietary equity data products.").

²⁶ Concept Release on Equity Market Structure, Securities Exchange Act Release No. 61358 (Jan. 14, 2010), 75 FR 3594 (Jan. 21, 2010) (File No. S7-02-10). This Concept Release included data from the third quarter of 2009 showing that no market center traded more than 20% of the volume of listed stocks, further evidencing the dispersal of and competition for trading activity. *Id.* at 3598. Data available on ArcaVision show that from June 30, 2013 to June 30, 2014, no exchange traded more than 12% of the volume of listed stocks by either trade or dollar volume, further evidencing the continued dispersal of and fierce competition for trading activity. See <https://www.arcavision.com/Arcavision/arcalogin.jsp>.

²⁷ Mary Jo White, Enhancing Our Equity Market Structure, Sandler O'Neill & Partners, L.P. Global Exchange and Brokerage Conference (June 5, 2014) (available on the Commission Web site), citing Tuttle, Laura, 2014, "OTC Trading: Description of Non-ATS OTC Trading in National Market System Stocks," at 7-8.

products offered by competing venues may become correspondingly more attractive. Thus, competition for quotations, order flow, and trade executions puts significant pressure on an exchange to maintain both execution and data fees at reasonable levels.

In addition, in the case of products that are also redistributed through market data vendors, such as Bloomberg and Thompson Reuters, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Vendors will not elect to make available NYSE Integrated Feed unless their customers request it, and customers will not elect to pay the proposed fees unless NYSE Integrated Feed can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

Joint Product Nature of Exchange Platform

Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, proprietary market data and trade executions are a paradigmatic example of joint products with joint costs. The decision of whether and on which platform to post an order will depend on the attributes of the platforms where the order can be posted, including the execution fees, data availability and quality, and price and distribution of data products. Without a platform to post quotations, receive orders, and execute trades, exchange data products would not exist.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's platform for posting quotes, accepting orders, and executing transactions and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs.

Moreover, an exchange's broker-dealer customers generally view the costs of transaction executions and

market data as a unified cost of doing business with the exchange. A broker-dealer will only choose to direct orders to an exchange if the revenue from the transaction exceeds its cost, including the cost of any market data that the broker-dealer chooses to buy in support of its order routing and trading decisions. If the costs of the transaction are not offset by its value, then the broker-dealer may choose instead not to purchase the product and trade away from that exchange. There is substantial evidence of the strong correlation between order flow and market data purchases. For example, in September 2015, more than 80% of the transaction volume on each of NYSE and NYSE's affiliates NYSE Arca and NYSE MKT was executed by market participants that purchased one or more proprietary market data products (the 20 firms were not the same for each market). A supra-competitive increase in the fees for either executions or market data would create a risk of reducing an exchange's revenues from both products.

Other market participants have noted that proprietary market data and trade executions are joint products of a joint platform and have common costs.²⁸ The Exchange agrees with and adopts those discussions and the arguments therein. The Exchange also notes that the economics literature confirms that there is no way to allocate common costs between joint products that would shed any light on competitive or efficient pricing.²⁹

²⁸ See Securities Exchange Act Release No. 72153 (May 12, 2014), 79 FR 28575, 28578 n.15 (May 16, 2014) (SR-NASDAQ-2014-045) (“[A]ll of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.”). See also Securities Exchange Act Release No. 62907 (Sept. 14, 2010), 75 FR 57314, 57317 (Sept. 20, 2010) (SR-NASDAQ-2010-110), and Securities Exchange Act Release No. 62908 (Sept. 14, 2010), 75 FR 57321, 57324 (Sept. 20, 2010) (SR-NASDAQ-2010-111).

²⁹ See generally Mark Hirschey, *Fundamentals of Managerial Economics*, at 600 (2009) (“It is important to note, however, that although it is possible to determine the separate marginal costs of goods produced in variable proportions, it is impossible to determine their individual average costs. This is because common costs are expenses necessary for manufacture of a joint product. Common costs of production—raw material and equipment costs, management expenses, and other overhead—cannot be allocated to each individual by-product on any economically sound basis. . . . Any allocation of common costs is wrong and arbitrary.”). This is not new economic theory. See, e.g., F. W. Taussig, “A Contribution to the Theory of Railway Rates,” *Quarterly Journal of Economics* V(4) 438, 465 (July 1891) (“Yet, surely, the division is purely arbitrary. These items of cost, in fact, are jointly incurred for both sorts of traffic; and I cannot share the hope entertained by the statistician of the

Analyzing the cost of market data product production and distribution in isolation from the cost of all of the inputs supporting the creation of market data and market data products will inevitably underestimate the cost of the data and data products because it is impossible to obtain the data inputs to create market data products without a fast, technologically robust, and well-regulated execution system, and system and regulatory costs affect the price of both obtaining the market data itself and creating and distributing market data products. It would be equally misleading, however, to attribute all of an exchange's costs to the market data portion of an exchange's joint products. Rather, all of an exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

As noted above, the level of competition and contestability in the market is evident in the numerous alternative venues that compete for order flow, including 11 equities self-regulatory organization (“SRO”) markets, as well as various forms of ATSS, including dark pools and electronic communication networks (“ECNs”), and internalizing broker-dealers. SRO markets compete to attract order flow and produce transaction reports via trade executions, and two FINRA-regulated Trade Reporting Facilities compete to attract transaction reports from the non-SRO venues.

Competition among trading platforms can be expected to constrain the aggregate return that each platform earns from the sale of its joint products, but different trading platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platforms may choose to pay rebates to attract orders, charge relatively low prices for market data products (or provide market data products free of charge), and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market data products, and setting relatively low prices for accessing posted liquidity. For example, BATS Global Markets (“BATS”) and Direct Edge, which

previously operated as ATSS and obtained exchange status in 2008 and 2010, respectively, provided certain market data at no charge on their Web sites in order to attract more order flow, and used revenue rebates from resulting additional executions to maintain low execution charges for their users.³⁰ In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering.

Existence of Alternatives

The large number of SROs, ATSS, and internalizing broker-dealers that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, ATS, and broker-dealer is currently permitted to produce and sell proprietary data products, and many currently do or have announced plans to do so, including but not limited to the Exchange, NYSE MKT, NYSE Arca, NASDAQ OMX, BATS, and Direct Edge.

The fact that proprietary data from ATSS, internalizing broker-dealers, and vendors can bypass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products. By way of example, BATS and NYSE Arca both published proprietary data on the Internet before registering as exchanges. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the amount of data available via proprietary products is greater in size than the actual number of orders and transaction reports that exist in the marketplace. With respect to NYSE Integrated Feed, competitors offer close substitute products.³¹ Because market data users can find suitable substitutes for most proprietary market data products, a market that overprices its market data products stands a high risk that users may substitute another source of market data information for its own.

Those competitive pressures imposed by available alternatives are evident in the Exchange's proposed pricing.

In addition to the competition and price discipline described above, the market for proprietary data products is

³⁰ This is simply a securities market-specific example of the well-established principle that in certain circumstances more sales at lower margins can be more profitable than fewer sales at higher margins; this example is additional evidence that market data is an inherent part of a market's joint platform.

³¹ See *supra* notes 19–20.

Commission, Professor Henry C. Adams, that we shall ever reach a mode of apportionment that will lead to trustworthy results.”).

also highly contestable because market entry is rapid and inexpensive. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TrackECN, BATS Trading and Direct Edge. As noted above, BATS launched as an ATS in 2006 and became an exchange in 2008, while Direct Edge began operations in 2007 and obtained exchange status in 2010.

In setting the proposed fees for the NYSE Integrated Feed, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all users. The existence of numerous alternatives to the Exchange's products, including proprietary data from other sources, and continued availability of the Exchange's separate data feeds at a lower price, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)³² of the Act and subparagraph (f)(2) of Rule 19b-4³³ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³⁴ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSE-2015-57 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSE-2015-57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions

should refer to File Number SR-NYSE-2015-57, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁵

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30077 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC-31907]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

November 20, 2015.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of November 2015. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 15, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

FOR FURTHER INFORMATION CONTACT: Chief Counsel's Office at (202) 551-6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549-8010.

³² 15 U.S.C. 78s(b)(3)(A).

³³ 17 CFR 240.19b-4(f)(2).

³⁴ 15 U.S.C. 78s(b)(2)(B).

³⁵ 17 CFR 200.30-3(a)(12).

BlackRock MuniYield Michigan Quality Fund II, Inc. [File No. 811-06501]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to BlackRock MuniYield Michigan Quality Fund, Inc., and effective September 14, 2015, made distributions to its shareholders based on net asset value. Expenses of approximately \$331,358 incurred in connection with the reorganization were paid by Applicant and Applicant's investment adviser.

Filing Dates: The application was filed on November 16, 2015.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

Asian Small Companies Portfolio [File No. 811-07529]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On January 27, 2015 and January 28, 2015, applicant made liquidating distributions to its shareholders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Dates: The application was filed on November 6, 2015, and amended on November 18, 2015.

Applicant's Address: Two International Place, Boston, MA 02110.

Parametric Market Neutral Portfolio [File No. 811-22597]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On September 19, 2014, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Dates: The application was filed on November 6, 2015, and amended on November 18, 2015.

Applicant's Address: Two International Place, Boston, MA 02110.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30093 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76490; File No. SR-BX-2015-073]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Period for the Retail Price Improvement Program Until December 1, 2016

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 12, 2015, NASDAQ OMX BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The [*sic*] to extend the pilot period for the Exchange's Retail Price Improvement ("RPI") Program (the "Program"), which is set to expire on December 1, 2015, for a period of one year, to expire on December 1, 2016.

The Exchange has designated December 1, 2015 as the date the proposed rule change becomes effective.

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqomxbx.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the pilot period of the RPI Program,³ currently scheduled to expire on December 1, 2015, for an additional year, until December 1, 2016.

Background

In November 2014, the Commission approved the RPI Program on a pilot basis.⁴ The Program is designed to attract retail order flow to the Exchange, and allow such order flow to receive potential price improvement. The Program is currently limited to trades occurring at prices equal to or greater than \$1.00 per share. Under the Program, a new class of market participant called a Retail Member Organization ("RMO") is eligible to submit certain retail order flow ("Retail Orders")⁵ to the Exchange. BX members ("Members") are permitted to provide potential price improvement for Retail Orders in the form of non-displayed interest that is priced more aggressively than the Protected National Best Bid or Offer ("Protected NBBO").⁶

The Program was approved by the Commission on a pilot basis running one-year from the date of implementation.⁷ The Commission approved the Program on November 28, 2014.⁸ The Exchange implemented the

³ Securities Exchange Act Release No. 73702 (November 28, 2014), 79 FR 72049 (December 4, 2014) ("RPI Approval Order") (SR-BX-2014-048).

⁴ See *id.*

⁵ A "Retail Order" is defined in BX Rule 4780(a)(2) by referencing BX Rule 4702, and BX Rule 4702(b)(6) says it is an order type with a non-display order attribute submitted to the Exchange by a RMO. A Retail Order must be an agency order, or riskless principal order that satisfies the criteria of is an agency or riskless principal order that originates from a natural person and is submitted to BX by a RMO, provided that no change is made to the terms of the order with respect to price (except in the case that a market order is changed to a marketable limit order) or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

⁶ The term Protected Quotation is defined in Chapter XII, Sec. 1(19) and has the same meaning as is set forth in Regulation NMS Rule 600(b)(58). The Protected NBBO is the best-priced protected bid and offer. Generally, the Protected NBBO and the national best bid and offer ("NBBO") will be the same. However, a market center is not required to route to the NBBO if that market center is subject to an exception under Regulation NMS Rule 611(b)(1) or if such NBBO is otherwise not available for an automatic execution. In such case, the Protected NBBO would be the best-priced protected bid or offer to which a market center must route interest pursuant to Regulation NMS Rule 611.

⁷ See RPI Approval Order, *supra* note 3 at 72053.

⁸ *Id.* at 72049.

Program on December 1, 2014. Thus, the pilot period for the Program is scheduled to end on December 1, 2015.

Proposal To Extend the Operation of the Program

The Exchange established the RPI Program in an attempt to attract retail order flow to the Exchange by potentially providing price improvement to such order flow. The Exchange believes that the Program promotes competition for retail order flow by allowing Exchange members to submit Retail Price Improvement Orders (“RPI Orders”)⁹ to interact with Retail Orders. Such competition has the ability to promote efficiency by facilitating the price discovery process and generating additional investor interest in trading securities, thereby promoting capital formation. The Exchange believes that extending the pilot is appropriate because it will allow the Exchange and the Commission additional time to analyze data regarding the Program that the Exchange has committed to provide.¹⁰ As such, the Exchange believes that it is appropriate to extend the current operation of the Program.¹¹ Through this filing, the Exchange seeks to extend the current pilot period of the Program until December 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹² in general, and with Section 6(b)(5) of the Act,¹³ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that extending the pilot period for the RPI Program is consistent with these principles because the Program is reasonably designed to

attract retail order flow to the exchange environment, while helping to ensure that retail investors benefit from the better price that liquidity providers are willing to give their orders.

Additionally, as previously stated, the competition promoted by the Program may facilitate the price discovery process and potentially generate additional investor interest in trading securities. The extension of the pilot period will allow the Commission and the Exchange to continue to monitor the Program for its potential effects on public price discovery, and on the broader market structure.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change extends an established pilot program for one year, thus allowing the RPI Program to enhance competition for retail order flow and contribute to the public price discovery process.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁴ and Rule 19b-4(f)(6)¹⁵ thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.¹⁶

A proposed rule change filed under Rule 19b-4(f)(6) normally may not become operative prior to 30 days after the date of filing. However, Rule 19b-

4(f)(6)(iii)¹⁷ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay period. The Exchange states that waiving the operative delay would allow the pilot period to continue uninterrupted, which the Exchange argues would be beneficial to market participants and would help to eliminate the potential for investor confusion.

The Commission believes that waiver of the 30-day operative delay period is consistent with the protection of investors and the public interest. Specifically, the Commission believes that the proposal would allow the RPI Program to continue uninterrupted and to provide additional time for data about the program to be generated and analyzed. For these reasons, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, and designates the proposed rule change to be operative upon filing with the Commission.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.¹⁹

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2015-073 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

⁹ A Retail Price Improvement Order is defined in BX Rule 4780(a)(3) by referencing BX Rule 4702 and BX Rule 4702(b)(5) says that it is as an order type with a non-display order attribute that is held on the Exchange Book in order to provide liquidity at a price at least \$0.001 better than the NBBO through a special execution process described in Rule 4780.

¹⁰ See RPI Approval Order, *supra* note 3 at 72051.

¹¹ Concurrently with this filing, the Exchange has submitted a request for an extension of the exemption under Regulation NMS Rule 612 previously granted by the Commission that permits it to accept and rank the RPI orders in sub-penny increments. See Letter from Jeffrey S. Davis, Vice President and Deputy General Counsel and Secretary, NASDAQ OMX BX, Inc. to Brent J. Fields, Secretary, Securities and Exchange Commission dated November 12, 2015.

¹² 15 U.S.C. 78f.

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange’s intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission is waiving this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6)(iii).

¹⁸ For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁹ 15 U.S.C. 78s(b)(3)(C).

All submissions should refer to File Number SR–BX–2015–073. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2015–073 and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015–30076 Filed 11–25–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76491; File No. SR–MIAX–2015–64]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange LLC To Amend Exchange Rule 519

November 20, 2015.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that

on November 13, 2015, Miami International Securities Exchange LLC (“MIAX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 519, MIAX Order Monitor (“MOM”) to codify the Open Order and Open Contract Protection features included in MOM.

The text of the proposed rule change is available on the Exchange's Web site at http://www.miaxoptions.com/filter/wotitle/rule_filing, at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 519, MIAX Order Monitor, to provide details regarding Open Order and Open Contract protections. The proposal codifies existing functionality applicable to orders on the Exchange. The Exchange is also proposing a clarifying amendment to current Rule 519(b) to provide consistency in that Rule with the proposed new rules.

The MOM is a risk management feature of the Exchange's System ³ that prevents certain orders from executing or being placed on the Book at prices outside pre-set standard limits ⁴ and if

the size of the order exceeds the order size protection designated by the Member submitting the order.⁵

Additionally, the System currently rejects any orders that exceed the maximum number of open orders held in the System on behalf of a particular Member (the “Open Order Protection”). The System also currently rejects any orders that cause the number of open contracts represented by orders held in the System on behalf of a particular Member (the “Open Contract Protection”) to exceed a specified maximum number of contracts. For each of these protections, the maximum number (of open orders and open contracts) is designated (or may be disabled) by the Member. The Exchange is proposing to codify the Open Order and Open Contract Protections in Rule 519.

Currently, Rule 519 only provides details regarding the System's Order Price Protections and Order Size Protections. However, in addition to order protections based on price and order size, the System also employs order protections based on the number of open orders held in the System and on the number of contracts represented by open orders held in the System. The Exchange now proposes to codify these existing order protections into Rule 519.

Members may designate or disable the Open Order and/or the Open Contract Protections on a firm wide basis. If the maximum number of open orders or contracts is not designated by the Member, the Exchange will set a maximum number of open orders or contracts on behalf of the Member by default. The default maximum number of open orders and open contracts are determined by the Exchange and announced to Members through a Regulatory Circular.⁶ The Open Order and Open Contract Protections provide market participants the flexibility to designate the level of protection they need to help prevent the potential submission of a number of orders and/or a number of contracts to the Exchange that would cause them to be at unintended risk levels.

The Exchange is also proposing a clarifying amendment to current Rule 519(b), Order Size Protections, to state that if the maximum size of orders is not designated by the Member, the Exchange will set a maximum size of orders on behalf of the Member by default. This is consistent with proposed new Rules 519(c) and (d), and

²⁰ 17 CFR 200.30–3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ The term “System” means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

⁴ See Exchange Rule 519(a).

⁵ See Exchange Rule 519(b).

⁶ The Exchange notes that the current default maximum number of open orders is 30,000 and the default number of open contracts is 1,000,000.

is intended to provide clarity, consistency and ease of reference regarding MOM protections available to users of the System.

The proposed rule change is designed to protect investors and the public interest by codifying the protections that apply to orders that help market participants avoid the potential submission of orders that would place them at unwanted risk on the Exchange. In addition, the Exchange believes that the proposed rule change removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by helping to eliminate potential confusion on behalf of market participants by clearly stating the System's functionality with regard to orders that trigger Open Order and Open Contract Protections.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act⁸ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule change is designed to protect investors and the public interest by codifying the Open Order and Open Contract Protections that help market participants avoid the potential submission of a number of orders and/or a number of contracts to the Exchange that would cause them to be at unintended risk levels.

In addition, the Exchange believes that the proposed amendment removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by helping to eliminate potential confusion on behalf of market participants by clearly stating the System's functionality with regard to Open Order and Open Contract Protections.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition because it applies to all MIAX participants equally. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal is intended to protect investors by providing further transparency regarding the MOM feature.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act⁹ and Rule 19b-4(f)(6)¹⁰ thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MIAX-2015-64 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-MIAX-2015-64. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-MIAX-2015-64, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-30081 Filed 11-25-15; 8:45 am]

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¹¹ 17 CFR 200.30-3(a)(12).

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76493; File No. SR-NYSEARCA-2015-86]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Adopt New Equity Trading Rules Relating to Auctions for Pillar, the Exchange's New Trading Technology Platform

November 20, 2015.

On September 22, 2015, NYSE Arca, Inc. ("Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt new equity trading rules relating to auctions for Pillar, the Exchange's new trading technology platform. The proposed rule change was published for comment in the **Federal Register** on October 13, 2015.³

Section 19(b)(2) of the Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is November 27, 2015. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change, so that it has sufficient time to consider this proposed rule change.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates January 11, 2016, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-NYSEARCA-2015-86).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30083 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76486; File No. SR-NYSEARCA-2015-110]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Amending NYSE Arca Equities Rule 8.600 To Adopt Generic Listing Standards for Managed Fund Shares

November 20, 2015.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on November 6, 2015, NYSE Arca, Inc. ("Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Equities Rule 8.600 to adopt generic listing standards for Managed Fund Shares. The proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rule 8.600 to adopt generic listing standards for Managed Fund Shares. Under the Exchange's current rules, a proposed rule change must be filed with the Securities and Exchange Commission ("SEC" or "Commission") for the listing and trading of each new series of Managed Fund Shares. The Exchange believes that it is appropriate to codify certain rules within Rule 8.600 that would generally eliminate the need for such proposed rule changes, which would create greater efficiency and promote uniform standards in the listing process.⁴

Background

Rule 8.600 sets forth certain rules related to the listing and trading of Managed Fund Shares.⁵ Under Rule 8.600(c)(1), the term "Managed Fund Share" means a security that:

(a) represents an interest in a registered investment company ("Investment Company") organized as an open-end management investment company or similar entity, that invests in a portfolio of securities selected by the Investment Company's investment adviser (hereafter "Adviser") consistent with the Investment Company's investment objectives and policies;

(b) is issued in a specified aggregate minimum number in return for a deposit of a specified portfolio of securities and/or a cash amount with a value equal to the next determined net asset value; and

⁴ The Exchange has previously filed a proposed rule change to amend NYSE Arca Equities Rule 8.600 to adopt generic listing standards for Managed Fund Shares. See Securities Exchange Act Release No. 74433 (March 4, 2015), 80 FR 12690 (March 10, 2015) (SR-NYSEARCA-2015-02). On June 3, 2015, the Exchange filed Amendment No. 1 to the proposed rule change. See Securities Exchange Act Release No. 75115 (June 5, 2015), 80 FR 33309 (June 11, 2015). On October 13, 2015, the Exchange withdrew the proposed rule change. See Securities Exchange Act Release No. 76186 (October 19, 2015), 80 FR 64461 (October 23, 2015).

⁵ See Securities Exchange Act Release No. 57619 (April 4, 2008), 73 FR 19544 (April 10, 2008) (SR-NYSEARCA-2008-25) (order approving NYSE Arca Equities Rule 8.600 and listing and trading of shares of certain issues of Managed Fund Shares) (the "Approval Order"). The Approval Order approved the rules permitting the listing and trading of Managed Fund Shares, trading hours and halts, listing fees applicable to Managed Fund Shares, and the listing and trading of several individual series of Managed Fund Shares.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 76085 (October 6, 2015), 80 FR 61513.

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2).

⁶ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

(c) when aggregated in the same specified minimum number, may be redeemed at a holder's request, which holder will be paid a specified portfolio of securities and/or cash with a value equal to the next determined net asset value.

Effectively, Managed Fund Shares are securities issued by an actively-managed open-end Investment Company (*i.e.*, an actively-managed exchange-traded fund ("ETF")). Because Managed Fund Shares are actively-managed, they do not seek to replicate the performance of a specified passive index of securities. Instead, they generally use an active investment strategy to seek to meet their investment objectives. In contrast, an open-end Investment Company that issues Investment Company Units ("Units"), listed and traded on the Exchange pursuant to NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that generally correspond to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

All Managed Fund Shares listed and/or traded pursuant to Rule 8.600 (including pursuant to unlisted trading privileges) are subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.⁶

In addition, Rule 8.600(d) currently provides for the criteria that Managed Fund Shares must satisfy for initial and continued listing on the Exchange, including, for example, that a minimum number of Managed Fund Shares are required to be outstanding at the time of commencement of trading on the Exchange. However, the current process for listing and trading new series of Managed Fund Shares on the Exchange requires that the Exchange submit a proposed rule change with the Commission. In this regard, Commentary .01 to Rule 8.600 specifies that the Exchange will file separate proposals under Section 19(b) of the Act (hereafter, a "proposed rule change") before listing and trading of shares of an issue of Managed Fund Shares.

Proposed Changes to Rule 8.600

The Exchange would amend Commentary .01 to Rule 8.600 to specify that the Exchange may approve Managed Fund Shares for listing and/or trading (including pursuant to unlisted trading privileges) pursuant to SEC Rule 19b-4(e) under the Act, which pertains to derivative securities products ("SEC

Rule 19b-4(e)").⁷ SEC Rule 19b-4(e)(1) provides that the listing and trading of a new derivative securities product by a self-regulatory organization ("SRO") is not deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b-4,⁸ if the Commission has approved, pursuant to section 19(b) of the Act, the SRO's trading rules, procedures and listing standards for the product class that would include the new derivative securities product and the SRO has a surveillance program for the product class. This is the current method pursuant to which "passive" ETFs are listed under NYSE Arca Equities Rule 5.2(j)(3).

The Exchange would also specify within Commentary .01 to Rule 8.600 that components of Managed Fund Shares listed pursuant to SEC Rule 19b-4(e) must satisfy on an initial and continued basis certain specific criteria, which the Exchange would include within Commentary .01, as described in greater detail below. As proposed, the Exchange would continue to file separate proposed rule changes before the listing and trading of Managed Fund Shares with components that do not satisfy the additional criteria described below or components other than those specified below. For example, if the components of a Managed Fund Share exceeded one of the applicable thresholds, the Exchange would file a separate proposed rule change before listing and trading such Managed Fund Share. Similarly, if the components of a Managed Fund Share included a security or asset that is not specified below, the Exchange would file a separate proposed rule change.

The Exchange would also add to the criteria of Rule 8.600(c) to provide that the Web site for each series of Managed Fund Shares shall disclose certain information regarding the Disclosed Portfolio, to the extent applicable. The required information includes the following, to the extent applicable: ticker symbol, CUSIP or other identifier, a description of the holding, identity of the asset upon which the derivative is based, the strike price for any options, the quantity of each security or other asset held as measured by select

metrics, maturity date, coupon rate, effective date, market value and percentage weight of the holding in the portfolio.⁹

In addition, the Exchange would amend Rule 8.600(d) to specify that all Managed Fund Shares must have a stated investment objective, which must be adhered to under normal market conditions.¹⁰

Finally, the Exchange would also amend the continued listing requirement in Rule 8.600(d)(2)(A) by changing the requirement that a Portfolio Indicative Value for Managed Fund Shares be widely disseminated by one or more major market data vendors at least every 15 seconds during the time when the Managed Fund Shares trade on the Exchange to a requirement that a Portfolio Indicative Value be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session (as defined in NYSE Arca Equities Rule 7.34).

Proposed Managed Fund Share Portfolio Standards

The Exchange is proposing standards that would pertain to Managed Fund Shares to qualify for listing and trading pursuant to SEC Rule 19b-4(e). These standards would be grouped according to security or asset type. The Exchange notes that the standards proposed for a Managed Fund Share portfolio that holds domestic equity securities, Derivative Securities Products and Index-Linked Securities are based in large part on the existing equity security standards applicable to Units in Commentary .01 to Rule 5.2(j)(3). The standards proposed for a Managed Fund Share portfolio that holds fixed income securities are based in large part on the existing fixed income security standards applicable to Units in Commentary .02 to Rule 5.2(j)(3). Many of the standards proposed for other types of holdings in a Managed Fund Share portfolio are based on previous proposed rule

⁹ Proposed rule changes for previously-listed series of Managed Fund Shares have similarly included disclosure requirements with respect to each portfolio holding, as applicable to the type of holding. *See, e.g.* Securities Exchange Act Release No. 72666 (July 3, 2014), 79 FR 44224 (July 30, 2014) (SR-NYSEArca-2013-122) (the "PIMCO Total Return Use of Derivatives Approval"), at 44227.

¹⁰ The Exchange would also add a new defined term under Rule 8.600(c)(5) to specify that the term "normal market conditions" includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

⁶ See Approval Order, *supra* note 5, at 19547.

⁷ 17 CFR 240.19b-4(e). As provided under SEC Rule 19b-4(e), the term "new derivative securities product" means any type of option, warrant, hybrid securities product or any other security, other than a single equity option or a security futures product, whose value is based, in whole or in part, upon the performance of, or interest in, an underlying instrument.

⁸ 17 CFR 240.19b-4(c)(1). As provided under SEC Rule 19b-4(c)(1), a stated policy, practice, or interpretation of the SRO shall be deemed to be a proposed rule change unless it is reasonably and fairly implied by an existing rule of the SRO.

changes for specific series of Managed Fund Shares.¹¹

Proposed Commentary .01(a) would describe the standards for a Managed Fund Share portfolio that holds equity securities, which are defined to be U.S. Component Stocks,¹² Derivative Securities Products,¹³ and Index-Linked Securities¹⁴ listed on a national securities exchange as follows:

(1) Component stocks (excluding Derivative Securities Products and Index-Linked Securities) that in the aggregate account for at least 90% of the equity weight of the portfolio (excluding such Derivative Securities Products and Index-Linked Securities) each must have a minimum market value of at least \$75 million;¹⁵

(2) Component stocks (excluding Derivative Securities Products and Index-Linked Securities) that in the aggregate account for at least 70% of the equity weight of the portfolio (excluding such Derivative Securities Products and Index-Linked Securities) each must have a minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of

¹¹ See the PIMCO Total Return Use of Derivatives Approval. See also, Securities Exchange Act Release Nos. 66321 (February 3, 2012), 77 FR 6850 (February 9, 2012) (SR-NYSEArca-2011-95) (the "PIMCO Total Return Approval"); 69244 (March 27, 2013), 78 FR 19766 (April 2, 2013) (SR-NYSEArca-2013-08) (the "SPDR Blackstone/GSO Senior Loan Approval"); 68870 (February 8, 2013), 78 FR 11245 (February 15, 2013) (SR-NYSEArca-2012-139) (the "First Trust Preferred Securities and Income Approval"); 69591 (May 16, 2013), 78 FR 30372 (May 22, 2013) (SR-NYSEArca-2013-33) (the "International Bear Approval"); 61697 (March 12, 2010), 75 FR 13616 (March 22, 2010) (SR-NYSEArca-2010-04) (the "WisdomTree Real Return Approval"); and 67054 (May 24, 2012), 77 FR 32161 (May 31, 2012) (SR-NYSEArca-2012-25) (the "WisdomTree Brazil Bond Approval"). Certain standards proposed herein for Managed Fund Shares are also based on previous proposed rule changes for specific series of Units for which Commission approval for listing was required due to the Units not satisfying certain standards of Commentary .01 and .02 to Rule 5.2(j)(3). See, e.g., Securities Exchange Act Release No. 69373 (April 15, 2013), 78 FR 23601 (April 19, 2013) (SR-NYSEArca-2012-108) (the "NYSE Arca U.S. Equity Synthetic Reverse Convertible Index Fund Approval").

¹² For the purposes of Commentary .01 and this proposal, the term "U.S. Component Stocks" would have the same meaning as defined in NYSE Arca Equities Rule 5.2(j)(3).

¹³ For the purposes of Commentary .01 and this proposal, the term "Derivative Securities Products" would have the same meaning as defined in NYSE Arca Equities Rule 7.34(a)(4)(A).

¹⁴ Index-Linked Securities are securities listed under NYSE Arca Equities Rule 5.2(j)(6).

¹⁵ This proposed text is identical to the corresponding text of Commentary .01(a)(A)(1) to Rule 5.2(j)(3), except for the omission of the reference to "index," which is not applicable, and the addition of the reference to Index-Linked Securities.

\$25,000,000, averaged over the last six months;¹⁶

(3) The most heavily weighted component stock (excluding Derivative Securities Products and Index-Linked Securities) must not exceed 30% of the equity weight of the portfolio, and, to the extent applicable, the five most heavily weighted component stocks (excluding Derivative Securities Products and Index-Linked Securities) must not exceed 65% of the equity weight of the portfolio;¹⁷

(4) A portfolio that includes any equity security as described in Commentary .01(a) shall include a minimum of 13 component stocks; provided, however, that there shall be no minimum number of component stocks if (a) one or more series of Derivative Securities Products or Index-Linked Securities constitute, at least in part, components underlying a series of Managed Fund Shares, or (b) one or more series of Derivative Securities Products or Index-Linked Securities account for 100% of the equity weight of the portfolio of a series of Managed Fund Shares;¹⁸

(5) Except as provided in proposed Commentary .01(a), equity securities in the portfolio must be U.S. Component Stocks listed on a national securities exchange and must be NMS Stocks as defined in Rule 600 of Regulation NMS;¹⁹

(6) For Derivative Securities Products and Index-Linked Securities, no more than 25% of the equity weight of the portfolio could include leveraged and/or inverse leveraged Derivative Securities Products or Index-Linked Securities; and

(7) American Depositary Receipts ("ADRs") may be sponsored or unsponsored. However no more than

¹⁶ This proposed text is identical to the corresponding text of Commentary .01(a)(A)(2) to Rule 5.2(j)(3), except for the omission of the reference to "index," which is not applicable, and the addition of the reference to Index-Linked Securities.

¹⁷ This proposed text is identical to the corresponding text of Commentary .01(a)(A)(3) to Rule 5.2(j)(3), except for the omission of the reference to "index," which is not applicable, and the addition of the reference to Index-Linked Securities.

¹⁸ This proposed text is identical to the corresponding text of Commentary .01(a)(A)(4) to Rule 5.2(j)(3), except for the omission of the reference to "index," which is not applicable, the addition of the reference to Index-Linked Securities, and the reference to the 100% limit applying to the "equity portion" of the portfolio.

¹⁹ 17 CFR 240.600. This proposed text is identical to the corresponding text of Commentary .01(a)(A)(5) to Rule 5.2(j)(3), except for the addition of "equity" to make clear that the standard applies to "equity securities", the exclusion of unsponsored ADRs, and the omission of the reference to "index," which is not applicable.

10% of the equity weight of the portfolio shall consist of unsponsored ADRs.

Proposed Commentary .01(b) would describe the standards for a Managed Fund Share portfolio that holds fixed income securities, which are debt securities²⁰ that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities ("Treasury Securities"), government-sponsored entity securities ("GSE Securities"), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof, investment grade and high yield corporate debt, bank loans, mortgage and asset backed securities, and commercial paper. The applicable portfolio holdings standards would be as follows:

(1) Components that in the aggregate account for at least 75% of the fixed income weight of the portfolio each shall have a minimum original principal amount outstanding of \$100 million or more;²¹

(2) No component fixed-income security (excluding Treasury Securities and GSE Securities) could represent more than 30% of the fixed income weight of the portfolio, and the five most heavily weighted component fixed income securities in the portfolio must not in the aggregate account for more than 65% of the fixed income weight of the portfolio;²²

(3) An underlying portfolio (excluding exempted securities) that includes fixed income securities must include a minimum of 13 non-affiliated issuers; provided, however, that there shall be no minimum number of non-affiliated issuers required for fixed income securities if at least 70% of the weight of the portfolio consists of equity securities as described in proposed Commentary .01(a).²³

²⁰ Debt securities include a variety of fixed income obligations, including, but not limited to, corporate debt securities, government securities, municipal securities, convertible securities, and mortgage-backed securities. Debt securities include investment-grade securities, non-investment-grade securities, and unrated securities. Debt securities also include variable and floating rate securities. To the extent a fund holds a convertible security, the equity security into which such security is converted would be required to meet the criteria of proposed Commentary .01(a).

²¹ This text of proposed Commentary .01(b)(1) to Rule 8.600 is based on the corresponding text of Commentary .02(a)(2) to Rule 5.2(j)(3).

²² This proposed text is identical to the corresponding text of Commentary .02(a)(4) to Rule 5.2(j)(3), except for the omission of the reference to "index," which is not applicable.

²³ This proposed text is similar to the corresponding text of Commentary .02(a)(5) to Rule 5.2(j)(3), except for the omission of the reference to

(4) Component securities that in aggregate account for at least 90% of the fixed income weight of the portfolio must be either (a) from issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide market value of its outstanding common equity held by non-affiliates of \$700 million or more; (c) from issuers that have outstanding securities that are notes, bonds debentures, or evidence of indebtedness having a total remaining principal amount of at least \$1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country; and

(5) Non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities components of a portfolio shall not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio.

Proposed Commentary .01(c) would describe the standards for a Managed Fund Share portfolio that holds cash and cash equivalents.²⁴ Specifically, the portfolio may hold short-term instruments with maturities of less than 3 months. There would be no limitation to the percentage of the portfolio invested in such holdings. Short-term instruments would include the following:²⁵

(1) U.S. Government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities;

(2) certificates of deposit issued against funds deposited in a bank or savings and loan association;

(3) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions;

"index," which is not applicable, the exclusion of the text "consisting entirely of exempted securities" and the provision that there shall be no minimum number of non-affiliated issuers required for fixed income securities if at least 70% of the weight of the portfolio consists of equity securities as described in proposed Commentary .01(a).

²⁴ Proposed rule changes for previously-listed series of Managed Fund Shares have similarly included the ability for such Managed Fund Share holdings to include cash and cash equivalents. *See, e.g.,* SPDR Blackstone/GSO Senior Loan Approval, *supra* note 10, at 19768–69 and First Trust Preferred Securities and Income Approval, *supra* note 11, at 76150.

²⁵ Proposed rule changes for previously-listed series of Managed Fund Shares have similarly specified short-term instruments with respect to their inclusion in Managed Fund Share holdings. *See, e.g.,* First Trust Preferred Securities and Income Approval, *supra* note 11, at 76150–51.

(4) repurchase agreements and reverse repurchase agreements;

(5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest;

(6) commercial paper, which are short-term unsecured promissory notes; and

(7) money market funds.

Proposed Commentary .01(d) would describe the standards for a Managed Fund Share portfolio that holds listed derivatives, including futures, options and swaps on commodities, currencies and financial instruments (*e.g.*, stocks, fixed income, interest rates, and volatility) or a basket or index of any of the foregoing.²⁶ There would be no limitation to the percentage of the portfolio invested in such holdings; provided, however, that, in the aggregate, at least 90% of the weight of such holdings invested in futures and exchange-traded options shall consist of futures and options whose principal market is a member of the Intermarket Surveillance Group ("ISG") or is a market with which the Exchange has a comprehensive surveillance sharing agreement ("CSSA").²⁷ Proposed Commentary .01(e) would describe the standards for a Managed Fund Share portfolio that holds over the counter ("OTC") derivatives, including forwards, options and swaps on commodities, currencies and financial instruments (*e.g.*, stocks, fixed income, interest rates, and volatility) or a basket or index of any of the foregoing.²⁸ Proposed Commentary .01(e)(1) would provide that no more than 20% of the assets in the portfolio may be invested in OTC derivatives.

Proposed Commentary .01(f) would provide that, to the extent that listed or OTC derivatives are used to gain exposure to individual equities and/or

²⁶ Proposed rule changes for previously-listed series of Managed Fund Shares have similarly included the ability for such Managed Fund Share holdings to include listed derivatives. *See, e.g.,* WisdomTree Real Return Approval, *supra* note 10, at 13617 and WisdomTree Brazil Bond Approval, *supra* note 11, at 32163.

²⁷ ISG is comprised of an international group of exchanges, market centers, and market regulators that perform front-line market surveillance in their respective jurisdictions. *See* <https://www.isgportal.org/home.html>.

²⁸ A proposed rule change for series of Units previously listed and traded on the Exchange pursuant to Rule 5.2(j)(3) similarly included the ability for such Units' holdings to include OTC derivatives, specifically OTC down-and-in put options, which are not NMS Stocks as defined in Rule 600 of Regulation NMS and therefore do not satisfy the requirements of Commentary .01(a)(A) to Rule 5.2(j)(3). *See, e.g.,* NYSE Arca U.S. Equity Synthetic Reverse Convertible Index Fund Approval, *supra* note 11, at 23602.

fixed income securities, or to indexes of equities and/or fixed income securities, such equities and/or fixed income securities, as applicable, shall meet the criteria set forth in Commentary .01(a) and .01(b) to Rule 8.600, respectively.

The Exchange believes that the proposed standards would continue to ensure transparency surrounding the listing process for Managed Fund Shares. Additionally, the Exchange believes that the proposed portfolio standards for listing and trading Managed Fund Shares, many of which track existing Exchange rules relating to Units, are reasonably designed to promote a fair and orderly market for such Managed Fund Shares.²⁹ These proposed standards would also work in conjunction with the existing initial and continued listing criteria related to surveillance procedures and trading guidelines.

In support of this proposal, the Exchange represents that:³⁰

(1) the Managed Fund Shares will continue to conform to the initial and continued listing criteria under Rule 8.600;

(2) the Exchange's surveillance procedures are adequate to continue to properly monitor the trading of the Managed Fund Shares in all trading sessions and to deter and detect violations of Exchange rules. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which will include Managed Fund Shares, to monitor trading in the Managed Fund Shares;

(3) prior to the commencement of trading of a particular series of Managed Fund Shares, the Exchange will inform its Equity Trading Permit ("ETP") Holders in a Bulletin of the special characteristics and risks associated with trading the Managed Fund Shares, including procedures for purchases and redemptions of Managed Fund Shares, suitability requirements under NYSE Arca Equities Rule 9.2(a), the risks involved in trading the Managed Fund Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated, information regarding the Portfolio Indicative Value and the Disclosed Portfolio, prospectus delivery requirements, and other trading information. In addition, the Bulletin will disclose that the Managed Fund Shares are subject to various fees and expenses, as described in the applicable

²⁹ *See* Approval Order, *supra* note 5 at 19548.

³⁰ The Exchange made similar representations in the Approval Order. *See id.* at 19549.

registration statement, and will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. Finally, the Bulletin will disclose that the net asset value for the Managed Fund Shares will be calculated after 4 p.m. ET each trading day; and

(4) the issuer of a series of Managed Fund Shares will be required to comply with Rule 10A-3 under the Act for the initial and continued listing of Managed Fund Shares, as provided under NYSE Arca Equities Rule 5.3.

The Exchange notes that the proposed change is not otherwise intended to address any other issues and that the Exchange is not aware of any problems that ETP Holders or issuers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,³¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,³² in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest because it would facilitate the listing and trading of additional Managed Fund Shares, which would enhance competition among market participants, to the benefit of investors and the marketplace. Specifically, after more than six years under the current process, whereby the Exchange is required to file a proposed rule change with the Commission for the listing and trading of each new series of Managed Fund Shares, the Exchange believes that it is appropriate to codify certain rules within Rule 8.600 that would generally eliminate the need for separate proposed rule changes. The Exchange believes that this would facilitate the listing and trading of additional types of Managed Fund Shares that have investment portfolios that are similar to investment portfolios for Units, which have been approved for listing and trading, thereby creating greater efficiencies in the listing process for the Exchange and the Commission. In this regard, the Exchange notes that the standards proposed for Managed Fund Share portfolios that include domestic

equity securities, Derivative Securities Products, and Index-Linked Securities are based in large part on the existing equity security standards applicable to Units in Commentary .01 to Rule 5.2(j)(3) and that the standards proposed for Managed Fund Share portfolios that include fixed income securities are based in large part on the existing fixed income standards applicable to Units in Commentary .02 to Rule 5.2(j)(3). Additionally, many of the standards proposed for other types of holdings of series of Managed Fund Shares are based on previous proposed rule changes for specific series of Managed Fund Shares.³³

With respect to the proposed addition to the criteria of Rule 8.600(c) to provide that the Web site for each series of Managed Fund Shares shall disclose certain information regarding the Disclosed Portfolio, to the extent applicable, the Exchange notes that proposed rule changes approved by the Commission for previously-listed series of Managed Fund Shares have similarly included disclosure requirements with respect to each portfolio holding, as applicable to the type of holding.³⁴ With respect to the proposed exclusion of Derivatives Securities Products and Index-Linked Securities from the requirements of proposed Commentary .01(a) of Rule 8.600, the Exchange believes it is appropriate to exclude Index-Linked Securities as well as Derivative Securities Products from certain component stock eligibility criteria for Managed Fund Shares in so far as Derivative Securities Products and Index-Linked Securities are themselves subject to specific quantitative listing and continued listing requirements of a national securities exchange on which such securities are listed. Derivative Securities Products and Index-Linked Securities that are components of a fund's portfolio would have been listed and traded on a national securities exchange pursuant to a proposed rule change approved by the Commission pursuant to Section 19(b)(2) of the Act³⁵ or submitted by a national securities exchange pursuant to Section 19(b)(3)(A) of the Act³⁶ or would have been listed by a national securities exchange pursuant to the requirements of Rule 19b-4(e) under the Act.³⁷ The Exchange also notes that Derivative Securities Products and Index-Linked Securities are derivatively priced, and, therefore, the Exchange believes that it

would not be necessary to apply the proposed generic quantitative criteria (e.g., market capitalization, trading volume, or portfolio component weighting) applicable to equity securities other than Derivative Securities Products or Index-Linked Securities (e.g., common stocks) to such products.³⁸

With respect to the proposed amendment to the continued listing requirement in Rule 8.600(d)(2)(A) to require dissemination of a Portfolio Indicative Value at least every 15 seconds during the Core Trading Session (as defined in NYSE Arca Equities Rule 7.34), such requirement conforms to the requirement applicable to the dissemination of the Intraday Indicative Value for Investment Company Units in Commentary .01(c) and Commentary .02 (c) to NYSE Arca Equities Rule 5.2(j)(3). In addition, such dissemination is consistent with representations made in proposed rule changes for issues of Managed Fund Shares previously approved by the Commission.³⁹

With respect to the proposed requirement in Commentary .01(b)(3) to Rule 8.600 that an underlying portfolio (excluding exempted securities) that includes fixed income securities must include a minimum of 13 non-affiliated issuers, but that there would be no minimum number of non-affiliated issuers required for fixed income securities if at least 70% of the weight of the portfolio consists of equity securities, the Exchange notes that such requirement is consistent with proposed Commentary .01(b)(2). The Exchange further notes that Commentary .02 (a)(4) to Rule 5.2(j)(3) currently provides that a single fixed income security can represent up to 30% of the weight of an index underlying a series of Investment Company Units. Proposed Commentary .01(b)(3) to Rule 8.600, therefore, provides for a maximum weighting of a fixed income security in a fund's portfolio comparable to existing rules applicable to Investment Company Units based on fixed income indexes.

With respect to proposed Commentary .01(d)(1) to Rule 8.600 relating to listed derivatives, the Exchange believes that it is appropriate

³⁸ See Securities Exchange Act Release Nos. 57561 (March 26, 2008), 73 FR 17390 (April 1, 2008) (SR-NYSEArca-2008-29) (notice of filing of proposed rule change to amend eligibility criteria for components of an index underlying Investment Company Units); 57751 (May 1, 2008), 73 FR 25818 (May 7, 2008) (SR-NYSEArca-2008-29) (order approving proposed rule change to amend eligibility criteria for components of an index underlying Investment Company Units).

³⁹ See, e.g., Approval Order, *supra* note 4; International Bear Approval, *supra* note 11.

³³ See *supra*, note 11.

³⁴ See *supra*, note 9.

³⁵ 15 U.S.C. 78s(b)(2).

³⁶ 15 U.S.C. 78s(b)(3)(A).

³⁷ 17 CFR 240.19b-4(e).

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5).

that there be no limit to the percentage of a portfolio invested in such holdings, provided that, in the aggregate, at least 90% of the weight of such holdings invested in futures and exchange-traded options would consist of futures and options whose principal market is a member of ISG or is a market with which the Exchange has a comprehensive surveillance sharing agreement. Such a requirement would facilitate information sharing among market participants trading shares of a series on Managed Fund Shares as well as futures and options that such series may hold. In addition, listed swaps would be centrally cleared, reducing counterparty risk and thereby furthering investor protection.⁴⁰

With respect to proposed Commentary .01(e) to Rule 8.600 relating to OTC derivatives, the Exchange believes that the limitation to 20% of assets for non-centrally cleared derivatives would assure that the preponderance of fund investments would not be in derivatives that are not listed and centrally cleared.

With respect to proposed Commentary .01(f) to Rule 8.600 relating to a fund's use of listed or OTC derivatives to gain exposure to individual equities and/or fixed income securities, or to indexes of equities and/or indexes of fixed income securities, the Exchange notes that such exposure would be required to meet the numerical and other criteria set forth in proposed Commentary .01(a) and .01(b) to Rule 8.600 respectively.

Quotation and other market information relating to listed futures and options is available from the exchanges listing such instruments as well as from market data vendors. With respect to listed swaps, which are centrally cleared and traded on "Swap Execution Facilities ("SEFs")", intraday pre-trade (quoting) information, including real time streaming quotes and market depth is available through the facilities of the applicable SEF.⁴¹

The Exchange notes that a fund's investments in derivative instruments

would be subject to limits on leverage imposed by the 1940 Act. Section 18(f) of the 1940 Act and related Commission guidance limit the amount of leverage an investment company can obtain. A fund's investments would be consistent with its investment objective and would not be used to enhance leverage. To limit the potential risk associated with a fund's use of derivatives, a fund will segregate or " earmark " assets determined to be liquid by a fund in accordance with the 1940 Act (or, as permitted by applicable regulation, enter into certain offsetting positions) to cover its obligations under derivative instruments. A fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.*, 2Xs and 3Xs) of a fund's broad-based securities market index (as defined in Form N-1A).⁴²

The proposed rule change is also designed to protect investors and the public interest because Managed Fund Shares listed and traded pursuant to Rule 8.600, including pursuant to the proposed new portfolio standards, would continue to be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.⁴³

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because the Managed Fund Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 8.600. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Managed Fund Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Financial Industry Regulatory Authority, Inc. ("FINRA"), on behalf of the Exchange, or the regulatory staff of the Exchange, will communicate as needed regarding trading in Managed Fund Shares with other markets that are members of the ISG, including all U.S. securities exchanges and futures exchanges on which the components are traded. In addition, the Exchange may obtain information regarding trading in Managed Fund Shares from other markets that are members of the ISG, including all U.S. securities exchanges and futures exchanges on which the

components are traded, or with which the Exchange has in place a CSSA.

The Exchange also believes that the proposed rule change would fulfill the intended objective of Rule 19b-4(e) under the Act by allowing Managed Fund Shares that satisfy the proposed listing standards to be listed and traded without separate Commission approval. However, as proposed, the Exchange would continue to file separate proposed rule changes before the listing and trading of Managed Fund Shares that do not satisfy the additional criteria described above.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁴⁴ the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed rule change would facilitate the listing and trading of additional types of Managed Fund Shares and result in a significantly more efficient process surrounding the listing and trading of Managed Fund Shares, which will enhance competition among market participants, to the benefit of investors and the marketplace. The Exchange believes that this would reduce the time frame for bringing Managed Fund Shares to market, thereby reducing the burdens on issuers and other market participants and promoting competition. In turn, the Exchange believes that the proposed change would make the process for listing Managed Fund Shares more competitive by applying uniform listing standards with respect to Managed Fund Shares.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory

⁴⁰ The Commission has noted that "[c]entral clearing mitigates counterparty risk among dealers and other institutions by shifting that risk from individual counterparties to [central counterparties ("CCPs")], thereby protecting CCPs from each other's potential failures." See Securities Exchange Act Release No. 67286 (June 28, 2012) (File No. S7-44-10) (Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies).

⁴¹ There are currently five categories of swaps eligible for central clearing: interest rate swaps; credit default swaps; foreign exchange swaps; equity swaps; and commodity swaps. The following entities provide central clearing for OTC derivatives: ICE Clear Credit (US); ICE Clear (EU); CME Group; LCH.Clearnet; and Eurex.

⁴² See, e.g., Securities Exchange Act Release No. 74842 (April 29, 2015), 86 FR 25723 (May 5, 2015) (SR-NYSEArca-2014-89) (order approving listing and trading of shares of eight PIMCO exchange-traded funds).

⁴³ See Approval Order, *supra* note 5, at 19547.

⁴⁴ 15 U.S.C. 78f(b)(8).

organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2015-110 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEArca-2015-110. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549 on official business days between 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at www.nyse.com. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2015-110 and

should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁵

Robert W. Errett,
Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76499; File No. SR-NASDAQ-2015-142]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Market Order Spread Protection

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 12, 2015, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the rules of the NASDAQ Options Market, LLC ("NOM"), NASDAQ's facility for executing and routing standardized equity and index options, at Chapter VI, Section 6, entitled "Acceptance of Quotes and Orders," specifically at Section 6(c) concerning Market Order Spread Protection.

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend Chapter VI, Section 6 entitled "Acceptance of Quotes and Orders," specifically, at paragraph (c) related to Market Order Spread Protection. This feature was adopted as an enhancement to NOM's Systems in 2011.³ The Market Order Spread Protection was designed to protect Market Orders⁴ from being executed in very wide markets. This feature is not optional and is set at the same threshold for all options traded on NOM. The Market Order Spread Protection is applicable to all Participants submitting Market Orders.

At this time, the Exchange is proposing to amend Section 6(c) which currently states, "System Orders that are Market Orders will be rejected if the NBBO is wider than a preset threshold at the time the order is received by the System." The Exchange proposes to amend this sentence as follows: "System Orders that are Market Orders will be rejected if the *best of the NBBO and the internal market BBO*⁵ (the "Reference BBO") is wider than a preset threshold at the time the order is received by the System." The Exchange is amending this rule text to account for both Price-Improving⁶ and Post-Only Orders.⁷ Both of these order types, as well as orders which would lock or cross another market,⁸ could result in non-displayed pricing and would result

³ See Securities Exchange Act Release No. 64667 (June 14, 2011), 76 FR 35930 (June 20, 2011) (SR-NASDAQ-2011-080).

⁴ "Market Orders" are orders to buy or sell at the best price available at the time of execution. Participants can designate that their Market Orders not executed after a pre-established period of time, as established by the Exchange, will be cancelled back to the Participant. See NOM Rules at Chapter VI, Section 1(e)(5).

⁵ Best Bid or Best Offer on NOM.

⁶ See NOM Rules at Chapter VI, Section 1(e)(6).

⁷ See NOM Rules at Chapter VI, Section 1(e)(11).

⁸ Options Order Protection and Locked and Crossed Market Rules are located in Chapter XII of NOM Rules. In the event of a locked and crossed market, the BBO will be repriced and displayed in accordance with NOM Rules at Chapter VI, Section 7(b)(3)(C).

⁴⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

in the internal market BBO being better than the NBBO.

Price Improving Orders are orders to buy or sell an option at a specified price at an increment smaller than the minimum price variation ("MPV") in the security. Price Improving Orders may be entered in increments as small as one cent. Price Improving Orders that are available for display shall be displayed at the minimum price variation in that security and shall be rounded up for sell orders and rounded down for buy orders.

Post-Only Orders are orders that will not remove liquidity from the System. Post-Only Orders are to be ranked and executed on the Exchange or cancelled, as appropriate, without routing away to another market. Post-Only Orders are evaluated at the time of entry with respect to locking or crossing other orders as follows: (i) If a Post-Only Order would lock or cross an order on the System, the order will be re-priced to \$.01 below the current low offer (for bids) or above the current best bid (for offers) and displayed by the System at one minimum price increment below the current low offer (for bids) or above the current best bid (for offers); and (ii) if a Post-Only Order would not lock or cross an order on the System but would lock or cross the NBBO as reflected in the protected quotation of another market center, the order will be handled pursuant to Chapter VI, Section 7(b)(3)(C). Participants may choose to have their Post-Only Orders returned whenever the order would lock or cross the NBBO or be placed on the book at a price other than its limit price. Post-Only Orders received prior to the opening will be eligible for execution during the opening cross and will be processed as per Chapter VI, Section 8. Post-Only Orders received after market close will be rejected.⁹ Similarly, with this order type, market participants are able to submit orders or quotes priced between the MPV.

The current rule text does not reflect the possibility that orders or quotes could be priced between the MPV. The proposed rule text amends the current rule text to account for Price Improving and Post-Only Orders and the results of repricing.

The following is an example of a Price Improving Order and Market Order Spread Protection. Assume an option MPV is scaled in \$.05 increments and a limit buy order of \$.05 exists on the Exchange. If a Price Improving sell order is entered at \$.11, this order will not

be displayed at its limit of \$.11, because the order is priced at a non-MPV increment. This order will be displayed at the nearest MPV price of \$.15 (because of the option's \$.05 MPV increment). Assume this order makes up the best offer on the Exchange. For this example, assume the Market Order Spread Threshold in the System is set at \$.09. Further assume a Market Order to buy is submitted to the Exchange. Based on the Exchange's proposed implementation of Market Order Spread Protection, the Market Order to buy would execute against the resting sell order at \$.11, since \$.11 is the best available offer and the internal market BBO spread is \$.06 (spread between the best bid of \$.05 and the best offer of \$.11) which is less than the Market Order Spread Threshold of \$.09. Based on the current rule text, a Participant could expect their Market Order to be rejected, since the NBBO spread is \$.10 (spread between the best NBB of \$.05 and the NBO of \$.15) which exceeds the \$.09 Market Order Spread Threshold. The Exchange is amending the rule text to provide for the internal market BBO being better than the NBBO.

The following is a similar example for a Post-Only Order. Assume an option MPV is scaled in \$.05 increments and a limit buy order of \$.05 exists on the Exchange. If a Post-Only Order is entered to sell at \$.05, this order will not immediately trade at its limit of \$.05 since by definition it will not remove liquidity from the System. Instead, the Post-Only Order will be available to trade \$.01 above the locking price of \$.05 (*i.e.*, \$.06) and displayed at the nearest MPV increment price of \$.10. Assume this order makes up the best offer on the Exchange. For this example, assume the Market Order Spread Threshold in the System is set at \$.04. Further assume a Market Order to buy is submitted to the Exchange. Based on the Exchange's proposed implementation of Market Order Spread Protection, the Market Order to buy would execute against the resting Post-Only Order at \$.06, since \$.06 is the best available offer and the internal market BBO spread is \$.01 (spread between the best bid of \$.05 and the best offer of \$.06) which is less than the Market Order Spread Threshold of \$.04. Based on the current rule text, a Participant could expect their Market Order to be rejected, since the NBBO spread is \$.05 (spread between the best NBB of \$.05 and the NBO of \$.10) which exceeds the \$.04 Market Order Spread Threshold.

This rule change will correct the existing rule text to reflect current

practice which accounts for non-displayed order types and reprices due to trade-through and locked and crossed market restrictions.¹⁰ Participants were notified via an Options Trader Alert of this rule text error.¹¹

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act¹² in general, and furthers the objectives of Section 6(b)(5) of the Act¹³ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by amending the rule text to reflect the impact of non-displayed order types and repricing due to trade-through and locked and crossed market restrictions.

Amending the current NOM rule text for Market Order Spread Protection to account for non-displayed orders such as Price-Improving and Post-Only Orders and repricing due to trade-through and locked and crossed market restrictions would provide Participants with the expected results of the Market Order Spread Protection feature. The Exchange believes that it is consistent with the Act to amend the rule text to reflect these non-displayed orders because today, these order types permit Participants to submit orders or quotes priced between the MPV, which will be rounded to the nearest MPV for display.

The Exchange believes that the amendment to the Market Order Spread Protection language does not otherwise create an impediment to a free and open market because these two order types already exist today and provide investors the opportunity to trade at a better price than would otherwise be available, *e.g.* inside the disseminated best bid and offer for a security, which could result in better executions for investors. Further, these order types incent Participants to compete by putting forth their best price to potentially match or better any Price Improving or Post-Only Orders or any other order resident in the System. This may result in more aggressive, rather than less aggressive, trading interest. This proposal reflects the impact of these order types on the Market Order Spread Protection feature.

By reflecting the proper rule text to account for these order types the

¹⁰ See Chapter XII of NOM Rules.

¹¹ See Options Regulatory Alert 2015-28 dated September 4, 2015.

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

⁹ Post-Only Orders may not have a time-in-force designation of Good Til Cancelled or Immediate or Cancel.

Exchange is providing Participants with additional information with which to anticipate the impact of the Market Order Spread Protection feature.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal to amend the Market Order Spread Protection rule text to account for Price Improving or Post-Only Orders or repricing due to trade-through and locked and crossed market restrictions creates an undue burden on competition because it will serve to provide Participants with greater information to anticipate the impact of the Market Order Spread Protection feature. Today, Participants are able to submit orders or quotes priced between the MPV for display at the nearest MPV. This rule change would reflect the ability to enter these types of orders on NOM and the impact of the Market Order Spread Protection feature. The purpose of this rule change is to protect orders resting on the Order Book when the market is wide. This feature will be applied in a similar manner to all Participants on NOM.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁴ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2015-142 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2015-142. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions

should refer to File Number SR-NASDAQ-2015-142 and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-30088 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31906; File No. 812-14475]

ETF Series Solutions and AlphaClone, Inc.; Notice of Application

November 19, 2015.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 15(a) of the Act and rule 18f-2 under the Act, as well as from certain disclosure requirements in rule 20a-1 under the Act, Item 19(a)(3) of Form N-1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and Sections 6-07(2)(a), (b), and (c) of Regulation S-X ("Disclosure Requirements"). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

Applicants: ETF Series Solutions (the "Trust"), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series, and AlphaClone, Inc. (the "Initial Adviser"), a Delaware corporation registered as an investment adviser under the Investment Advisers Act of 1940.

Filing Dates: The application was filed on May 28, 2015 and amended on September 25, 2015.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 14, 2015, and

¹⁶ 17 CFR 200.30-3(a)(12).

¹⁴ 15 U.S.C. 78s(b)(3)(a)(iii).

¹⁵ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

Applicants: ETF Series Solutions, 615 E. Michigan Street, Milwaukee, WI 53202, and AlphaClone, Inc., One Market Street, Steuart Tower, Suite 1208, San Francisco, CA 94105.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel, at (202) 551–6812, or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission’s Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551–8090.

Summary of the Application

1. The Initial Adviser is the investment adviser to the Trust’s AlphaClone Small Cap ETF, AlphaClone International ETF, AlphaClone Activist ETF, and AlphaClone Value ETF (collectively, “Initial Funds”) pursuant to an investment management agreement with the Trust (“Investment Management Agreement”).¹ Under the terms of the

¹ Applicants request relief with respect to the Initial Funds, as well as to any future series of the Trust and any other existing or future registered open-end management investment company or series thereof that, in each case, is advised by the Initial Adviser or any entity controlling, controlled by, or under common control with, the Initial Adviser or its successors (each, also an “Adviser”), uses the multi-manager structure described in the application, and complies with the terms and conditions set forth in the application (each, a “Subadvised Fund”). For purposes of the requested order, “successor” is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization. Future Subadvised Funds may be operated as a master-feeder structure pursuant to section 12(d)(1)(E) of the Act. In such a structure, certain series of the Trust (each, a “Feeder Fund”) may invest substantially all of their assets in a Subadvised Fund (a “Master Fund”) pursuant to section 12(d)(1)(E) of the Act. No Feeder Fund will engage any sub-advisers other than through approving the engagement of one or more of the Master Fund’s sub-advisers.

Investment Management Agreement, the Adviser, subject to the supervision of the board of trustees of the Trust (“Board”), provides continuous investment management of the assets of each Subadvised Fund. Consistent with the terms of the Investment Management Agreement, the Adviser may, subject to the approval of the Board, delegate portfolio management responsibilities of all or a portion of the assets of a Subadvised Fund to one or more Sub-Advisers.² The Adviser will continue to have overall responsibility for the management and investment of the assets of each Subadvised Fund. The Adviser will evaluate, select, and recommend Sub-Advisers to manage the assets of a Subadvised Fund and will oversee, monitor and review the Sub-Advisers and their performance and recommend the removal or replacement of Sub-Advisers.

2. Applicants request an order to permit the Adviser, subject to the approval of the Board, to enter into investment sub-advisory agreements with the Sub-Advisers (each, a “Sub-Advisory Agreement”) and materially amend such Sub-Advisory Agreements without obtaining the shareholder approval required under section 15(a) of the Act and rule 18f–2 under the Act.³ Applicants also seek an exemption from the Disclosure Requirements to permit a Subadvised Fund to disclose (as both a dollar amount and a percentage of the Subadvised Fund’s net assets): (a) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Adviser; (b) the aggregate fees paid to Non-Affiliated Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, Aggregate Fee Disclosure”).⁴

² As used herein, a “Sub-Adviser” for a Subadvised Fund is (1) an indirect or direct “wholly owned subsidiary” (as such term is defined in the Act) of the Adviser for that Subadvised Fund, or (2) a sister company of the Adviser for that Subadvised Fund that is an indirect or direct “wholly-owned subsidiary” of the same company that, indirectly or directly, wholly owns the Adviser (each of (1) and (2) a “Wholly-Owned Sub-Adviser” and collectively, the “Wholly-Owned Sub-Advisers”), or (3) not an “affiliated person” (as such term is defined in section 2(a)(3) of the Act) of the Subadvised Fund, any Feeder Fund invested in a Master Fund, the Trust, or the Adviser, except to the extent that an affiliation arises solely because the Sub-Adviser serves as a sub-adviser to a Subadvised Fund (“Non-Affiliated Sub-Advisers”).

³ The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, who is an affiliated person, as defined in section 2(a)(3) of the Act, of the Subadvised Fund, of any Feeder Fund, or of the Adviser, other than by reason of serving as a sub-adviser to one or more of the Subadvised Funds (“Affiliated Sub-Adviser”).

⁴ For any Subadvised Fund that is a Master Fund, the relief would also permit any Feeder Fund

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Subadvised Funds’ shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of the Subadvised Funds’ shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the application, the Investment Management Agreements will remain subject to shareholder approval, while the role of the Sub-Advisers is substantially equivalent to that of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Subadvised Funds. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser’s ability to negotiate fees paid to the Sub-Advisers that are more advantageous for the Subadvised Funds.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015–30092 Filed 11–25–15; 8:45 am]

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invested in that Master Fund to disclose Aggregate Fee Disclosure.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76496; File No. SR-OCC-2015-016]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Modify The Options Clearing Corporation's Margin Methodology by Incorporating Variations in Implied Volatility

November 20, 2015.

On October 5, 2015, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change SR-OCC-2015-016 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")¹ and Rule 19b-4 thereunder.² The proposed rule change was published for comment in the *Federal Register* on October 19, 2015.³ The Commission did not receive any comments on the proposed rule change.

Section 19(b)(2) of the Exchange Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day from the publication of notice of filing of this proposed rule change is December 3, 2015.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on OCC's proposed rule change.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4. OCC also filed this proposal as an advance notice pursuant to Section 802(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 and Rule 19b-4(n)(1) under the Exchange Act. 15 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1). See Securities Exchange Act Release No. 76421 (November 10, 2015), 80 FR 71900 (November 17, 2015) (SR-OCC-2015-804). To date, the Commission has not received any comments on the advance notice.

³ Securities Exchange Act Release No. 76128 (October 13, 2015), 80 FR 63264 (October 19, 2015) (SR-OCC-2015-016).

⁴ 15 U.S.C. 78s(b)(2).

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Exchange Act,⁵ the Commission designates January 17, 2016, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-OCC-2015-016).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30085 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76500; File No. SR-ISEGemini-2015-26]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 6, 2015, ISE Gemini, LLC (the "Exchange" or "ISE Gemini") filed with the Securities and Exchange Commission ("Commission") the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ISE Gemini proposes to amend the Schedule of Fees as described in more detail below. The text of the proposed rule change is available on the Exchange's Internet Web site at <http://www.ise.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

⁵ 15 U.S.C. 19(b)(2)(A)(ii)(I).

⁶ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange currently offers three real-time market data feed offerings.³ In order to encourage subscriptions to multiple market data feeds, ISE Gemini adopted a multi-product subscription discount, which offers a ten percent (10%) discount for customers who subscribe to two data feeds.⁴ The Exchange now proposes to remove this multi-product subscription discount from its Schedule of Fees.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁵ in general, and Section 6(b)(4) of the Act,⁶ in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

In particular, the Exchange believes the removal of the subscription discount is reasonable and equitable because the discount is no longer necessary to encourage subscriptions to multiple data feeds. Further, the Exchange believes that the proposed removal of the discount is not unfairly discriminatory because it applies to all similarly situated market participations who subscribe to the feeds.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁷ the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The removal of the multi-product, market data

³ The market data feeds are: the ISE Gemini Order Feed, the ISE Gemini Top Quote Feed, and the ISE Gemini Real-Time Depth of Market Raw Data Feed.

⁴ See Securities Exchange Act Release No. 34-71614 (February 25, 2014), 79 FR 11840 (March 3, 2014) (SR-ISE Gemini-2014-10).

⁵ 15 U.S.C. 78f.

⁶ 15 U.S.C. 78f(b)(4).

⁷ 15 U.S.C. 78f(b)(8).

discount reflects the intense competition among exchanges and the cost of producing market data as further described below.

Notwithstanding its determination that the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the *NetCoalition* [sic] court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive. The Exchange believes that a record may readily be established to demonstrate the competitive nature of the market in question.

For the reasons discussed above, the Exchange believes that the Dodd-Frank Act amendments to Section 19 materially alter the scope of the Commission's review of future market data filings, by creating a presumption that all fees may take effect immediately, without prior analysis by the Commission of the competitive environment. Even in the absence of this important statutory change, however, the Exchange believes that a record may readily be established to demonstrate the competitive nature of the market in question.

There is intense competition between exchanges that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which exchange to post an order will depend on the attributes of the exchange where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without the prospect of a taking order seeing and reacting to a posted order on a particular exchange, the posting of the order would accomplish little. Without trade executions, exchange data products cannot exist. Data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that an exchange earns reflects the revenues it

receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the broker-dealer will choose not to buy it.

Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable. Thus, a super-competitive increase in the fees charged for either transactions or data has the potential to impair revenues from both products. "No one disputes that competition for order flow is 'fierce'."⁸ However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus,

because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among exchanges can be expected to constrain the aggregate return each exchange earns from the sale of its joint products, but different exchanges may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some exchanges may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other exchanges may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end users. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers.

⁸ *NetCoalition*, at 24.

Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract “eyeballs” that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue.

Although the business models may differ, these vendors’ pricing discipline is the same: they can simply refuse to purchase any proprietary data product that fails to provide sufficient value. The Exchange and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,⁹ and subparagraph (f)(2) of Rule 19b-4 thereunder,¹⁰ because it establishes a due, fee, or other charge imposed by ISE Gemini.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-ISEGemini-2015-26 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-ISEGemini-2015-26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-ISEGemini-2015-26, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30089 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76501; File No. SR-ISE-2015-40]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 6, 2015, the International Securities Exchange, LLC (the “Exchange” or “ISE”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

ISE proposes to amend the Schedule of Fees as described in more detail below. The text of the proposed rule change is available on the Exchange’s Internet Web site at <http://www.ise.com>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Schedule of Fees to offer a one (1) month free trial of the

⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁰ 17 CFR 240.19b-4(f)(2).

¹¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

ISE Open/Close Trade Profile End of Day market data offering to all members and non-members who have never before subscribed to the offering and to remove the discounts offered to subscribers of multiple market data feeds.

ISE Open/Close Trade Profile

ISE currently sells a market data offering comprised of the entire opening and closing trade data of ISE listed options of both customers and firms, referred to by the Exchange as the ISE Open/Close Trade Profile. The ISE Open/Close Trade Profile offering is subdivided by origin code (*i.e.*, customer or firm) and the customer data is then further subdivided by order size. The volume data is summarized by day and series (*i.e.*, symbol, expiration date, strike price, call or put). The ISE Open/Close Trade Profile enables subscribers to create their own proprietary put/call calculations. The data is compiled and formatted by ISE as an end of day file (“ISE Open/Close Trade Profile End of Day”). This market data offering is currently available to both members and non-members on an annual subscription basis. The current subscription rate for both members and non-members is \$750 per month with an annual subscription.

The Exchange now proposes to amend its Schedule of Fees to offer a one (1) month free trial of the ISE Open/Close Trade Profile End of Day market data offering to all members and non-members that have never before subscribed to the offering. This will give potential subscribers the ability to use and test the data offering before signing up for an annual subscription.

Multi-Fee Discount

The Exchange currently offers five real-time market data feed offerings.³ In order to encourage subscriptions to multiple market data feeds, ISE adopted a multi-product subscription discount, which offers a ten percent (10%) discount for subscribers who subscribe to two feeds and twenty percent (20%) discount for subscribers who subscribe to three feeds.⁴ The Exchange now proposes to remove the discounts for subscribers of multiple feeds.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

the provisions of Section 6 of the Act,⁵ in general, and Section 6(b)(4) of the Act,⁶ in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

In particular, the Exchange believes the proposed free trial is reasonable and equitable because it gives potential subscribers the ability to use and test the ISE Open/Close Trade Profile End of Day offering prior to committing to an annual subscription. Furthermore, the Exchange believes that the proposed free trial is not unfairly discriminatory because it is available to all similarly-situated market participants—members and non-members who have never subscribed to the market data offering. Similarly, the removal of the multi-product subscription discount is also reasonable and equitable because the ISE believes the discount is no longer necessary to encourage multiple subscriptions. Further, the Exchange believes that the proposed removal of the discount is not unfairly discriminatory because it applies to all members and non-members who are subscribers to the feeds.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁷ the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. First, the proposed free trial does not affect competition because it is designed to give potential subscribers the ability to use and test the ISE data offering prior to committing to an annual subscription. Next, the removal of the multi-product, market data discount reflects the intense competition among exchanges and the cost of producing market data as further described below.

Notwithstanding its determination that the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the *NetCoalition* [sic] court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive. The Exchange believes that a record may readily be established to demonstrate the competitive nature of the market in question.

For the reasons discussed above, the Exchange believes that the Dodd-Frank Act amendments to Section 19 materially alter the scope of the Commission's review of future market data filings, by creating a presumption that all fees may take effect immediately, without prior analysis by the Commission of the competitive environment. Even in the absence of this important statutory change, however, the Exchange believes that a record may readily be established to demonstrate the competitive nature of the market in question.

There is intense competition between exchanges that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which exchange to post an order will depend on the attributes of the exchange where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without the prospect of a taking order seeing and reacting to a posted order on a particular exchange, the posting of the order would accomplish little. Without trade executions, exchange data products cannot exist. Data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that an exchange earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected

³ The market data feeds are: Real-time Depth of Market Raw Data Feed, ISE Order Feed, ISE Top Quote Feed, ISE Spread Feed, and ISE Implied Volatility and Greeks Feed.

⁴ See Securities Exchange Act Release No. 34-65002 (August 1, 2011), 76 FR 47630 (August 5, 2011) (SR-ISE-2011-50).

⁵ 15 U.S.C. 78f.

⁶ 15 U.S.C. 78f(b)(4).

⁷ 15 U.S.C. 78f(b)(8).

value, the broker-dealer will choose not to buy it.

Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable. Thus, a super-competitive increase in the fees charged for either transactions or data has the potential to impair revenues from both products. "No one disputes that competition for order flow is 'fierce'."⁸ However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among exchanges can be expected to constrain the aggregate return each exchange earns from the sale of its joint products, but different exchanges may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some exchanges may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other exchanges may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end users. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract "eyeballs" that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: they can simply refuse to purchase any proprietary data product that fails to provide sufficient value. The Exchange and other producers of proprietary data products must understand and respond to these

varying business models and pricing disciplines in order to market proprietary data products successfully.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,⁹ and subparagraph (f)(2) of Rule 19b-4 thereunder,¹⁰ because it establishes a due, fee, or other charge imposed by ISE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-ISE-2015-40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-ISE-2015-40. This file number should be included on the subject line if email is used. To help the Commission process and review your

⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁰ 17 CFR 240.19b-4(f)(2).

⁸ *NetCoalition*, at 24.

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-ISE-2015-40, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30090 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76487; File No. SR-BX-2015-068]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to BX PRISM

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 9, 2015, NASDAQ OMX BX, Inc. ("BX" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been

prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX Rules at Chapter VI, Section 9, entitled "Price Improvement Auction ("PRISM")," to correct two cross-references to BX Rules. The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqomxbx.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BX Rules at Chapter VI, Section 9, entitled "Price Improvement Auction ("PRISM")" to correct two cross-references to BX Rules. Specifically, the Exchange cited to its Size Pro-Rata allocation algorithm in the BX PRISM Rule at Chapter VI, Section 9(ii)(E). The cite was to Chapter VI, Section 10(1)(C)(1)(a) when it should have cited to Section 10(1)(C)(2). Further, the Exchange cited to its Price/Time allocation algorithm in the BX PRISM Rule at Chapter VI, Section 9(ii)(F). The cite was to Chapter VI, Section 10(1)(C)(2)(1) when it should have cited to Section 10(1)(C)(1). These clarifications to the BX PRISM rule will update the Rulebook and help avoid confusion for Participants. The proposed changes are non-substantive rule changes.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

of the Act³ in general, and furthers the objectives of Section 6(b)(5) of the Act⁴ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by correcting citation errors within the BX Rulebook.

The Exchange's proposal to correct the citations will serve to avoid confusion as to the correct algorithm. The proposed changes are non-substantive rule changes.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose any burden on competition, rather, the non-substantive rule changes correct incorrect references within the Rulebook. As a result, there will be no substantive changes to the Exchange's operations or its rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act⁵ and Rule 19b-4(f)(6) thereunder.⁶ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)

³ 15 U.S.C. 78f(b).

⁴ 15 U.S.C. 78f(b)(5).

⁵ 15 U.S.C. 78s(b)(3)(A)(iii).

⁶ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

of the Act and Rule 19b-4(f)(6)(iii) thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has stated that updating the existing rule text to reflect the correct citations sooner, rather than later, will avoid confusion for Participants. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because this waiver will enable the Exchange to provide the correct citations to the applicable allocation rules for its PRISM rule in a timely manner, and thereby avoid confusion for the Exchange's Participants with respect to how PRISM executions would be allocated.⁷ For this reason, the Commission hereby waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing.⁸

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)⁹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

⁷ The Exchange stated in its proposal for the PRISM rule that it anticipated that it would deploy the PRISM mechanism within 45 days of Commission approval. See Securities Exchange Act Release No. 75827 (Sept. 30, 2015), 80 FR 54601 (Sept. 10, 2015) (notice for SR-BX-2015-032). The Commission approved the proposed PRISM rule on October 29, 2015. See Securities Exchange Act Release No. 76301, 80 FR 68347 (Nov. 4, 2015) (order approving SR-BX-2015-032).

⁸ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁹ 15 U.S.C. 78s(b)(2)(B).

- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2015-068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2015-068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2015-068, and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30079 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76495; File No. SR-BX-2014-048]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Order Granting an Extension To Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program Until December 1, 2016

November 20, 2015.

On November 28, 2014, the Commission issued an order pursuant to its authority under Rule 612(c) of Regulation NMS¹ ("Sub-Penny Rule") that granted the NASDAQ OMX BX, Inc. ("BX" or "Exchange") a limited exemption from the Sub-Penny Rule in connection with the operation of the Exchange's Retail Price Improvement Program ("RPI Program").² The limited exemption was granted concurrently with the Commission's approval of the Exchange's proposal to adopt the RPI Program on a one-year pilot term. The Commission granted the exemption coterminous with the effectiveness of the RPI Program—both the RPI Program and the exemption are scheduled to expire on December 1, 2015.

The Exchange now seeks to extend the exemption until December 1, 2016.³ The Exchange's request was made in conjunction with an immediately effectively filing that extends the operation of the RPI Program until December 1, 2016.⁴ In its request to extend the exemption, the Exchange notes that given the gradual implementation of the RPI Program and the preliminary participation and results, extending the exemption would provide additional opportunities for greater participation and assessment of the results. Accordingly, the Exchange has asked additional time to allow it and the Commission to analyze data concerning the RPI Program, which the Exchange committed to provide to the Commission.⁵ For this reason and the reasons stated in the RPI Approval Order originally granting the limited exemption, the Commission, pursuant to its authority under Rule 612(c) of Regulation NMS, finds that pursuant to its authority under Rule 612(c) of

¹ 17 CFR 242.612(c).

² See Securities Exchange Act Release No. 73702, 79 FR 72049 (December 4, 2014) (SR-BX-2014-048) ("RPI Approval Order").

³ See Letter from Jeffrey S. Davis, Vice President & Deputy General Counsel, Exchange, to Brent J. Fields, Secretary, Commission, dated November 12, 2015.

⁴ See SR-BX-2015-073.

⁵ See RPI Approval Order, *supra* note 2.

¹⁰ 17 CFR 200.30-3(a)(12).

Regulation NMS, extending the exemption is appropriate in the public interest and consistent with the protection of investors.

Therefore, it is hereby ordered that, pursuant to Rule 612(c) of Regulation NMS, the Exchange is granted an extension of the limited exemption from Rule 612 of Regulation NMS that allows the Exchange to accept and rank orders priced equal to or greater than \$1.00 per share in increments of \$0.001, in connection with the operation of its RPI Program, until December 1, 2016.

The limited and temporary exemption extended by this Order is subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Act. Responsibility for compliance with any applicable provisions of the Federal securities laws must rest with the persons relying on the exemption that are the subject of this Order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30084 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76488; File No. SR-C2-2015-032]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Technical Disconnect Mechanism

November 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 9, 2015, C2 Options Exchange, Incorporated (the "Exchange" or "C2") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

⁶ 17 CFR 200.30-3(a)(83).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.48 related to the Exchange's Technical Disconnect Mechanism. The text of the proposed rule change is provided below. (additions are italicized; deletions are [bracketed])

C2 Options Exchange, Incorporated

Rules

* * * * *

Rule 6.48. Technical Disconnect

(a) When a CBOE Application Server ("CAS") loses communication with a Client Application such that a CAS does not receive an appropriate response to a Heartbeat Request within "x" period of time, the Technical Disconnect Mechanism will automatically logoff the Permit Holder's affected Client Application and [, if applicable, will] automatically cancel all the Permit Holder's Market-Maker quotes, *if applicable, and open orders with a time-in-force of "day" ("day orders"), if the Permit Holder enables that optional service*, posted through the affected Client Application. The following describes how the Technical Disconnect Mechanism works for each of the Exchange's application programming interfaces ("APIs"):

(i) *CBOE Market Interface 2.0 ("CMi 2") API*. A CAS shall generate a Heartbeat Request to a Client Application (i) after the CAS does not receive any messages from a particular Client Application for "n" period of time or (ii) after every "n" period of time. A Permit Holder shall determine the value of "n." In no event shall "n" be less than three (3) seconds or exceed twenty (20) seconds. If a CAS generates a Heartbeat Request only after it does not receive any messages from a particular Client Application for "n" period of time, the value of "x" shall be set at a half (.5) second. If a CAS generates a Heartbeat Request every "n" period of time, the value of "x" shall be equal to the value of "n."

(ii) *Financial Information eXchange ("FIX") Protocol API*. A CAS shall generate a Heartbeat Message to a Client Application after the CAS does not receive any messages from a particular Client Application for "n" period of time. If the CAS does not receive a response to the Heartbeat Message from the Client Application for "n" period of time, the CAS shall generate a Heartbeat Request to the Client Application. A Permit Holder shall determine the value of "n" at logon. In no event shall "n"

be less than five (5) seconds. The value of "x" shall be equal to the value of "n."

(b) The Technical Disconnect Mechanism is enabled for all Permit Holders and may not be disabled by Permit Holders, *except the automatic cancellation of a Permit Holder's day orders is an optional service that the Permit Holder may enable or disable through the API.*

(c) The trigger of the Technical Disconnect Mechanism is event- and Client Application- specific. The automatic cancellation of a Market-Maker's quotes (*if applicable*) or a Permit Holder's day orders (*if enabled by the Permit Holder*) entered into a CAS via a particular Client Application will neither impact nor determine the treatment of the quotes of the same or other Market-Makers or orders of the same Permit Holder entered into the CAS via a separate and distinct Client Application. *Except for day orders the Technical Disconnect Mechanism automatically cancels if a Permit Holder enables that optional service*, [T]he Technical Disconnect Mechanism will not impact or determine the treatment of orders a Permit Holder previously entered into the CAS.

. . . Interpretations and Policies:

.01 No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (<http://www.c2exchange.com/Legal/>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.48 related to the Exchange's Technical Disconnect Mechanism. Rule 6.48(a) provides that when a CBOE

Application Server (“CAS”)³ loses communication with a Client Application⁴ such that a CAS does not receive an appropriate response to a Heartbeat Request⁵ within “x” period of time, the Technical Disconnect Mechanism will automatically logoff the Permit Holder’s affected Client Application. If that occurs, the current rule provides that the Technical Disconnect Mechanism, if applicable, will automatically cancel all the Permit Holder’s Market-Maker quotes posted through the affected Client Application.⁶ The Technical Disconnect Mechanism is intended to help mitigate the potential risks associated with a loss of communication with a Client Application, such as erroneous or unintended executions for stale quotes that are resting in the C2 book. This mechanism serves to assist a Permit Holder when a technical or system issue occurs, as well as assist the Exchange in maintaining a fair and orderly market.

The proposed rule change provides Permit Holders with an optional service that, if enabled by a Permit Holder, will cause the Technical Disconnect Mechanism to also automatically cancel all the Permit Holder’s open orders with a time-in-force of “day” (“day orders”) posted through the affected Client Application if the CAS loses communication with the Client Application. The proposed rule change amends Rule 6.48(b) to provide that the Permit Holder may enable or disable this optional service through its application programming interface (“API”) (all other aspects of the Technical Disconnect Mechanism continue to otherwise be enabled for all Permit Holders and may not be disabled

by Permit Holders).⁷ The proposed rule change makes corresponding changes to Rule 6.48(c) that indicate the Technical Disconnect Mechanism will automatically cancel a Permit Holder’s day orders (in addition to a Market-Maker’s quotes), if the Permit Holder enables the proposed optional service.⁸ As is the case in the event the Technical Disconnect Mechanism automatically logs a Permit Holder off and cancels its Market-Maker quotes (if applicable), if a Permit Holder enables this proposed optional service, and the Technical Disconnect Mechanism automatically logs a Permit Holder off and cancels the Permit Holder’s day orders due to lost communication with Permit Holder’s Client Application, the Permit Holder may send messages to the CAS to enter new orders once it reestablishes connectivity to the Client Application. In addition, any nonconnectivity will continue to be event- and Client Application-specific. In other words, any cancellation of day orders entered into a CAS via a particular Client Application will neither impact nor determine the treatment of the quotes of the same Permit Holder entered into a CAS via a separate and distinct Client Application. The Technical Disconnect Mechanism will not impact or determine the treatment of orders previously entered into a CAS if the Permit Holder does not enable this optional service, nor will it impact or determine the treatment of non-day orders previously entered into a CAS by the Permit Holder. The Exchange notes use of this service will be voluntary and within the sole discretion of each Permit Holder.

The proposed optional service is an additional preventative risk control measure that C2 is making available to Permit Holders. It is intended to help further mitigate the potential risks associated with a loss of communication with a Client Application. While orders may be static in nature and rest in the book, Permit Holders often enter day orders more frequently in response to then-current market conditions. Therefore, if a Permit Holder’s Client Application is disconnected for any period of time, it is possible that market conditions upon which it based its day orders may change during that time and make those orders stale. Consequently,

any resulting executions of those orders may be erroneous or unintended. The Exchange believes it is appropriate to limit this optional service to day orders and exclude good-til-cancelled orders,⁹ as those orders are intended to rest in the book for a period of time and thus have lower risk of erroneous or unintended executions during and after the Technical Disconnect Mechanism logs off a Permit Holder.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹⁰ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹² requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change helps maintain a fair and orderly market and protects investors and the public interest. The Technical Disconnect Mechanism is a valuable tool that is designed to help maintain a fair and orderly market. The Exchange believes that providing Permit Holders with the option to have the Technical Disconnect Mechanism cancel its day orders, in addition to Market-Maker quotes (if applicable), further mitigates the potential risks associated with a loss in communication with a Client Application. The Exchange believes it is reasonable to offer to cancel only day orders. Unlike non-day orders, day orders are more likely to be reflective of then-current market conditions and are intended to rest in the book for a limited period of time. As a result, in the event

³ C2 currently has numerous CASs serving Permit Holders.

⁴ For relevant purposes, a “Client Application” is the system component, such as a C2-supported workstation or a Permit Holder’s custom trading application, through which a Permit Holder communicates its quotes and/or orders to a CAS. Messages are passed between a Client Application and a CAS. A Market-Maker may send quotes to the Exchange from one or more Client Applications, and a Permit Holder may send orders to the Exchange from one or more Client Applications.

⁵ A “Heartbeat Request” refers to a message from a CAS to a Client Application to check connectivity and which requires a response from the Client Application in order to avoid logoff. The Heartbeat Request acts as a virtual pulse between a CAS and a Client Application and allows a CAS to continually monitor its connection with a Client Application. Failure to receive a response to a Heartbeat Request within the Heartbeat Response Time is indicative of a technical or system issue.

⁶ See Rule 6.48 and Securities Exchange Act Release No. 34-70112 (August 5, 2013), 78 FR 48738 (August 9, 2013) (SR-C2-2013-029) for further information regarding the Technical Disconnect Mechanism.

⁷ C2 currently makes available two APIs: CBOE Market Interface 2.0 (“CMI 2”) and Financial Information eXchange Protocol (“FIX”).

⁸ In addition, the proposed rule change makes nonsubstantive changes to Rule 6.48 including moving the phrase “if applicable” to ensure that phrase clearly applies to the cancellation of a Market-Maker’s quotes (as that functionality only applies to Permit Holders that are Market-Makers).

⁹ Currently, the Exchange offers two time-in-force order types: day and good-til-cancelled. The proposed optional service will apply to orders that include the “day” marking.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹² *Id.*

that a CAS loses connectivity with a Client Application, execution of day orders during that time are more likely to result in erroneous or unintended executions, while risk of such executions is lower for non-day orders. The proposed optional service protects Permit Holders from these potential erroneous or unintended executions, as well as protects investors and the efficiency and fairness of the markets in general. The Exchange believes this functionality enhances the overall market quality for options traded on C2. The Exchange notes that other exchanges offer their members similar services that cancels a member's orders if it disconnects from the exchange.¹³

The Exchange also believes that the proposed rule change is designed to not permit unfair discrimination among market participants. Use of the optional service will be voluntary and within the sole discretion of each Permit Holder. The proposed optional service is available to all Permit Holders and will apply to the same order types of all Permit Holders.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe the proposed rule change will cause any burden on intramarket competition because the optional service will be available to all Permit Holders. Use of this optional service will be within the sole discretion of each Permit Holder. The proposed rule change will have no impact on Permit Holders that do not enable the proposed optional service. For Permit Holders that elect to enable the proposed optional service, the only impact on those Permit Holders will be cancellation of day orders (in addition to Market-Maker quotes) upon loss of connectivity. The Technical Disconnect Mechanism will otherwise continue to function in the same manner as it does today. Further, the Exchange does not

¹³ See, e.g., BZX Exchange US Equities FIX Specification, Version 1.33.5 (October 8, 2014), available at http://www.batstrading.com/resources/membership/BATS_FIX_Specification.pdf (see Section 5.1 for description of automatic cancel on disconnection or malfunction); MIAX Options Market Protections Handout (March 2015), available at https://www.miaxoptions.com/sites/default/files/MIAX_Market_Protections_March_2015.pdf (see page 5 for description of auto cancel on disconnect order protection); and NYSE UTPDirect (CGC Binary) API Specification, V1.4 (February 26, 2015), available at https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSEUTPDirect_Specification.pdf (see Section 3.8 for description of cancel on disconnect service).

believe that such change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change modifies a mechanism available on C2's system and applies only to orders entered on C2. The Exchange notes that, should the proposed change make C2 a more attractive place for trading, market participants trading on other exchanges are welcome to become Permit Holders and trade at C2 if they determine that this proposed change has made C2 more attractive or favorable. Additionally, as discussed above, other options exchanges offer their members similar functionality.¹⁴

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and paragraph (f) of Rule 19b-4¹⁶ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-C2-2015-032 on the subject line.

¹⁴ *Id.*

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f).

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-C2-2015-032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-C2-2015-032 and should be submitted on or before December 18, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-30074 Filed 11-25-15; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 14467 and # 14468]

Colorado Disaster # CO-00073

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Administrative disaster declaration for the State of COLORADO dated 09/16/2015.

¹⁷ 17 CFR 200.30-3(a)(12).

Incident: Landslides.
Incident Period: 04/24/2015 and continuing through 11/16/2015.
Effective Date: 11/19/2015.
Physical Loan Application Deadline Date: 11/16/2015.
Economic Injury (EIDL) Loan Application Deadline Date: 06/16/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Administrative disaster declaration for the State of Colorado, dated 09/16/2015 is hereby amended to establish the incident period for this disaster as beginning 04/24/2015 and continuing through 11/16/2015.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: November 19, 2015.

Maria Contreras-Sweet,
Administrator.

[FR Doc. 2015-30233 Filed 11-25-15; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14544 and #14545]

South Carolina Disaster # SC-00034

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of South Carolina dated 11/19/2015.

Incident: Severe Storms and Flooding.
Incident Period: 11/04/2015.
Effective Date: 11/19/2015.
Physical Loan Application Deadline Date: 01/19/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 08/19/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the

Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Marion.

Contiguous Counties:

South Carolina; Dillon; Florence; Georgetown; Horry; Williamsburg.
 The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners With Credit Available Elsewhere	3.625
Homeowners Without Credit Available Elsewhere	1.813
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14544 6 and for economic injury is 14545 0

The State which received an EIDL Declaration # is South Carolina.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: November 19, 2015.

Maria Contreras-Sweet,
Administrator.

[FR Doc. 2015-30234 Filed 11-25-15; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2015-63]

Petition for Exemption; Summary of Petition Received; Israel Aerospace Industries Ltd

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation

in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 17, 2015.

ADDRESSES: Send comments identified by docket number FAA-2015-4012 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brent Hart (202) 267-4034, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 20, 2015.

Dale Bouffiuo,
Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2015-4012

Petitioner: Israel Aerospace Industries Ltd

Section(s) of 14 CFR Affected:

45.13(a)(1)

Description of Relief Sought: Israel Aerospace Industries Ltd (IAI) seeks relief from the requirements of § 45.13(a)(1) to permit relief from the requirement to list the aircraft builder's name on the aircraft identification plate for Gulfstream G150 and G280 model aircraft.

[FR Doc. 2015-30109 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2015-0337]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 44 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2015-0337 using any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Mail: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- Hand Delivery: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Fax: 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any

personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 44 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

Michael E. Adrieansen

Mr. Adrieansen, 34, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Adrieansen understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Adrieansen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

David A. August

Mr. August, 58, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. August understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. August meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Colorado.

Samuel M. Balis

Mr. Balis, 73, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Balis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Balis meets the requirements of the vision standard at 49 CFR

391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

Dwight J. Banks

Mr. Banks, 66, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Banks understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Banks meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

David R. Bauman, III

Mr. Bauman, 43, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bauman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bauman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a chauffeur's license from Michigan.

George E. Britt

Mr. Britt, 43, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Britt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV

safely. Mr. Britt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Cris A. Brown

Mr. Brown, 54, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Michigan.

Dustin D. Brown

Mr. Brown, 34, has had ITDM since 1983. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Wisconsin.

Thomas W. Camp

Mr. Camp, 58, has had ITDM since 1993. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Camp understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Camp meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Virginia.

Nathan G. Carnes

Mr. Carnes, 37, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Carnes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Carnes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oregon.

Vincenzo A. Cortese

Mr. Cortese, 57, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Cortese understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Cortese meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable proliferative diabetic retinopathy. He holds a Class B CDL from Connecticut.

Vernon L. Davidson

Mr. Davidson, 66, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in

the last 5 years. His endocrinologist certifies that Mr. Davidson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Davidson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Nebraska.

Damiano DiFlorio

Mr. DiFlorio, 66, has had ITDM since 2002. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. DiFlorio understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. DiFlorio meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from New Jersey.

Matthew D. Fox

Mr. Fox, 29, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fox understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fox meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Indiana.

Sammy N. Fox

Mr. Fox, 69, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the

past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fox understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fox meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Chadwick E. Gainey

Mr. Gainey, 49, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gainey understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gainey meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

Jamal A. George

Mr. George, 36, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. George understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. George meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Ohio.

John M. Halm

Mr. Halm, 55, has had ITDM since 2006. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the

past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Halm understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Halm meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Washington.

William R. Hardy

Mr. Hardy, 59, has had ITDM since 2004. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hardy understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hardy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a chauffeur's license from Michigan.

Craig A. Hendrickson

Mr. Hendrickson, 46, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hendrickson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hendrickson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

William D. Hoopes

Mr. Hoopes, 53, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the

assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hoopes understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hoopes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Ohio.

Jeffrey L. Jones

Mr. Jones, 44, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jones understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jones meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Arkansas.

Brent S. LaBree, II

Mr. LaBree, 40, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. LaBree understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. LaBree meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Vermont.

Michael C. Landers

Mr. Landers, 54, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no

severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Landers understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Landers meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

Duane F. Light

Mr. Light, 63, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Light understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Light meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Connecticut.

Darold W. Mahlstedt

Mr. Mahlstedt, 68, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mahlstedt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mahlstedt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Iowa.

Robert L. McConnell

Mr. McConnell, 59, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McConnell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McConnell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Mark R.S. McMillan

Mr. McMillan, 59, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McMillan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McMillan meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

Keith R. Miller

Mr. Miller, 60, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Miller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Miller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His

ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from West Virginia.

Randall T. Mitchell

Mr. Mitchell, 50, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mitchell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mitchell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Alabama.

Ernest Nez, Sr.

Mr. Nez, 56, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Nez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Nez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Arizona.

Shawn P. O'Malley

Mr. O'Malley, 45, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. O'Malley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. O'Malley meets the

requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Felipe N. Perez

Mr. Perez, 26, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Perez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Perez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Florida.

Kenneth W. Phillips

Mr. Phillips, 66, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Phillips understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Phillips meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Tony L. Prouty

Mr. Prouty, 32, has had ITDM since 1986. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Prouty understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV

safely. Mr. Prouty meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Iowa.

Jim T. Repass

Mr. Repass, 56, has had ITDM since 1985. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Repass understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Repass meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Indiana.

Jakob K. Siler

Mr. Siler, 28, has had ITDM since 1995. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Siler understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Siler meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oklahoma.

Darren G. Steil

Mr. Steil, 46, has had ITDM since 1986. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Steil understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Steil meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Iowa.

Steven P. Stokke

Mr. Stokke, 53, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stokke understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stokke meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a class A CDL from Wisconsin.

Richard E. Wagner

Mr. Wagner, 74, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wagner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wagner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Harold W. Welch

Mr. Welch, 76, has had ITDM since 1998. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in

the last 5 years. His endocrinologist certifies that Mr. Welch understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Welch meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Nebraska.

John F. Wesoloski, Jr.

Mr. Wesoloski, 57, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wesoloski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wesoloski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from North Dakota.

Levon Wright, Sr.

Mr. Wright, 65, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wright understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wright meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Florida.

Tadeusz S. Wrzesinski

Mr. Wrzesinski, 60, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in

impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wrzesinski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wrzesinski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Pennsylvania.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).¹ The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136 (e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and

¹ Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-2015-0337 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-2015-0337 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to the proposed rulemaking.

Issued on: November 16, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015-30151 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2007-29035; FMCSA-2008-0293; FMCSA-2009-0242; FMCSA-2011-0277; FMCSA-2011-0278; FMCSA-2013-0184; FMCSA-2013-0187; FMCSA-2013-0190]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions of 133 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. FMCSA has statutory authority to exempt individuals from this rule if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: Each group of renewed exemptions are effective from the dates stated in the discussions below. Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. FMCSA-2007-29035; FMCSA-2008-0293; FMCSA-2009-0242; FMCSA-2011-0277; FMCSA-2011-0278; FMCSA-2013-0184; FMCSA-2013-0187; FMCSA-2013-0190, using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received

without change to <http://www.regulations.gov>, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001. Office hours are from 8 a.m. to 5:30 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the Federal Motor Carrier Safety Regulations 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 133 individuals listed in this notice have recently become eligible for a renewed exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. The drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that

would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

Exemption Decision

This notice addresses 133 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. These 133 drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. Therefore, FMCSA has decided to extend each exemption for a renewable two-year period. Each individual is identified according to the renewal date.

The exemptions are renewed subject to the following conditions: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual submit an annual ophthalmologist's or optometrist's report; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. The following groups of drivers received renewed exemptions in the month of December and are discussed below.

As of December 1, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 10 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (74 FR 48338; 74 FR 62883):

Charles E. Boyd (NE)
Warren B. Copple, Jr. (MI)
Hernan Hernandez (CT)

Jeffrey E. Kiehl (MI)
Jesus G. Maesse (TX)
Jackson R. Olive (NY)
Thomas N. Pico (PA)
Paul Ramirez (OK)
Jon C. Thomas (MT)
Dennis M. Thyfault (UT)

The drivers were included in Docket No. FMCSA-2009-0242. Their exemptions are effective as of December 1, 2015 and will expire on December 1, 2017.

As of December 10, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 7 individuals, have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (73 FR 63042; 73 FR 75163):

Herschel J. Crawford (AK)
James E. Gaines (NJ)
Allan D. Gralapp (IA)
Scott L. Halm (OH)
Jason P. Smith (GA)
Dean A. Sullivan (KY)
Lawrence W. Thomas (AR)

The drivers were included in Docket No. FMCSA-2008-0293. Their exemptions are effective as of December 10, 2015 and will expire on December 10, 2017.

As of December 17, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 60 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (78 FR 63298; 78 FR 76397):

James L. Barnes (GA)
Toni Benfield (SC)
Peter J. Benz (FL)
Robert J. Berger, III (PA)
Daniel A. Bryan (PA)
Travis D. Clarkston (IN)
Romero Coleman (WI)
Michael L. Collins (WA)
Thomas S. Crawford (NY)
Stephen A. Cronin (FL)
Steven M. Dent (IA)
John S. Duvall (PA)
Robert S. Engel (IN)
Steven M. Ference (CT)
David W. Foster (TN)
Francis M. Garlach III (PA)
Allen D. Goddard (MO)
Brian L. Gregory (IL)
Alfonso Grijalva (CA)
Jason E. Jacobus (KY)
Bobby H. Johnson (GA)
Isadore Johnson Jr. (NY)
Jerry D. Joseph (OH)
Neal S. Kassebaum (TN)
Ervin A. Klocko, Jr.
Kevin E. Kneff (MO)
Margaret Lopez (NY)
John D. May (KS)

Kenneth B. Maynard, Jr. (NH)
Mike C. McDowell (TX)
Charles B. McKay (FL)
Norman C. Mertz (PA)
Travis F. Moon (GA)
Ronald Mooney (ID)
Martin J. Mostyn (OH)
Floyd P. Murray, Jr. (UT)
Steven D. Nowakowski (MD)
Gary D. Peters (NE)
Mark A. Pille (IA)
Stephen Plesz (CT)
Glen E. Pozernick (ID)
Jody R. Prause (MI)
Walter A. Przewrocki, Jr. (PA)
Andrew Quaglia (NY)
Stanley A. Sabin (KY)
Joseph F. Schafer, Jr. (PA)
Francis J. Schultz (PA)
Gary A. Sjkovist (ND)
Gary L. Snelling (AL)
Charles W. Sterling (WA)
Thomas L. Stoudnour (PA)
Matthew S. Thompson (PA)
Robin S. Travis (CO)
Richard A. Treadwell (PA)
James R. Troutman (PA)
William R. Van Gog (WA)
Charles S. Watson (IL)
William E. Wyant III (IA)
Mark A. Yurian (MT)
David M. Zanicky (PA)

The drivers were included in Docket No. FMCSA-2013-0187. Their exemptions are effective as of December 17, 2015 and will expire on December 17, 2017.

As of December 19, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 27 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (72 FR 62514; 72 FR 71996; 76 FR 64165; 76 FR 78718):

Robin R. Baumgartner (WI)
Joseph K. Beasley (GA)
Toni A. Brown (AR)
Glenn W. Burke (NY)
David P. Charest (FL)
Charles Demesmin (NJ)
Derek E. Dowling (PA)
Donald E. Dupke, Jr. (IN)
Frederick E. Dyer (MA)
Donald N. Ellis (IN)
Tim E. Holmberg (WI)
Russell D. Jordan (ND)
Warren D. Knabe (NE)
Jackie L. Lane (TX)
Dennis L. Lorenz (IN)
Robert J. Malone (NJ)
Clayton A. Powers (CA)
Dennis R. Scheel (SD)
Michael K. Schulist (MI)
Andrew P. Shirk (MS)
Jerry L. Smit (MN)
Reese L. Sullivan (TX)

Randy J. Voss (IL)
 Robert M. Walker (PA)
 Robert E. Weiss (MI)
 Robert A. Wild (OR)
 Randy L. Wyant (OR)

The drivers were included in Docket No. FMCSA–2007–29035; FMCSA–2011–0277. Their exemptions are effective as of December 19, 2015 and will expire on December 19, 2017.

As of December 22, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 11 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (76 FR 66120; 76 FR 79759):

Lennie D. Cook (OH)
 David R. Cornelius (IL)
 Scott A. Edwards (PA)
 Ronald J. Ezell (MO)
 Marcus M. Gagne (ME)
 David P. Govero (MO)
 Christopher A. Jones (WY)
 Donald R. McClure, Jr. (PA)
 Clyde G. Rishel, Jr. (PA)
 Kurt Schneider (VT)
 Douglas O. Sundby (ND)

The drivers were included in Docket No. FMCSA–2011–0278. Their exemptions are effective as of December 22, 2015 and will expire on December 22, 2017.

As of December 24, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 17 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (78 FR 64267; 78 FR 77784):

John D. Clark (NJ)
 David S. Monroe (KS)
 William I. Harbolt (MT)
 Mark G. Kahler (TX)
 Larry W. Hines (NM)
 Theair L. Coleman (VA)
 Michael W. McCrary (GA)
 Jerry D. Zimmerman (ND)
 James S. Tracy (ID)
 John Baltich (PA)
 Donald A. Spivey (TN)
 Thomas B. Quirk (CT)
 Steven M. Oliver (AZ)
 Sean T. McMahan (WI)
 David G. Shultz (PA)
 Ryan L. Harrier (MI)
 John E. Parker (KS)

The drivers were included in Docket No. FMCSA–2013–0184. Their exemptions are effective as of December 24, 2015 and will expire on December 24, 2017.

As of December 31, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, Gary L. Crawford (OH), has satisfied the renewal

conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (78 FR 65034; 79 FR 3917).

The driver was included in Docket No. FMCSA–2013–0190. The exemption is effective as of December 31, 2015 and will expire on December 31, 2017.

Each of the 133 drivers in the aforementioned groups qualifies for a renewal of the exemption. They have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of the 133 drivers for a period of two years is likely to achieve a level of safety equal to that existing without the exemption. The drivers were included in docket numbers FMCSA–2007–29035; FMCSA–2008–0293; FMCSA–2009–0242; FMCSA–2011–0277; FMCSA–2011–0278; FMCSA–2013–0184; FMCSA–2013–0187; FMCSA–2013–0190.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 28, 2015.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 133 individuals from rule prohibiting persons with ITDM from operating CMVs in interstate commerce in 49 CFR 391.41(b)(3). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the medical condition of each applicant for an exemption from rule prohibiting persons with ITDM from operating

CMVs in interstate commerce. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket numbers FMCSA–2007–29035; FMCSA–2008–0293; FMCSA–2009–0242; FMCSA–2011–0277; FMCSA–2011–0278; FMCSA–2013–0184; FMCSA–2013–0187; FMCSA–2013–0190 and click the search button. When the new screen appears, click on the blue “Comment Now!” button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, to submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA–2007–29035; FMCSA–2008–

0293; FMCSA–2009–0242; FMCSA–2011–0277; FMCSA–2011–0278; FMCSA–2013–0184; FMCSA–2013–0187; FMCSA–2013–0190 and click “Search.” Next, click “Open Docket Folder” and you will find all documents and comments related to the proposed rulemaking.

Issued on: November 16, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–30164 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0397]

Commercial Driver’s License: Oregon Department of Transportation; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from the Oregon Department of Transportation (ODOT) for a limited exemption from the Agency’s commercial learner’s permit (CLP) requirement in 49 CFR 383.25(c). The regulation provides that the CLP be valid for no more than 180 days from the date of issuance. The State of issuance may renew the CLP for an additional 180 days without requiring the CLP holder to retake the general and endorsement knowledge tests. ODOT proposes that it be allowed to extend the 180-day timeline to one year for CLPs issued to its drivers for multiple reasons. ODOT believes that there would be no impact on safety if the exemption is granted. FMCSA requests public comment on ODOT’s application for exemption. In addition, because the issues concerning ODOT’s request could be applicable to each State, FMCSA requests public comments whether the exemption, if granted, should apply to all State Driver’s Licensing Agencies (SDLAs).

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2015–0397 using any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* 1–202–493–2251

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2015–0397), indicate the specific section of this document to

which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2015–0397” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may grant or not grant this application based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, “FMCSA–2015–0397” in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

ODOT requests an exemption from the Agency's CLP requirement in 49 CFR 383.25(c). The regulation provides that the CLP be valid for no more than 180 days from the date of issuance. The State may renew the CLP for an additional 180 days without requiring the CLP holder to retake the general and endorsement knowledge tests. ODOT proposes that it be allowed to extend the 180-day timeline to one year for CLPs issued to its drivers.

ODOT provided multiple reasons for regulatory relief from the CLP rule. First, ODOT believes that the 180-day time line required to renew the CLP adds nothing to the effectiveness of the rule itself, the purpose of which is to "enhance safety by ensuring that only qualified drivers are allowed to operate commercial vehicles on our nation's highways" (76 FR 26854, May 9, 2011). ODOT asserts that neither FMCSA staff nor the States were able to identify any highway safety enhancement arising from this requirement. ODOT states that it is unaware of any data suggesting that persons who have not renewed their CLP or obtained their CDL within six months pose less risk on the Nation's highways.

Second, ODOT agrees that requiring CLP holders to retake the knowledge test after not obtaining a CDL within one year improves highway safety, but disagrees that the requirement for renewal at six months is needed. According to ODOT, if the exemption is granted, ODOT's CLP would have a validity period of one year with no renewal allowed. All applicable knowledge tests would be required before a new CDL could be issued, which would accomplish the objective of not allowing a person to have a CLP longer than one year without passing knowledge tests.

The third reason for the request ODOT advises; is that Oregon's "Department of Motor Vehicle (DMV) field offices have a very large volume of work to accomplish and, at best, limited resources with which to accomplish it. Adding the bureaucratic requirement for a CLP holder to visit a DMV office and pay a fee in order to get a second six months of CLP validity will add unnecessary workload to offices already stretched to the limit. ODOT is confident there would be no negative impact on safety if the exemption is granted."

According to ODOT, "If this exemption is not granted, Oregon drivers with CLPs who have not passed the CDL skills test within six months of CLP issuance would have to go to a DMV office and pay for a renewal of the CLP. This would cause undue hardship to the drivers, from the perspectives of both their time and their pocketbooks. It would also cause undue hardship to our agency, where scarce resources would be used to process bureaucratic transactions that add nothing to highway safety." ODOT advises that it would not be able to change the validity period of the CLP until a statutory change can be made.

In addition, because the issues concerning ODOT's request could be applicable in each State, FMCSA requests public comment on whether the exemption, if granted, should apply to all SDLAs.

A copy of ODOT's application for exemption is available for review in the docket for this notice.

Dated: November 6, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015-30143 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2015-0371]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of 7 applications for exemptions from the cardiovascular standard [49 CFR 391.41(b)(4)]. These 7 individuals are requesting an exemption due to the

presence of implantable cardioverter defibrillators (ICD) as a result of their underlying cardiac condition. If granted, the exemptions would enable these individuals with ICDs to operate commercial motor vehicles (CMVs) in interstate commerce for up to 2 years.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2015-0371 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Follow the on-line instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov, at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200

New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission. To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number “FMCSA–2015–0371” and click the search button. When the new screen appears, click on the blue “Comment Now!” button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this notice, or to submit your comment online, go to www.regulations.gov and in the search box insert the docket number “FMCSA–2015–0371” and click “Search.” Next, click “Open Docket Folder” and you will find all documents and comments related to the proposed rulemaking.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** [49 CFR 381.315(a)]. The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also

provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The Agency may grant an exemption subject to specified terms and conditions. The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

The FMCSA provides medical advisory criteria for use by medical examiners in determining whether drivers with certain medical conditions should be certified to operate CMVs in interstate commerce. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4) indicate that the term “has no current clinical diagnosis of” is specifically designed to encompass:

“a clinical diagnosis of” (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term “known to be accompanied by” is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure.

Summary of Applications

Ellis James Benson

Mr. Benson is a 53 year old Class A CDL holder in Minnesota. A June 2, 2015 letter from his cardiologist reports that Mr. Benson’s defibrillator was implanted on November 12, 2008. His records show that his defibrillator delivered therapies on February 27, 2014, and on February 28, 2015. In 2008 (his most recent study) showed a left ejection fraction of 55–60%.

Jon Carey

Mr. Carey is a 51 year old route salesman in Colorado. A May 2015 letter from his cardiologist reports that Mr.

Carey’s ICD “was implanted in March 2009 after he experienced a ventricular fibrillation arrest”. “Since that incident, his defibrillator has never gone off and he’s had no progression of coronary disease”. Recent echocardiography shows “improved ventricular function with an EF of 40–50%”. “Mr. Carey is active without limitations without angina, heart failure, or arrhythmia symptoms”. “The patient is clear to receive a CDL license from my standpoint. I see no issues with him driving commercial vehicles.”

Martin Carter

Mr. Carter is a 47 year old Class A CDL holder in Maine. A March 11, 2015 letter from his cardiologist reports that Mr. Carter underwent ICD implantation on 4/1/2011. “At the time of the ICD placement, his ejection fraction was between 30–35%”. His cardiologists note that “since that time, the patient has gotten progressively stronger”. “Ejection fraction 10/5/2012 was 37% and 11/26/13 was 44%”. “The patient had a stress test 11/26/2013 which showed no inducible myocardial ischemia”. “In a patient such as this, the ICD would never have been considered for implantation”. “His ICD has never discharged and he has been followed regularly”. “The patient’s cardiovascular status has recovered to the point that the ICD is no longer medically necessary but no cardiologist is willing to remove the device”. “It is my medical opinion that the patient has recovered sufficiently from his ischemic cardiomyopathy that he no longer meets the restriction of ejection fraction less than 40% limiting his ability to drive. I would ask that he be considered for reinstatement of commercial tractor-trailer license”. “Prior to the placement of his ICD, Mr. Carter was treated medically and surgically and responded well”. “He had a near syncopal episode on 3/2/2010 felt to be secondary to excessive medication and dehydration. He has had no recurrences since that time.”

Carl Jeglum

Mr. Jeglum is a 58 year old Class A CDL holder in Washington. An October 22, 2015 letter from his cardiologist reports that in “March of 2005, (Mr. Jeglum) had an Internal Cardiac Defibrillator placed.” “Since then his implantable device has been checked frequently and has remained stable without further incident.” “The device has never been discharged or deployed since the time he has had the device in place.” “He has not had any ongoing cardiac symptoms and in my opinion is fully capable of performing his usual

duties as a driver as per the guidelines for the Department of Transportation.” Mr. Jeglum writes, “I already have a intrastate waiver with no problems in the past 10 years.”

William Kastner

Mr. Kastner is a 61 year old CDL holder in New Jersey. A May 2015 letter from his cardiologist reports that Mr. Kastner’s defibrillator “was implanted in 2006 after he experienced a myocardial infarction resulting in reduced left ventricular ejection fraction”. His cardiologist notes that “Mr. Kastner has never had an episode of syncope, symptomatic palpitations, loss of consciousness, cardiac arrest, documented ventricular tachycardia or ventricular fibrillation.” His electrophysiology group has recommended “that it is safe for him to continue to ride his motorcycle, and he has had no adverse events or effects from this”. He is followed regularly by his electrophysiologist office and has no untoward events with his defibrillator. “He has never had any syncope, palpitations, or discharges from his cardiac defibrillator.”

Mark Todd Smith

Mr. Smith is a 52 year old class A–CDL holder in Georgia. Medical documentation from his cardiologist between 2013 and June 2015 reports that he was upgraded from a dual chamber ICD to a biventricular ICD for ventricular arrhythmias. Mr. Smith had a pulmonary valve replacement in 2015. A September 2015 report from his cardiologist states “he has no complaints of PND (paroxysmal nocturnal dyspnea), orthopnea, LE (lower extremity) edema, syncope, or pre-syncope”. An October 2015 letter from his cardiologist reports that his ICD has “shown normal function”. “He also uses it as a pacemaker.” “Since 2014, he has not had ICD therapy because he underwent a procedure to correct that problem”. “Considering his cardiac issues, he is safer to drive professionally now than he ever has been.”

Andre Williams

Mr. Williams is a 57 year old CDL holder in Georgia. An August 2015 letter from his cardiologist reports that Mr. Williams’s ICD was implanted in February 2013. “His ICD has been checked every 6 months and has not fired/deployed”. “He has done well with no ICD shocks”.

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public

comment from all interested persons on the exemption applications described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in the notice.

Issued on: November 13, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–30156 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0394]

Driver Qualification Files: Application for Exemption; Atlantic and Pacific Freightways, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Atlantic and Pacific Freightways, Inc. (A&P) has applied for an exemption from 49 CFR 391.51(b)(7)(ii) requiring motor carriers to obtain an updated motor vehicle record (MVR) of any driver holding a commercial driver’s license (CDL) when he or she undergoes a new medical examination. A&P is requesting the exemption of behalf of all motor carriers that are required to obtain an MVR under this rule. FMCSA requests public comments on the application for exemption.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2015–0394 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to

www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Mr. Robert Schultz, Transportation Specialist, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325; email MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2015–0394), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket

number, “FMCSA–2015–0394” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may grant or not grant this application based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, “FMCSA–2015–0394” in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from the FMCSRs. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted, and must provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from

which exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Background

The Commercial Motor Vehicle Safety Act of 1986 (CMVSA) was designed to improve highway safety by ensuring that truck and bus drivers are qualified to drive a commercial motor vehicle (CMV).¹ CMVSA mandated that the Federal government establish minimum requirements for issuance of a commercial driver’s license (CDL) to be issued by the States. It provided for removal of driving privileges from unsafe and unqualified drivers. The CMVSA also mandated the creation of the Commercial Driver’s Licensing Information System (CDLIS), a cooperative exchange of the 50 States and the District of Columbia. CDLIS documents the issuance of a CDL by a State and all subsequent actions by a State driver licensing agency (SDLA) relative to that CDL, such as suspension, downgrade or removal of all driving privileges. Thus, each CDL driver has a single motor vehicle record (MVR). Federal and State law enforcement officials access CDLIS electronically at roadside to verify the licensing status of CMV drivers.

The FMCSRs (49 CFR part 350 *et seq.*) require operators of CMVs to be medically examined and found physically qualified to perform their job-related duties (49 CFR 391.41(a)(1)(i)). CMV drivers must be re-examined every two years (49 CFR 391.45(b)(1)) or more frequently for medical reasons. Only medical examiners (MEs) approved by FMCSA and listed on the Agency’s National Registry of Certified Medical Examiners may perform medical examinations of CDL drivers (49 CFR 391.42).

¹ The CMVSA definition of “commercial motor vehicle” was adopted verbatim by 49 CFR 383.5: “Commercial motor vehicle means a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the motor vehicle is a—(1) Combination Vehicle (Group A)—having a gross combination weight rating or gross combination weight of 11,794 kilograms or more (26,001 pounds or more), whichever is greater, inclusive of a towed unit(s) with a gross vehicle weight rating or gross vehicle weight of more than 4,536 kilograms (10,000 pounds), whichever is greater; or (2) Heavy Straight Vehicle (Group B)—having a gross vehicle weight rating or gross vehicle weight of 11,794 or more kilograms (26,001 pounds or more), whichever is greater; or (3) Small Vehicle (Group C)—(i) that does not meet Group A or B requirements; (ii) is designed to transport 16 or more passengers, including the driver; or (iii) is of any size and is used in the transportation of certain hazardous materials (49 CFR 383.5).”

ME’s must transmit the result of each driver medical examination they conduct to FMCSA electronically (391.41(g)(5)(i)(a)). FMCSA transmits the information to CDLIS, and SDLAs are required to extract the information from CDLIS and post on each MVR whether the driver is medically qualified to operate a CMV (49 CFR 383.73(b)(5)). Motor carriers must obtain the revised MVR of its drivers from the State of licensure within 15 days of the date of a medical examination and retain it in the driver’s qualification file (49 CFR 391.51(b)(7)(ii)). Some motor carriers retain third-party agents to manage this and other recordkeeping requirements. Some SDLAs will not provide revised MVRs to third-party agents.

IV. Request for Exemption

Applicant A&P retains a third-party agent to obtain revised MVRs of its CMV drivers. It has applied for exemption from the requirement of 49 CFR 391.51(b)(7)(ii) that motor carriers obtain the revised MVR of the driver from the State that licenses the driver within 15 days of the date of the medical examination. A&P has applied on behalf of all motor carriers who must obtain MVRs of their CDL drivers. A&P suggests that motor carriers be permitted to “have a copy of [the] current MVR from the third party provider and proof the medical certificate has been filed” with the SDLA in lieu of the existing requirement.

A copy of A&P’s application is in the docket of this matter.

Dated: November 6, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–30152 Filed 11–25–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2015–0134]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LOCURA; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for

such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0134. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LOCURA is:

Intended Commercial Use of Vessel: "Private Vessel Charters, Passengers Only".

Geographic Region: "Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, California, Oregon, Washington and Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])."

The complete application is given in DOT docket MARAD-2015-0134 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments

should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.
Dated: November 19, 2015.

Thomas M. Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2015-30204 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2015-0132]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CHEYENNE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-built requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0132. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this

docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION:

As described by the applicant the intended service of the vessel CHEYENNE is:

Intended Commercial Use of Vessel: "Ocean observations, sightseeing, diving."

Geographic Region: "Washington State, California, Hawaii, Texas, Florida, Georgia, New Jersey, Maryland, Delaware, Washington DC, New York, Rhode Island, Massachusetts, Puerto Rico."

The complete application is given in DOT docket MARAD-2015-0132 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30202 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2015-0137]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MUSIC; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0137. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MUSIC is:

Intended Commercial Use of Vessel: "Day sailing charters and overnight stays in coastal waters."

Geographic Region: "Florida, Georgia, North Carolina, South Carolina, Virginia, Maryland, Pennsylvania, Connecticut, Rhode Island, Massachusetts, New Hampshire, Maine."

The complete application is given in DOT docket MARAD-2015-0137 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30209 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2015 0130]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VAN DUTCH; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build

requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0130. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel VAN DUTCH is:

Intended Commercial Use of Vessel: "Sightseeing Tours."

Geographic Region: "Florida, New York, New Jersey, Connecticut."

The complete application is given in DOT docket MARAD-2015-0130 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30210 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration**

[Docket No. MARAD-2015 0136]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HOYA SAXA; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0136. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HOYA SAXA is:

Intended Commercial Use Of Vessel: "Carrying Six Passengers Or Less For Sunset Cruises Or Longer Overnight Charters".

Geographic Region: "Florida, Rhode Island, Massachusetts, Maine, Connecticut, New York, New Jersey".

The complete application is given in DOT docket MARAD-2015-0136 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30213 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration**

[Docket No. MARAD-2015-0128]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VELLAMO; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0128. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel VELLAMO is:

Intended Commercial Use of Vessel: "Sight-seeing and sport fishing."

Geographic Region: "Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])."

The complete application is given in DOT docket MARAD-2015-0128 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.
Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2015-30201 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2015 0135]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel TRINITY; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0135. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TRINITY is:

Intended Commercial Use Of Vessel: "Sailing excursions primarily as part of wellness programs for the elderly and people with disabilities and sunset sails."

Geographic Region: "Maine, New Hampshire, Massachusetts, Rhode Island, New York, New Jersey, Maryland, Delaware, Virginia, North Carolina, South Carolina, Florida."

The complete application is given in DOT docket MARAD-2015-0135 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.
Dated: November 19, 2015.

T Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2015-30212 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2015-0129]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel AKARI II; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0129. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel AKARI II is:

Intended Commercial Use of Vessel: "Bareboat chartering and sailing instruction in Puget Sound and vicinity."

Geographic Region: "Washington State."

The complete application is given in DOT docket MARAD-2015-0129 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30203 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration**

[Docket No. MARAD-2015 0133]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MAGNA CARTA; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0133. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MAGNA CARTA is:

Intended Commercial Use Of Vessel: "Private Vessel Charters, Passengers Only".

Geographic Region: "Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida,

California, Oregon, Washington and Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])."

The complete application is given in DOT docket MARAD-2015-0133 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

Thomas M. Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30211 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration**

[Docket No. MARAD-2015 0131]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CAROBELLE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under

certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 28, 2015.

ADDRESSES: Comments should refer to docket number MARAD-2015-0131. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email Linda.Williams@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CAROBELLE is:

INTENDED COMMERCIAL USE OF VESSEL: "Passenger Charter."
GEOGRAPHIC REGION: "FLORIDA, GEORGIA, SOUTH CAROLINA, NORTH CAROLINA, VIRGINIA, MARYLAND, DELAWARE, NEW JERSEY, NEW YORK, CONNECTICUT, RHODE ISLAND, MASSACHUSETTS, MAINE, ALABAMA, MISSISSIPPI, LOUISIANA, TEXAS."

The complete application is given in DOT docket MARAD-2015-0131 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state

the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: November 19, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-30200 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Acceptance of Applications for the Potential Award of Maritime Security Program Operating Agreements

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of Application Period for the Maritime Security Program.

SUMMARY: The Maritime Administration (MARAD) is issuing this request for applications for eligible vessels to potentially enroll in one or more MSP Operating Agreements in accordance with the provisions of the Maritime Security Act of 2003, Public Law 108-136, div. C, title XXXV, as amended by Section 3508 of the National Defense Authorization Act for Fiscal Year (FY) 2013, Public Law 112-239, (NDAA 2013). The Maritime Security Program (MSP) maintains a fleet of active, commercially-viable, privately-owned vessels to meet national defense and other security requirements and to maintain a United States presence in international commercial shipping. This request for applications provides, among other things, application criteria and a deadline for submitting applications for potential vessel enrollment in the MSP.

DATES: Applications for the potential enrollment of one or more vessels must be received no later than December 28, 2015. Applications should be submitted to the address listed in the **ADDRESSES** section below.

ADDRESSES: Application forms and instructions are available by electronic

mail request addressed to William.G.Mcdonald@dot.gov.

Submit applications for the enrollment of vessels in the MSP to William G. McDonald, Director, Office of Sealift Support, W25-310, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: William G. McDonald, Director, Office of Sealift Support, Maritime Administration, (202) 366-0688. For legal questions, call Ryan Kabacinski, Chief, Division of Maritime Programs, Maritime Administration, (202) 366-5176. For military-utility questions, call Mr. Tim Boemecke, United States Transportation Command, (618) 220-1452.

SUPPLEMENTARY INFORMATION: The NDAA 2013 extended the MSP from FY 2016 through FY 2025 and revised the associated annual MSP payment schedule. This program provides financial assistance to operators of U.S.-flag vessels that meet certain qualifications. Section 53102(a) of Title 46, United States Code, directs the Secretary of Transportation (Secretary), in consultation with the Secretary of Defense (SecDef), to establish a fleet of active, commercially-viable, militarily-useful, privately-owned vessels to meet national defense and other security requirements. Section 53111 of Title 46, United States Code, authorizes \$186 million annually for FYs 2012, 2013, 2014, 2015, 2016, 2017 and 2018; \$210 million annually for FYs 2019, 2020 and 2021; and \$222 million annually for each FY thereafter through FY 2025 to support the operation of up to 60 U.S.-flag vessels in the foreign commerce of the United States. Payment to participating operators are limited under 46 U.S.C. § 53106(a)(1) to \$3.1 million per ship, per year, through FY 2018; \$3.5 million per ship per year for FY 2019 through 2021; and \$3.7 million per ship per year for FY 2022 through 2025. Payments are subject to the availability of appropriations. Participating operators are required to make their commercial transportation resources available upon request by SecDef during times of war or national emergency.

Application Criteria

The NDAA 2013 amended the procedures in 46 U.S.C. § 53103(c) for awarding new MSP Operating Agreements. The amended statute provides that the Secretary may enter into a new Operating Agreement with an applicant that meets the citizenship requirements of 46 U.S.C. § 53102(c), for

a vessel that meets the eligibility requirements of 46 U.S.C. § 53102(b). Priority for the award of Operating Agreements under the amended 46 U.S.C. § 53103(c) shall be on the basis of vessel type established by military requirements of SecDef. The military requirements established by SecDef, through the United States Transportation Command (USTRANSCOM), are provided below. As provided by the amended statute, after consideration of military requirements, priority for the award of Operating Agreements shall be given to applicants that are United States citizens under 46 U.S.C. § 50501.

Vessel Requirements

Acceptable vessels for this MSP Operating Agreement must meet the requirements of 46 U.S.C. § 53102(b) and 46 CFR § 296.11. In addition, the Commander, USTRANSCOM, has established Department of Defense general evaluation criteria on the military requirements for eligible MSP vessels. Priority consideration, consistent with the requirements of 46 U.S.C. § 53103(c), will be given to applications providing for enrollment of the following vessel types in order of priority:

1. Roll-on/Roll-off (RO/RO)
2. Tanker
3. Heavy Lift
4. Geared Containerships
5. All other vessel types will be considered after all applications for the above listed vessel types have been reviewed.

National Security Requirements

If an applicant is chosen to receive a MSP Operating Agreement the applicant will be required to enter into an Emergency Preparedness Agreement (EPA) pursuant 46 U.S.C. § 53107. The EPA shall be a document incorporating the terms of the Voluntary Intermodal Sealift Agreement (VISA), as approved by the Secretary and SecDef, or such other agreement as may be approved by the Secretaries.

Documentation

If a vessel is chosen to be the subject of an MSP Operating Agreement, and if such vessel is currently documented under a foreign register, such vessel must be documented in the United States under 46 U.S.C. Ch. 121 prior to being eligible for MSP payments. Further, proof of U.S. Coast Guard vessel documentation and all relevant charter and management agreements for

the chosen vessels, if any, must be approved by MARAD before the vessel will be eligible to receive MSP payments.

Payments

If an applicant is awarded an MSP Operating Agreement, the applicant will be eligible for payments in accordance with 46 U.S.C. § 53106 and 46 CFR § 296.41.

Vessel Operation

The vessels under an MSP Operating Agreement shall be operated exclusively in foreign commerce as defined in 46 U.S.C. § 53101(4) or in permissible mixed foreign commerce and domestic trade as provided by 46 U.S.C. § 53105(a)(1)(A).

U.S. Merchant Marine Academy Cadets (Midshipmen)

In the course of operation of the vessel, the MSP Operator shall agree to carry contemporaneously up to two U.S. Merchant Marine Academy midshipmen upon request.

Award

No guarantee is provided that MARAD will award any MSP Operating Agreements in response to applications submitted under this Notice. In the event that no awards are made or an application is not selected for an award, the applicant will be provided a written reason why the application was denied, consistent with the requirements of 46 U.S.C. § 53103(c).

(Authority: 49 CFR Sections 1.92 and 1.93)

By Order of the Maritime Administrator.

Dated: November 23, 2015.

Jay R. Gordon,

Acting Secretary, Maritime Administration.

[FR Doc. 2015-30199 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Application for Modification of Special Permit

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Application for Modification of Special Permits

SUMMARY: In accordance with the procedures governing the application

for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modification of special permits (*e.g.* to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "M" denote a modification request. These applications have been separated from the new application for special permits to facilitate processing.

DATES: Comments must be received on or before December 14, 2015.

Address Comments To: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for modification of special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(6); 49 CFR I.53(b)).

Issued in Washington, DC, November 4, 2015.

Don Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of permit thereof
MODIFICATION SPECIAL PERMITS				
7765-M		Carleton Technologies, Inc., Orchard Park, NY.	49 CFR 173.302(a)(4); 175.3	To modify the special permit to authorize a competent internal Carleton inspector to perform the required duties outlined in § 178.35(c).
12399-M		Linde Gas, North America LLC., Murray Hill, NJ.	49 CFR 180.209	To modify the special permit to authorize DOT Specification 3AL cylinders made of 6351-T6 aluminum to be requalified by ultrasonic examination and eddy current examination in accordance with 49 CFR Appendix C to Part 180.
12562-M		Taeyang Corporation, Chung Nam.	49 CFR 173.304(d)(3)(ii)	To modify the special permit to authorize additional Division 2.1 hazardous materials, add an additional inside container design, mark each container "DOT-SP 12562" instead of "DOTE-12562" and company name change.
13192-M		Thomas Gray & Associates, Inc., Orange, CA.	49 CFR 173.12(b)	To modify the special permit to authorize transportation of radioactive materials.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of permit thereof
MODIFICATION SPECIAL PERMITS				
14206-M	Digital Wave Corporation, Centennial, CO.	49 CFR 172.203(a), 172.301(c), and 180.205.	To modify the special permit to add DOT Specification 3AX, 3AAX cylinders and 3T tubes which exceed 125 lbs water capacity for requalification by ultrasonic examination once every ten years.
14625-M	KIK Piedmont LLC, Gainesville, GA.	49 CFR 173.306(a)(3)(v)	To modify the special permit to allow an additional DOT Specification 2Q aluminum non-refillable inside container.
16361-M	The University of Cincinnati, Cincinnati, OH.	49 CFR 173.196	To modify the special permit to eliminate the requirement for the transport vehicle to be equipped with an environmental control backup system capable of turning on power to maintain a temperature of at -30 degrees Celsius or below.
16490-M	William T. Poe & Associates Inc. d/b/a Explosive Service International, Baton Rouge, LA.	49 CFR 176.63; 176.83; 176.116(e); 176.120; 176.137(a)(7); 176.138(b); 176.144(e); 176.145(b); 176.164(e); 176.178(b).	To modify the special permit originally issued on an emergency basis to authorize an additional two years.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of permit thereof
MODIFICATION SPECIAL PERMITS				
16492-M	Construction Helicopters, Inc., Howell, MI.	49 CFR 172.101 Hazardous Materials Table Column (9B), Subpart C of Part 172, 172.301(c), 172.302(c), 173.27(b)(2), 175.30, Part 178.	To modify the special permit to remove the provision "training or qualification of a new crew member will not take place during the execution of this special permit."

[FR Doc. 2015-29955 Filed 11-25-15; 8:45 am]

BILLING CODE 4909-60-M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Application for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for

which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: Send comments to Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and

Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 4, 2015.

Donald Burger,
Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of permit thereof
NEW SPECIAL PERMITS				
16591-N	Department of Defense, Scott AFB, IL.	49 CFR 171.3(a), 173.302a, ICAO TI Packing Instruction 200, IMDG Code Packing Instruction P200.	To authorize the transportation in commerce of compressed argon in non-DOT specification cylinders. (modes 1, 3, 4).
16592-N	Stericycle Specialty Waste Solutions, Inc., Minneapolis, MN.	49 CFR Subparts A through E of Part 173.	To authorize the transportation in commerce of certain Drug Enforcement Administration (DEA) controlled substances transported for the purpose of disposal. (mode 1).
16596-N	Great Slave Helicopters, Ltd., Yellowknife, Canada, NT.	49 CFR 172.101 Hazardous Materials Table Column (9B), Subpart C of Part 172, 172.301(c), 175.30, Part 173.	To authorize transportation in commerce in the U.S. only of certain hazardous materials by Rotorcraft External Load Operations transporting hazardous materials attached to or suspended from an aircraft without being subject to certain hazard communication requirements, quantity limitations, packaging and loading and storage requirements. (mode 4).
16598-N	Spaceflights, Inc., Tukwila, WA.	49 CFR 173.24(b)(1), 173.304a, 173.185(a)(1).	To authorize the transportation in commerce of the SHERPA spacecraft containing non-DOT specification cylinders filled with a Division 2.1 gas and three lithium ion batteries contained in equipment that are not of a type proven to meet the criteria in Part III, sub-section 38.3 of the UN Manual of Tests and Criteria. (mode 1).
16601-N	SAFC Hitech, Inc., Haverhill, MA.	49 CFR 173.181(b), IMDG Code Packing Instruction P400, paragraph (2).	To authorize the manufacture, mark, sale and use of specially-designed combination packagings for the transportation in commerce of certain pyrophoric hazardous materials. (modes 1, 3).
16602-N	Hydrite Chemical Co., Brookfield, WI.	49 CFR 173.158(b), 173.158(e), 173.158(f).	To authorize the transportation in commerce of nitric acid with a concentration up to 50% in UN 3H1 jerricans and UN 1H1 plastic drums. (mode 1).

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Delayed Applications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of application delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), PHMSA is publishing the following list of special permit applications that have been in process for 180 days or more.

The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Special Permits and Approvals, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

Key to "Reason for Delay"

1. Awaiting additional information from applicant
2. Extensive public comment under review

3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis

4. Staff review delayed by other priority issues or volume of special permit applications

Meaning of Application Number Suffixes

- N—New application
- M—Modification request
- R—Renewal Request
- P—Party To Exemption Request

Issued in Washington, DC, on November 4, 2015.

Donald Burger,
Chief, General Approvals and Permits.

Application No.	Applicant	Reason for delay	Estimated date of completion
Modification to Special Permits			
16142-M	Nantong CIMC, Tank Equipment Co. Ltd., Jiangsu, Province	4	11-20-2015
14437-M	Columbiana Boiler Company (CBCo) LLC, Columbiana, OH	4	11-30-2015
14808-M	Amtrol-Alfa Metalomecanica, S.A., West Warwick, RI	4	12-05-2015
New Special Permit Applications			
15767-N	Union Pacific Railroad Company, Omaha, NE	3	11-20-2015
16220-N	Americase, Waxahache, TX	4	11-20-2015
16249-N	Optimized Energy Solutions, LLC, Durango, CO	3	11-15-2015
16337-N	Volkswagen Group of America (VWGoA), Herndon, VA	4	12-31-2015
16366-N	Department of Defense, Scott AFB, IL	4	11-30-2015
16371-N	Volkswagen Group of America (VWGoA), Herndon, VA	4	11-30-2015
16416-N	INOX India Limited, Gujarat, India	4	12-31-2015
16465-N	Helimax Aviation, Inc., McClellan, CA	4	11-30-2015
16461-N	Coastal Hydrotesting LLC, Baltimore, MD	4	12-20-2015
16452-N	The Procter & Gamble Company, Cincinnati, OH	4	11-30-2015
16469-N	ACS UE Testing LLC, Denver, CO	4	12-31-2015
16463-N	Salco Products, Lemont, IL	3	12-31-2015
16001-N	VELTEK Associates, Inc., Malvern, PA	3	11-20-2015
Renewal Special Permits Applications			
11860-R	GATX Corporation, Chicago, IL	4	12-31-2015
8009-R	NK Co., Ltd., Busan City, KR	4	11-30-2015

[FR Doc. 2015-29937 Filed 11-25-15; 8:45 am]
BILLING CODE 4910-60-M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Actions on Special Permit Applications

AGENCY: Pipeline And Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given of the actions on special permits applications in (October to October 2014). The mode of transportation involved are identified by a number in the "Nature of Application" portion of the table below

as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Special Permits. It should be noted that some of the sections cited were those in effect at the time certain special permits were issued.

Issued in Washington, DC, on November 4, 2015.

Don Burger,
Chief, Special Permits and Approvals Branch.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
MODIFICATION SPECIAL PERMIT GRANTED			
15744-M	Praxair Distribution, Inc., Danbury, CT.	49 CFR 180.205; 180.209	To modify the special permit to exempt the notation "DOT-SP" 15744 on shipping papers.
12562-M	Taeyang Industrial Company Ltd., Chung Nam.	49 CFR 173.304(d)(3)(ii)	To modify the special permit to authorize additional Division 2.1 hazardous materials and to add an additional inside container design.
16302-M	Ametek Inc., Pittsburgh, PA.	49 CFR 171.1	To modify the special permit to authorize glass ampules with a 31 ml actual capacity and remove the 30 kg limit when ampules are installed in analyzing equipment.
16239-M	Trinity Containers, LLC, Dallas, TX.	49 CFR 171.7	To reissue the special permit that was originally issued on an emergency basis with a two year renewal.
11054-M	Welker Inc., Sugar Land, TX.	49 CFR 178.36 subpart C	To modify the special permit to authorize additional hazardous materials.
NEW SPECIAL PERMIT GRANTED			
16395-N	Chandler Instruments Company LLC Broken Arrow, OK.	49 CFR 173.201, 173.301(f), 173.302(a), 173.304.	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders used in oil well sampling. (modes 1, 2, 3, 4).
16414-N	Gardner Cryogenics Department of Air Products and Chemicals Inc., Allentown, PA.	49 CFR 178.338	To authorize the manufacture mark and sell of MC338 cargo tanks built to ASME Section XII standards(version in effect at time of manufacture) and stamping them with a "T" stamp associated with that section rather than the "U" stamp of current Federal Regulations. (modes 1, 3).
16498-N	FIBA Technologies, Inc. Littleton, MA.	49 CFR 172.203(a), 173.302a, 173.304a.	Authorizes the manufacture, mark, sale and use of specification DOT 3T cylinders using an alternative heat treatment batch size. (modes 1, 2, 3).
16530-N	3M Company, Saint Paul, MN.	49 CFR 173.301(f)	To authorize the transportation in commerce of Specification DOT 4BW cylinders containing certain toxic gases without pressure relief devices. (modes 1, 2, 3).
EMERGENCY SPECIAL PERMIT GRANTED			
16590-N	U.S. Environmental Protection Agency, Middletown, CA.	49 CFR 171-180	To authorize the transportation in commerce of hazardous materials used to support the recovery and relief efforts from and within Lake and Calaveras Counties in California, under conditions that may not meet the Hazardous Materials Regulations (HMR). (mode 1).
MODIFICATION SPECIAL PERMIT WITHDRAWN			
5022-M	Aerojet Rocketdyne, Sacramento, CA.	49 CFR 174.101(L); 174.104(d); 174.112(a); 177.834(l)(1).	
NEW SPECIAL PERMIT WITHDRAWN			
16597-N	Aerojet/Rocketdyne Rancho Cordova, CA.	49 CFR 172.102(c)(1), special provision 37.	To authorize the transportation in commerce of liquid propellant (UN0497) that cannot meet § 172.102(c)(1), special provision 37. (mode 1).
DENIED			
16396-N	Request by Eniware LLC Washington, DC October 7, 2015. To authorize the manufacture, mark, sale and use of sterilization devices containing two toxic gases in non-DOT specification containers (steel gas cartridges) as excepted quantities.		
16356-N	Request by United Launch Alliance, LLC Centennial, CO October 16, 2015, the transportation in commerce of articles containing not more than 25 grams of solid explosive or pyrotechnic material that has energy density not significantly greater than that of pentaerythritol tetranitrate (PETN), classed as Division 1.4E when packed in a special shipping container.		
16430-N	Request by Eniware LLC Washington, DC October 16, 2015. To authorize the manufacture, mark, sale and use of specialized packaging used to transport sterilization devices containing nitric acid as excepted quantities.		
16575-N	Request by FIBA Technologies, Inc. Littleton, MA October 9, 2015. To authorize the manufacture, mark, sale and use of certain specification DOT 3AA, 3AAX, and 3T cylinders and UN ISO 11120 tubes that were witnessed during manufacture with real-time video feeds by an Independent Inspection Agency for certain tests.		

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
16582-N	Request by Spectrum Brands Inc. Middleton, WI	October 9, 2015.	To authorize the transportation in commerce of damaged lithium metal cells for disposal in alternative packaging.

[FR Doc. 2015-29957 Filed 11-25-15; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35897]

R. J. Corman Railroad Company/ Carolina Lines, LLC—Acquisition and Operation Exemption—The Baltimore and Annapolis Railroad Company d/b/ a Carolina Southern Railroad Company

AGENCY: Surface Transportation Board,
DOT.

ACTION: Correction to notice of
exemption.

On January 12, 2015, R. J. Corman Railroad Company/Carolina Lines, LLC (RJC-Carolina), a noncarrier, filed a verified notice of exemption under 49 CFR 1150.31 to acquire from The Baltimore and Annapolis Railroad Company d/b/a Carolina Southern Railroad Company (CALA) and operate two interconnected rail lines totaling approximately 74.9 miles in North Carolina and South Carolina (the Line). RJC-Carolina stated that the Line extends from: (1) Milepost AL 326.0, at Mullins, S.C., to milepost AC 290.0, at Whiteville, N.C.; and (2) milepost ACH 297.2, at Chadbourn, N.C., to milepost ACH 336.1, at Conway, S.C. RJC-Carolina also sought to acquire one mile of incidental, local trackage rights from CALA, extending between milepost AC 290.0 and milepost AC 289.0, at or near Whiteville.¹ On January 28, 2015, notice of the exemption was served and published in the **Federal Register** (80 FR 4634). The exemption became effective on February 11, 2015.

On October 5, 2015, RJC-Carolina filed a letter stating that milepost ACH 336.1 should have been more precisely stated as ACH 336.18. As a result, RJC-Carolina states that the total length of the Line is approximately 74.98 miles as

¹ This transaction is related to a concurrently filed verified notice of exemption in *R.J. Corman Railroad Group—Continuance in Control Exemption—R.J. Corman Railroad/Carolina Lines*, Docket No. FD 35898, in which R.J. Corman Railroad Group, LLC, and R.J. Corman Railroad Company, LLC, sought Board approval under 49 CFR 1180.2(d)(2) to continue in control of RJC-Carolina upon RJC-Carolina's becoming a Class III rail carrier.

opposed to 74.9 miles. This notice corrects the description of the milepost and total length of the Line. All other information in the notice is correct.

Board decisions and notices are available on our Web site at www.stb.dot.gov.

Decided: November 20, 2015.

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2015-30080 Filed 11-25-15; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Updating of Specially Designated Nationals and Blocked Persons Pursuant to the Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets
Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is updating the identifying information for one vessel that was previously identified as blocked property pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act) (21 U.S.C. Sections 1901-1908, 8 U.S.C. Section 1182).

DATES: The update to the list of Specially Designated Nationals and Blocked Persons (SDN List) of the vessel identified in this notice, is effective on November 12, 2015.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622-2420.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at www.treasury.gov/ofac or via facsimile through a 24-hour fax-on demand service at (202) 622-0077.

Background

On December 3, 1999, the Kingpin Act was signed into law by the President of the United States. The Kingpin Act provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and to the benefits of trade and transactions involving U.S. persons and entities.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property or interests in property, subject to U.S. jurisdiction, of persons or entities found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; and/or (3) playing a significant role in international narcotics trafficking.

On November 12, 2015, the Associate Director of the Office of Global Targeting updated the SDN listing of the vessel listed below pursuant to the Kingpin Act:

Vessel

1. CITY OF TOKYO (D5GK6) Liberia flag; Vessel Registration Identification IMO 8709145; MMSI 636016488 (vessel) [SDNTK] (Linked To: MERHI, Merhi Ali Abou; Linked To: ABOU-MERHI LINES SAL).

To

1. CITY OF TOKYO (3ELV6) Panama flag; Vessel Registration Identification IMO 8709145; MMSI 636016488 (vessel) [SDNTK] (Linked To: MERHI, Merhi Ali

Abou; Linked To: ABOU-MERHI LINES SAL).

Dated: November 12, 2015.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2015-30117 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons Pursuant to the Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of two individuals whose property and interests in property have been unblocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act) (21 U.S.C. Sections 1901-1908, 8 U.S.C. Section 1182).

DATES: The unblocking and removal from the list of Specially Designated Nationals and Blocked Persons (SDN List) of the individuals identified in this notice whose property and interests in property were blocked pursuant to the Kingpin Act, is effective on November 19, 2015.

FOR FURTHER INFORMATION CONTACT:

Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622-2420.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at www.treas.gov/ofac or via facsimile through a 24-hour fax-on demand service at (202) 622-0077.

Background

On December 3, 1999, the Kingpin Act was signed into law by the President of the United States. The Kingpin Act provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and to the benefits of

trade and transactions involving U.S. persons and entities.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property or interests in property, subject to U.S. jurisdiction, of persons or entities found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; and/or (3) playing a significant role in international narcotics trafficking.

On November 19, 2015, the Associate Director of the Office of Global Targeting removed from the SDN List the individuals listed below, whose property and interests in property were blocked pursuant to the Kingpin Act:

Individuals

1. HANDAL LARACH, Jose Miguel, San Pedro Sula, Cortes, Honduras; DOB 18 Jan 1941; citizen Honduras; National ID No. 0401-1941-00086 (Honduras) (individual) [SDNTK] (Linked To: AUTO PARTES HANDAL S. DE R.L. DE C.V.; Linked To: SUPERTIENDAS HANDAL S. DE R.L.; Linked To: RANCHO LA HERRADURA).
2. URREGO ESCUDERO, Carlos Agustin (a.k.a. BENALCAZAR FURMAN, Moshe), Colombia; DOB 19 Feb 1976; citizen Colombia; Cedula No. 79928745 (Colombia); Passport AF392658 (Colombia) (individual) [SDNTK].

Dated: November 19, 2015.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2015-30116 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Removal of Specially Designated Nationals and Blocked Persons Pursuant to the Cuban Assets Control Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of 19 individuals whose names have been removed from the list of Specially Designated Nationals and Blocked Persons (SDN List) pursuant to the Cuban Assets Control Regulations, 31 CFR part 515.

DATES: The removal from the SDN List of the individuals identified in this notice is effective November 19, 2015.

FOR FURTHER INFORMATION CONTACT:

Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622-2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC are available from OFAC's Web site (www.treas.gov/ofac). Certain general information pertaining to OFAC's sanctions programs is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622-0077.

Background

On November 19, 2015, the Associate Director of OFAC removed from the SDN List the individuals listed below, whose names were included on the SDN List pursuant to the Cuban Assets Control Regulations:

Individuals

1. AGUIAR, Raul [CUBA].
2. CHAO, Lazaro R. [CUBA].
3. IMPERATORI, Julio A. [CUBA].
4. LEBREDO, Jose A. [CUBA].
5. LOPEZ, Miguel A. [CUBA].
6. RODRIQUEZ, Jose Julio [CUBA].
7. TOLEDO, R.F. [CUBA].
8. TORRES, Manuel [CUBA].
9. VAZ, Jose [CUBA].
10. ALVAREZ AGUIRRE, Manuel [CUBA].
11. COLON BETANCOURT, Eduardo [CUBA].
12. LOBATO, Julio (a.k.a. PRADO, Julio) [CUBA].
13. PENA TORRES, Jose [CUBA].
14. REYES VERGARA, Guillermo [CUBA].
15. ROCHA, Antonio [CUBA].
16. RODRIQUEZ BORGES, Jesus (a.k.a. RODRIQUEZ BORJES, Jesus) [CUBA].

17. PEREZ CRUZ, Osvaldo [CUBA].
 18. RUIZ POO, Ramon Miguel [CUBA].
 19. TOSCO GARCIA, Arnaldo [CUBA].

Dated: November 19, 2015.

Gregory T. Gatjanis,

*Associate Director, Office of Global Targeting,
 Office of Foreign Assets Control.*

[FR Doc. 2015-30115 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Updating of Specially Designated Nationals and Blocked Persons Pursuant to Executive Order 12978

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is updating the identifying information for two individuals that were previously designated pursuant to Executive Order 12978 (Blocking Assets and Prohibiting Transactions with Significant Narcotics Traffickers).

DATES: The update to the list of Specially Designated Nationals and Blocked Persons (SDN List) of the individuals identified in this notice whose property and interests in property are blocked pursuant to Executive Order 12978, is effective on November 12, 2015.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622-2420.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at www.treasury.gov/ofac or via facsimile through a 24-hour fax-on demand service at (202) 622-0077.

Background

On October 21, 1995, the President, invoking the authority, inter alia, of the International Emergency Economic Powers Act (50 U.S.C. 1701-1706), issued Executive Order 12978, "Blocking Assets and Prohibiting Transactions with Significant Narcotics Traffickers" (the Order). In the Order, the President declared a national emergency to deal with the threat posed by significant foreign narcotics traffickers centered in Colombia and the

harm that they cause in the United States and abroad.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons, of: (1) The persons listed in an Annex to the Order; (2) any foreign person determined by the Secretary of Treasury, in consultation with the Attorney General and the Secretary of State, to play a significant role in international narcotics trafficking centered in Colombia, or materially to assist in, or provide financial or technological support for or goods or services in support of, the narcotics trafficking activities of persons designated in or pursuant to the Order; and (3) persons determined by the Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State, to be owned or controlled by, or to act for or on behalf of, persons designated pursuant to the Order.

On November 12, 2015, the Associate Director of the Office of Global Targeting updated the SDN listing of the two individuals listed below, whose property and interests in property are blocked pursuant to Executive Order 12978:

Individual

1. SANTAGRUZ LONDONO, Jose (a.k.a. "CHEPE"; a.k.a. "DON CHEPE"; a.k.a. "EL GORDO CHEPE"), Cali, Colombia; DOB 01 Oct 1943; Cedula No. 14432230 (Colombia); Passport AB149814 (Colombia) (individual) [SDNT].

-to-

SANTAGRUZ LONDONO, Jose (a.k.a. "CHEPE"; a.k.a. "DON CHEPE"; a.k.a. "EL GORDO CHEPE"), Cali, Colombia; DOB 01 Oct 1943; Passport AB149814 (Colombia) (individual) [SDNT].

2. GARCIA PIZARRO, Gentil Velez, c/o GALAPAGOS S.A., Cali, Colombia; Cedula No. 6616986 (Colombia) (individual) [SDNT].

-to-

GARCIA PIZARRO, Gentil Velez, Cali, Colombia (individual) [SDNT] (Linked To: GALAPAGOS S.A.).

Dated: November 12, 2015.

Gregory T. Gatjanis,

*Associate Director, Office of Global Targeting,
 Office of Foreign Assets Control.*

[FR Doc. 2015-30118 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Information Collection Tools

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099-PATR, Taxable Distributions Received From Cooperatives; Conduit Arrangements Regulations (TD 8611); Form 8903, Domestic Production Activities Deduction; and the rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical amendment to external review for Multi-State Plan Program (TD 9640).

DATES: Written comments should be received on or before January 26, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 317-5746, or through the internet at RJoseph.Durbala@irs.gov.

SUPPLEMENTARY INFORMATION: Currently, the IRS is seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

(1) *Title:* Taxable Distributions Received From Cooperatives.

OMB Number: 1545-0118.

Form Number: 1099-PART.

Abstract: Form 1099-PATR is used to report patronage dividends paid by

cooperatives in accordance with Internal Revenue Code section 6044. The information is used by IRS to verify reporting compliance on the part of the recipient.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,961,131.

Estimated Time Per Respondent: 15 min.

Estimated Total Annual Burden Hours: 509,895.

(2) *Title:* Conduit Arrangements Regulations.

OMB Number: 1545-1440.

Form Number: TD 8611 (INTL-64-93).

Abstract: This regulation provides rules that permit the district director to recharacterize a financing arrangement as a conduit arrangement. The recharacterization will affect the amount of U.S. withholding tax due on financing transactions that are part of the financing arrangement. This regulation affects withholding agents and foreign investors who engage in multi-party financing arrangements.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 10 min.

Estimated Total Annual Burden Hours: 10,000.

(3) *Title:* Domestic Production Activities Deduction.

OMB Number: 1545-1984.

Form Number: 8903.

Abstract: Taxpayers will use Form 8903 and related instructions to calculate the domestic production activities deduction.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 300,000.

Estimated Time Per Respondent: 24 hours 40 min.

Estimated Total Annual Burden Hours: 7,398,000.

(4) *Title:* Rules under the Paul Wellstone and Pete Domenici Mental

Health Parity and Addiction Equity Act of 2008: Technical amendment to external review for Multi-State Plan Program.

OMB Number: 1545-2165.

Form Number: TD 9640.

Abstract: This document contains final rules implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, which requires parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and group and individual health insurance coverage.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 424,000.

Estimated Time Per Respondent: 1 min.

Estimated Total Annual Burden Hours: 1,900.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 19, 2015.

R. Joseph Durbala,

IRS, Tax Analyst.

[FR Doc. 2015-30101 Filed 11-25-15; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Departmental Offices; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on a currently approved information collection form that is due for extension approval by the Office of Management and Budget. The Terrorism Risk Insurance Program Office, which is part of the Federal Insurance Office within the Department of the Treasury, is soliciting comments concerning the Record Keeping Requirements set forth in 31 CFR part 50, subpart J (Sec. 50.94).

DATES: Written comments must be received not later than January 26, 2016.

ADDRESSES: Interested persons may submit comments electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>, in accordance with the instructions on that site. In general, the Department will post all comments to www.regulations.gov without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department will also make such comments available for public inspection and copying in the Treasury's Library, 1500 Pennsylvania Avenue NW., Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 622-0990. All comments, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Electronic submissions are encouraged.

Comments may also be mailed to the Department of the Treasury, Terrorism Risk Insurance Office, MT 1410, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, Room 1319,

Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220, at (202) 622-2922 (this is not a toll-free number) or Kevin Meehan, Policy Advisor, Federal Insurance Office, Room 1410, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220, at (202) 622-7009 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION:

OMB Number: 1505-0208.

Title: Terrorism Risk Insurance Program—Program Cap on Annual Liability.

Abstract: The Terrorism Risk Insurance Act of 2002, as amended (TRIA),¹ established the Terrorism Risk Insurance Program (TRIP),² which the Secretary of the U.S. Department of the Treasury (Secretary) administers, with the assistance of the Federal Insurance Office.³ Section 103(e) of TRIA sets a limit on the annual liability for insured losses at \$100 billion. This section requires the Secretary to notify Congress not later than 15 days after an act of terrorism as to whether aggregate insured losses are estimated to exceed the cap. TRIA, as amended, also requires the Secretary to determine the pro rata share of insured losses under the Program when insured losses exceed the cap, and to issue regulations for carrying this out. In order to meet these requirements, Treasury may need to obtain loss information from involved insurers. This would be accomplished by the issuance of a “data call” to ascertain insurer losses. In the event of the imposition on insurers of a “pro rata loss percentage”, it will be necessary to determine compliance when processing insurer claims for payment of the Federal share of compensation. The Terrorism Risk Insurance Program Reauthorization Act of 2015 (Pub. L. 114-1) (2015 Reauthorization Act) requires insurers participating in the Program to submit to Treasury certain information regarding the operation of the Program. Treasury is presently considering the information that should be collected under the 2015 Reauthorization Act. It is possible that information that will be collected pursuant to this process under consideration might affect the amount of information that would need to be

collected pursuant to this currently approved data collection. Treasury will address such issues in connection with any notice that it issues concerning data collection under the Terrorism Risk Insurance Program Reauthorization Act of 2015. This extension is sought to maintain the existing approved data collection in place, consistent with the requirements of the Paperwork Reduction Act, pending the proposal by Treasury of any additional data collection in connection with the Program.

Type of Review: Extension of a currently approved data collection.

Affected Public: Business/Financial Institutions.

Estimated Number of Respondents: 200.

Estimated Average Time per Respondent: 5 hours.

Estimated Total Annual Burden Hours: 1,000 hours.

Request for Comments: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collections; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Michael T. McRaith,

Director, Federal Insurance Office.

[FR Doc. 2015-30142 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

**Submission for OMB Review;
Comment Request**

AGENCY: Department of the Treasury.

ACTION: Notice.

The Department of the Treasury will submit the following information

collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 28, 2015 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT:

Copies of the submission(s) may be obtained by email at PRA@treasury.gov or the entire information collection request may be found at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

OMB Number: 1545-0432.

Type of Review: Extension without change of a previously approved collection.

Title: Request for Discharge from Personal Liability Under Internal Revenue Code Section 2204 or 6905.

Form: 5495.

Abstract: Form 5495 provides guidance under sections 2204 and 6905 for executors of estates and fiduciaries of decedent’s trusts. The form, filed after regular filing of an Estate, Gift, or Income Tax Return for a Decedent, is used by the executor or fiduciary to request discharge from personal liability for any deficiency for the tax and periods shown on the form.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 306,500.

OMB Number: 1545-0973.

Type of Review: Extension without change of a previously approved collection.

Title: Geographic Availability Statement.

Form: 8569.

Abstract: The data collected from this form is used by the executive panels responsible for screening internal and external applicants for the SES Candidate Development Program, and other executive position.

¹ 15 U.S.C. 6701 note. Because the provisions of TRIA (as amended) appear in a note, instead of particular sections, of the United States Code, the provisions of TRIA are identified by the sections of the law.

² See 31 CFR part 50.

³ 31 U.S.C. 313(c)(1)(D).

Affected Public: Individuals and Households.
Estimated Annual Burden Hours: 84.
OMB Number: 1545–1251.

Type of Review: Extension without change of a previously approved collection.

Title: TD 8437—Limitations on Percentage Depletion in the Case of Oil and Gas Wells.

Abstract: Section 1.613A–3(e)(6)(i) of the regulations requires each partner to separately keep records of the partner's share of the adjusted basis of partnership oil and gas property.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 49,550.

OMB Number: 1545–1344.

Type of Review: Extension without change of a previously approved collection.

Title: TD 8560 (CO–30–92) Consolidated Returns—Stock Basis and Excess Loss Accounts, Earnings and Profits, Absorption of Deductions and Losses, Joining and Leaving Consolidated Groups, Worthless (Final).

Abstract: The reporting requirements affect consolidated taxpayers who will be making elections (if made) to treat certain loss carryovers as expiring and an election (if made) allocating items between returns. The information will facilitate enforcement of consolidated return regulations.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 18,600.

OMB Number: 1545–1499.

Type of Review: Extension without change of a previously approved collection.

Title: Revenue Procedure 2006–10, Acceptance Agents.

Abstract: Revenue Procedure 2006–10 describes application procedures for becoming an acceptance agent and the requisite agreement that an agent must execute with IRS.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 24,960.

OMB Number: 1545–1541.

Type of Review: Revision of a previously approved collection.

Title: Revenue Procedure 97–27, Changes in Methods of Accounting.

Abstract: The information requested in sections 6, 8, and 13 of Revenue Procedure 97–27 is required in order for the Commissioner to determine whether the taxpayer is properly requesting to change its method of accounting and the terms and condition of that change.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 9,083.

OMB Number: 1545–1545.

Type of Review: Extension without change of a previously approved collection.

Title: TD 8769—(REG–107644–97) Permitted Elimination of Pre-retirement Optional Forms of Benefit.

Abstract: The final regulations permit taxpayers to amend qualified plans to eliminate plan provisions for benefit distributions before retirement but after age 70–1/2, if certain conditions are satisfied.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 48,800.

OMB Number: 1545–1674.

Type of Review: Extension without change of a previously approved collection.

Title: Revenue Procedure 2015–36 Master and Prototype and Volume Submitter Plans (previously Rev. Proc. 2011–49 & 2005–16).

Abstract: This revenue procedure modifies Rev. Proc. 2011–49, 2011–44 I.R.B. 608. Rev. Proc. 2011–49 sets forth the procedures for issuing opinion and advisory letters regarding the acceptability under §§ 401 and 403(b) of the form of pre-approved plans (that it, master and prototype (M&P) and volume submitter (VS) plans. Rev. Proc. 2011–49 provided that the procedures for applying for opinion and advisory letters will be updated from time to time. This revenue procedure expands the scope of the pre-approved program to include defined benefit plans containing cash balance features and defined contribution plans containing employee stock ownership plan (ESOP) features. Plans with these types of features have been previously excluded from the pre-approved program. This revenue procedure also reflects changes that were made to the determination letter program to eliminate features that were of limited usefulness to sponsors and to improve program efficiency by reducing the time it takes to process determination letter requests.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 988,290.

OMB Number: 1545–1828.

Type of Review: Extension without change of a previously approved collection.

Title: TD 9048; 9254—Guidance under Section 1502; Suspension of

Losses on Certain Stock Disposition (REG–131478–02).

Abstract: The information in Sec. 1.1502–35(c) is necessary to ensure that a consolidated group does not obtain more than one tax benefit from both the utilization of a loss from the disposition of stock and the utilization of a loss or deduction with respect to another asset that reflects the same economic loss; to allow the taxpayer to make an election under Sec. 1.1502–35(c)(5) that would benefit the taxpayer, the election in Sec. 1.1502–35(f) provides taxpayers the choice in the case of a worthless stock deduction or absorb the subsidiary's losses; and Sec. 1.1502–35(g)(3) applies to ensure that taxpayers do not circumvent the loss suspension rule of § 1.1502–35(c) by deconsolidating a subsidiary and then re-importing to the group losses of such subsidiary.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 15,000.

OMB Number: 1545–1841.

Type of Review: Extension without change of a previously approved collection.

Title: TD 9142 (Final), Deemed IRAs in Qualified Retirement Plans (REG–157302–02).

Abstract: Section 408(q), added to the Internal Revenue Code by section 602 of the Economic Growth and Tax Relief Reconciliation Act of 2001, provides that separate accounts and annuities may be added to qualified employer plans and deemed to be individual retirement accounts and individual retirement annuities if certain requirements are met. Section 1.408(q)–1(f)(2) provides that these deemed IRAs must be held in a trust or annuity contract separate from the trust or annuity contract of the qualified employer plan. This collection of information is required to ensure that the separate requirements of qualified employer plans.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 40,000.

OMB Number: 1545–1969.

Type of Review: Extension without change of a previously approved collection.

Title: Form 13751—Waiver of Right to Consistent Agreement of Partnership Items and Partnership-Level Determinations as to Penalties, Additions to Tax, and Additional Amounts.

Form: 13751.

Abstract: Per the IRS Global Settlement Initiative, the information

requested on Form 13751 will be used to determine the eligibility for participation in the settlement initiative of taxpayers related through TEFRA (Tax Equity and Fiscal Responsibility Act of 1982) partnerships to ineligible applicants. Such determinations will involve partnership items and partnership-level determinations, as well as the calculation of tax liabilities resolved under this initiative, including penalties and interest.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 100.

OMB Number: 1545–1986.

Type of Review: Extension without change of a previously approved collection.

Title: Notice 2006–47, Elections Created or Effected by the American Jobs Creation Act of 2004.

Abstract: The collection of information will enable the Internal Revenue Service to ensure that the eligibility requirements for the various elections or revocations have been satisfied and are in compliance with the requisite sections.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,034,765.

OMB Number: 1545–1990.

Type of Review: Extension without change of a previously approved collection.

Title: Application of Section 338 to Insurance Companies.

Abstract: These regulations will allow companies to retroactively apply the regulations to transactions completed prior to the effective date and to stop an election to use a historic loss payment pattern.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 12.

OMB Number: 1545–2115.

Type of Review: Extension without change of a previously approved collection.

Title: TD 9481—Travel Expenses of State Legislators (REG–119518–07).

Abstract: This document contains regulations relating to travel expenses of state legislators. The regulations affect state legislators who make the election under section 162(h) of the Internal Revenue Code to treat their residences in their legislative districts as their tax homes.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 3,700.

OMB Number: 1545–2133.

Type of Review: Extension without change of a previously approved collection.

Title: Rev. Proc. 2009–16, Section 168(k)(4) Election Procedures and Rev. Proc. 2009–33, Section 168(k)(4) Extension Property Elections.

Abstract: Rev. Proc. 2009–16 provides the time and manner for making the election to apply section 168(k)(4) of the Internal Revenue Code, for making the allocation of the bonus depreciation amount to increase certain limitation, and for making the election to apply section 3081(b) of the Housing and Economic Recovery Act of 2008. It provides the time and manner for a corporation to make the elections provided under new section 168(k)(4)(H) of the Internal Revenue Code with respect to the acceleration of claiming research or alternative minimum tax credits in lieu of claiming the bonus depreciation deduction.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 2,700.

OMB Number: 1545–2134.

Type of Review: Extension without change of a previously approved collection.

Title: Notice 2009–41—Credit for Residential Energy Efficient Property.

Abstract: This notice provides guidance about the procedures by which a manufacturer can certify that residential energy efficient property qualifies for the § 25D credit. This notice is intended to provide (1) guidance concerning the methods by which manufacturers can provide such certifications to taxpayers, and (2) guidance concerning the methods by which taxpayers can claim such credits.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 350.

OMB Number: 1545–2137.

Type of Review: Extension without change of a previously approved collection.

Title: Form 8936—Qualified Plug-in Electric Drive Motor Vehicle Credit (Notice 2009–89).

Abstract: The notice sets forth interim guidance, pending the issuance of regulations, relating to the new qualified plug-in electric drive motor vehicle credit under § 30D of the Internal Revenue Code, as in effect for vehicles acquired after December 31, 2009. For tax years beginning after 2008, Form 8936 is used to figure the credit for qualified plug-in electric drive motor vehicles placed in service during the tax year. The credit attributable to depreciable property (vehicles used for

business or investment purposes) is treated as a general business credit. Any credit not attributable to depreciable property is treated as a personal credit.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 267,780.

OMB Number: 1545–2138.

Type of Review: Extension without change of a previously approved collection.

Title: Form W–8CE—Notice of Expatriation and Waiver of Treaty Benefits.

Form: W–8CE.

Abstract: Information used by taxpayer to notify payer of expatriation so that proper tax treatment is applied by payer. The taxpayer is required to file this form to obtain any benefit accorded by the statute.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 2,840.

OMB Number: 1545–2139.

Type of Review: Extension without change of a previously approved collection.

Title: Identity Theft Affidavit.

Form: 14039, 14039–B, 14039 (SP), 14039–B (SP).

Abstract: The primary purpose of the form is to provide a method of reporting identity theft issues to the IRS so that the IRS may document situations where individuals are or may be victims of identity theft. Additional purposes include the use in the determination of proper tax liability and to relieve taxpayer burden. The information may be disclosed only as provided by 26 U.S.C 6103.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 25,000.

Dated: November 23, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015–30178 Filed 11–25–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

AGENCY: Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in

accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 28, 2015 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing PRA@treasury.gov or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Bureau of the Fiscal Service (FS)

OMB Number: 1530-0007.

Type of Review: Extension without change of a currently approved collection.

Title: Pools and Associations—Annual Letter.

Abstract: Information collected determines acceptable percent for each pool and association Treasury Certified companies are given credit for on Treasury Schedule F for authorized ceded reinsurance in determining the companies' underwriting limitations.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Annual Burden Hours: 126.

OMB Number: 1530-0026.

Type of Review: Extension without change of a currently approved collection.

Title: Certificate of Identity.

Form: FS Form 0385.

Abstract: The information is requested to establish the identity of the owner of U.S. Savings Securities in a claim for payment by a disinterested person.

Affected Public: Individuals or Households.
Estimated Annual Burden Hours: 835.

OMB Number: 1530-0028.

Type of Review: Revision of a currently approved collection.

Title: Special Form of Request for Payment of U.S. Savings and Retirement Sec. Where Use of a Detached Request is Authorized.

Form: FS Form 1522.

Abstract: The information is requested to establish ownership and request for payment of United States Savings Bonds, Savings Notes, Retirement Plan Bonds, and Individual Retirement Bonds.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 5,750.

OMB Number: 1530-0029.

Type of Review: Revision of a currently approved collection.

Title: Claim for lost, stolen or destroyed United States registered Securities

Form: FS Form 1025.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Registered Securities.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 183.

OMB Number: 1530-0033.

Type of Review: Extension without change of a currently approved collection.

Title: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Individuals).

Form: FS Form 1022-1.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities owned by individuals.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 92.

OMB Number: 1530-0034.

Type of Review: Extension without change of a currently approved collection.

Title: Report/Application for Relief on Account of Loss, Theft or Destruction of U.S. Bearer Securities (Organizations).

Form: FS Form 1022-1.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 92.

OMB Number: 1530-0037.

Type of Review: Revision of a currently approved collection.

Title: Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes.

Form: FS Form 2980 and 2490.

Abstract: The information collected is necessary to obtain information

describing an owner's holding of United States Securities.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 310.

OMB Number: 1530-0040.

Type of Review: Revision of a currently approved collection.

Title: Affidavit of Forgery for United States Savings Bonds.

Form: FS Form 0974.

Abstract: The information is requested to establish whether the registered owner signed the request for payment or if the signature was a forgery.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 250.

OMB Number: 1530-0047.

Type of Review: Revision of a currently approved collection.

Title: Affidavit by Individual Surety.

Form: FS Form 4094.

Abstract: The information is requested to support a request to serve as surety for an indemnification agreement on a Bond of Indemnity.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 183.

Dated: November 23, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015-30196 Filed 11-25-15; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF VETERANS AFFAIRS

Commission on Care; Notice of Meeting

In accordance with the Federal Advisory Committee Act, 5 U.S.C., App. 2, the Commission on Care gives notice that it will meet on Monday, December 14, 2015, Tuesday, December 15, 2015, and Wednesday, December 16, 2015 at the J.W. Marriott, Jr. ASAE Conference Center, 1575 I St. NW., Washington, DC 20005. The meeting will convene at 8:30 a.m. and end at 12:30 p.m. on all days. The meeting is open to the public.

The purpose of the Commission, as described in section 202 of the Veterans Access, Choice, and Accountability Act of 2014, is to examine the access of veterans to health care from the Department of Veterans Affairs and strategically examine how best to organize the Veterans Health Administration, locate health care resources, and deliver health care to veterans during the next 20 years.

On the mornings of December 14, 15, and 16, the Commission will hear from

experts who will provide insights on work to be done by the Commission. On the afternoons of December 14, 15, and 16, the Commission will convene closed sessions in accordance with The Government in the Sunshine Act, 5 U.S.C. 552b (c)(2) and (c)(9)(B), or to conduct administrative work.

No time will be allocated at this meeting for receiving oral presentations from the public. The public may submit written statements for the Commission's review to Sharon Gilles or John Goodrich, Designated Federal Officers, Commission on Care, at sharon.gilles@va.gov or john.goodrich@va.gov, respectively. Any member of the public

wanting to attend may contact Ms. Gilles or Mr. Goodrich.

Dated: November 20, 2015.

Sharon Gilles,

Designated Federal Officer, Commission on Care.

[FR Doc. 2015-30072 Filed 11-25-15; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 11, and 111

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, and 111

[Docket No. FDA-2011-N-0143]

RIN 0910-AG64

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The regulation requires importers to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA). The regulation will help ensure the safety of imported food.

DATES: This rule is effective January 26, 2016. For the applicable compliance dates, see “Effective and Compliance Dates” in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614; or Domenic Veneziano, Office of Enforcement and Import Operations (ELEM-3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301-796-6673.

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Executive Summary

Purpose and Coverage of the Rule

This rule is part of FDA’s implementation of the FDA Food Safety Modernization Act (FSMA), which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule adopts provisions concerning FSVPs that importers must create and follow to help ensure the safety of imported food. The regulation is designed to be flexible based on risk, and the requirements vary based on the type of food product (such as processed foods, produce, and dietary supplements) and category of importer.

Congress required importers to perform risk-based foreign supplier verification activities and directed FDA to promulgate regulations on the content of FSVPs in section 301 of FSMA, codified in section 805 of the FD&C Act. The rule requires importers to implement FSVPs to provide adequate assurances that the importer’s foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the FD&C Act, as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.

This rule is the result of significant stakeholder engagement. We took this approach to help ensure that the rule achieves its public health goal, reflects industry practice, and strikes the right balance between flexibility and accountability.

Summary of the Major Provisions of the Final Rule

We are finalizing a flexible, risk-based approach to foreign supplier verification. The FSVP regulation focuses on known or reasonably foreseeable food safety hazards, identified and considered through a hazard analysis and evaluation process, rather than all adulteration covered by the adulteration provisions in section 402 of the FD&C Act. After considering the comments on the proposed rule and the subsequently revised proposal along with other stakeholder input, we continue to believe that hazard analysis, which is well accepted and understood throughout the international food safety community, provides the most effective way to implement a risk-based framework in which importers can evaluate potential products and suppliers and ensure that appropriate verification activities occur.

The FSVP regulation aligns with key components of the food safety plans that facilities that manufacture, process, pack, or hold must establish and follow under FDA’s recently issued regulations on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food and animal food (preventive controls regulations). In particular, the FSVP final rule is consistent with the supply-chain program provisions of those regulations to the extent feasible and appropriate. The general FSVP framework, together with the modified

requirements applicable to certain importers and foods, are intended to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade.

Although FSVP requirements apply to most imported food under FDA's regulatory jurisdiction, certain categories of imported food are not covered under the FSVP regulation. These exemptions include certain juice, fish, and fishery products (which are already subject to verification under FDA's hazard analysis and critical control point (HACCP) regulations for those products), food for research or evaluation, food for personal consumption, alcoholic beverages, food that is transshipped, food imported for processing and future export, food exported from and returned to the United States without manufacturing/processing in a foreign country, and certain meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA).

In the final rule, we have added new provisions to allow greater flexibility with respect to certain requirements to better reflect modern food supply and distribution chains. Under the FSVP regulation, importers are responsible for:

1. Determining the hazards reasonably likely to cause illness or injury with each food. Importers can conduct their own analysis of the potential hazards with a food or review and assess a hazard analysis conducted by another entity.

2. Evaluating the risk posed by a food, using the results of the hazard analysis, and evaluating the foreign supplier's performance. This evaluation informs the approval of foreign suppliers and the determination of appropriate supplier verification activities. An importer may rely on another entity to conduct this evaluation and to determine the appropriate supplier verification activities as long as the importer reviews and assesses the evaluation, determination, or both, as applicable. An importer must approve its own foreign suppliers.

3. Conducting supplier verification activities. In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved. However, importers may import food from unapproved foreign suppliers, on a temporary basis when necessary and appropriate, if they subject the food from these suppliers to adequate verification activities before importing it.

Importers are responsible for determining and documenting foreign supplier verification activities (as well as the frequency with which those activities must be conducted) that are appropriate to provide assurance that hazards requiring a control in food are significantly minimized or prevented. Importers must conduct supplier verification activities for each foreign supplier before importing a food into the United States and periodically thereafter. An importer may determine, document, and conduct these activities itself or may rely on other entities to perform those tasks, as long as the importer reviews and assesses the relevant documentation, including the results of supplier verification activities.

The appropriate verification activities and their frequency will vary depending on the food, the foreign supplier, and the nature of the control. Appropriate verification activities include: onsite auditing, sampling and testing of a food, review of the foreign supplier's relevant food safety records, and other activities that are appropriate based on the evaluation of the risk posed by the food and foreign supplier performance.

When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the default appropriate verification activity under the regulation is an annual onsite audit of the foreign supplier. To provide flexibility even in these circumstances, the rule allows for the performance of a different supplier verification activity and/or less frequent onsite auditing provided an adequate written determination is made that the other approach will meet the public health purpose of supplier verification.

4. Performing appropriate activities in other circumstances. The final rule also adds flexibility and recognizes the reality of modern distribution chains by not requiring an importer to conduct supplier verification (or evaluate the risk posed by a food and the foreign supplier's performance) when the hazard requiring a control in a food will be controlled by a subsequent entity in the distribution chain in the United States. For example, if an importer's customer will control the hazard, the importer can rely on its customer to provide written assurance that the food will be processed for food safety and must disclose that the food has not been processed to control the identified hazard. If the hazard will be controlled by a subsequent entity in the distribution chain, the final rule requires disclosure that the food has not

been processed to control the identified hazard as well as a series of written assurances starting with assurances from the customer to the importer and continuing the obligation to provide written assurance of processing for food safety throughout the distribution chain. We also have provided flexibility for an importer to establish, document, and implement an alternative system that ensures adequate control, at a later distribution step, of the hazards in a food product distributed by a manufacturing/processing facility.

5. Conducting corrective actions. An importer must take appropriate corrective actions promptly if it determines that a foreign supplier of a food it imports does not produce the food in compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, verification activities, or other information. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the problem is resolved.

6. Identifying themselves as the importer of the food for each line of food product offered for importation into the United States.

7. Retaining records of FSVP activities.

Modified Provisions for Certain Types of Importers

The rule provides several exceptions to the standard FSVP requirements for certain types of importers. First, for dietary supplements and dietary supplement components, importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) under the dietary supplement CGMP regulations will not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. The same exception would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements. In contrast, importers of other dietary supplements would be required to comply with most of the standard FSVP requirements but would

not have to conduct hazard analyses, and their supplier verification activities would focus on verifying that the supplier is in compliance with the dietary supplement CGMP regulation, rather than verifying that hazards requiring a control are significantly minimized or prevented, as required under the standard supplier verification activity provisions.

Second, the rule establishes modified FSVP requirements for very small importers and importers of food from certain small foreign suppliers. We have aligned the definition of “very small importer” with the definitions of “very small business” under the regulations on preventive controls for human food and animal food. With respect to the importation of human food, the definition of very small importer has an annual sales ceiling of \$1,000,000, which is consistent with the \$1,000,000 annual sales ceiling for a very small business under the preventive controls for human food regulation. With respect to the importation of animal food, the definition of very small importer has an annual sales ceiling of \$2,500,000, which is consistent with the \$2,500,000 annual sales ceiling for a very small business under the preventive controls for animal food regulation.

In addition, food from three types of small foreign suppliers is not subject to standard supplier verification requirements. Those foreign suppliers are: (1) Qualified facilities under either of the preventive controls regulations, (2) farms that are not “covered farms” under the produce safety regulation in part 112 (21 CFR part 112) in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, and (3) shell egg producers not subject to part 118 (21 CFR part 118) because the shell egg producer has fewer than 3,000 laying hens. Each of these types

of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these producers.

The relatively small volume of food imported by and from these entities should reduce consumers’ exposure to, and potential risk from, this imported food. Therefore, we are proposing that in these situations the importer would not be required to conduct a hazard analysis and would be able to verify their foreign suppliers by obtaining written assurance of their supplier’s compliance with the applicable food safety regulations (or, in some cases, the supplier’s acknowledgement that it is subject to the adulteration provisions of the FD&C Act). This policy is similarly reflected in the supply-chain program provisions of the preventive controls regulations.

Third, the rule excludes from most of the standard FSVP requirements (including hazard analysis and verification that identified hazards are significantly minimized or prevented) certain types of food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that:

- The food is within the scope of the relevant official recognition or equivalency determination;
- The importer determines that the foreign supplier of the food is in good compliance standing with the relevant food safety authority; and
- The food is not intended for further processing in the United States, e.g., packaged food products and raw agricultural commodities (RACs) that will not be processed further before consumption.

These provisions are consistent with our risk-based approach to foreign supplier verification because they enable both importers and FDA to leverage the regulatory efforts of food safety authorities in countries the Agency has officially determined to have food safety systems that are comparable or equivalent to that of the United States.

Costs and Benefits

This final rule requires importers of human and animal food to establish foreign supplier verification programs. It includes requirements regarding use of qualified individuals, evaluation of hazards in food and foreign supplier performance, verification of suppliers (through activities such as onsite audits, testing, and records review), and importer identification at entry. The total annualized costs of the final rule are estimated to be approximately \$435 million per year under 3 percent and 7 percent discount rates over 10 years. In the proposed rule’s Preliminary Regulatory Impact Analysis (PRIA), we calculated costs under three different scenarios reflecting different percentages of importers who, under proposed Option 2 for supplier verification requirements, might choose to conduct onsite audits of their foreign suppliers rather than perform different permitted verification activities. We present the Scenario 1 estimate (under which 63 percent of the importers we estimated would need to conduct mandatory onsite audits of their foreign suppliers under proposed Option 1 would conduct onsite audits under the final rule) as the overall estimate to facilitate comparison with the summary tables in the PRIA and the Supplemental PRIA; however, the summary table provides totals costs under all three scenarios.

TOTAL ANNUAL COST SUMMARY FOR ALL ELEMENTS OF FINAL RULE
[Rounded to nearest million]

	Total
Year 1	
Hiring Qualified Individuals:	
Scenario 1	\$34
Scenario 2	33
Scenario 3	32
Conducting Information Collection and Food and Supplier Evaluations	89
Writing and Maintaining Procedures Relating to Verification Requirements	51
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Receipt of Food From Approved Suppliers:	
Scenario 1	245
Scenario 2	241
Scenario 3	237
Obtaining Written Assurances From Foreign Suppliers, Customers, and Other Entities in U.S. Distribution	31
Documenting Very Small Importer or Small Supplier Status	6
Conducting Corrective Actions	1

TOTAL ANNUAL COST SUMMARY FOR ALL ELEMENTS OF FINAL RULE—Continued
 [Rounded to nearest million]

	Total
Importer Identification	7
Grand Total Year 1:	
Scenario 1	464
Scenario 2	459
Scenario 3	456
Every Year After Year 1	
Hiring Qualified Individuals:	
Scenario 1	34
Scenario 2	33
Scenario 3	32
Conducting Information Collection and Food and Supplier Evaluations	74
Writing and Maintaining Procedures Relating to Verification Requirements	42
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Receipt of Food From Approved Suppliers:	
Scenario 1	245
Scenario 2	241
Scenario 3	237
Obtaining Written Assurances From Foreign Suppliers, Customers, and Other Entities in U.S. Distribution	23
Documenting Very Small Importer or Small Supplier Status	6
Conducting Corrective Actions	1
Importer Identification	7
Grand Total Every Year After Year 1:	
Scenario 1	431
Scenario 2	426
Scenario 3	422

Although the FSVP regulation does not establish safety requirements for food manufacturing and processing, it benefits the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations. The Regulatory Impact Analyses for the final rules on preventive controls for human food and standards for produce safety consider and analyze the number of illnesses and deaths that those regulations are aimed at reducing. The greater the compliance with those regulations, the greater the expected reduction in illnesses and deaths as well as the costs associated with them. The FSVP regulation will be an important mechanism for improving and helping to ensure compliance with the above-noted food safety regulations as they apply to imported food. For this reason,

and because we do not have sufficient data to determine the extent to which particular regulations might be responsible for the expected reduction in foodborne illnesses resulting from the FSMA final rules, we account for the public health benefits of the FSVP regulation in the preventive controls, produce safety, and other applicable food safety regulations instead of in this final rule.

I. Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety

problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to problems when they occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry’s implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in Table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 preventive controls for human food proposed rule.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 produce safety proposed rule	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 preventive controls for animal food proposed rule.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	2013 FSVP proposed rule	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 third-party certification proposed rule.	78 FR 45782, July 29, 2013.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA—Continued

Title	Abbreviation	Publication
Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.	2013 intentional adulteration proposed rule.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 sanitary transportation proposed rule.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in Table 2 and requested comments on specific issues identified in each supplemental notice.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 preventive controls for human food supplemental notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 produce safety supplemental notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 preventive controls for animal food supplemental notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	2014 FSVP supplemental notice	79 FR 58574, September 29, 2014.

We finalized two of the foundational rulemakings listed in Table 3 in September 2015.

TABLE 3—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	Preventive controls for human food final rule.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	Preventive controls for animal food final rule.	80 FR 56170, September 17, 2015.

As we finalize these seven foundational rulemakings, we are putting in place a modern framework for food safety that brings to bear the most current science on the regulation of food safety, is risk-based and focuses efforts on known or reasonably foreseeable hazards, and is flexible and practical given existing food safety practices. To achieve this, we have engaged in extensive outreach to the stakeholder community to find the right balance of flexibility and accountability in this regulation.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 1–3). As a result of this stakeholder dialogue, we decided to issue the four supplemental notices of proposed rulemaking to announce several changes to our proposals, share our current thinking on key issues, and

get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. We believe these seven foundational final rules will effectively implement the paradigm shift toward prevention envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

B. Stages in the FSVP Rulemaking

Section 301 of FSMA added section 805 to the FD&C Act (21 U.S.C. 384a) to require persons who import food into the United States to perform risk-based foreign supplier verification activities. Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of FSVPs.

We published a proposed rule on FSVPs in 2013 (78 FR 45730, July 29,

2013). We published new and revised provisions in a 2014 supplemental notice of proposed rulemaking (Supplemental Notice) (79 FR 58574, September 29, 2014). In the Supplemental Notice, we reopened the comment period on the proposed rule only with respect to specific proposed provisions. In addition, we emphasized that the revised provisions we included in the regulatory text were based on a preliminary review of the comments.

In this document, we use the terms “FSVP proposed regulations” or “proposed rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed rule and the new and revised provisions we published in the 2014 Supplemental Notice. We use the terms “2013 FSVP proposed rule” and “Supplemental Notice” to refer to specific text published in those documents. We use the terms “FSVP regulation,” “final rule,” and “this rule” to refer to the regulation we are establishing as a result of this

rulemaking. We also use the term “preventive controls regulations” to refer to the regulations on preventive controls for human food and preventive controls for animal food collectively.

C. Summary of the Major Provisions of the Proposed Rule

The proposed FSVP regulation, set forth in proposed subpart L of part 1 (21 CFR part 1), would require importers of most imported food to take risk-based steps to verify that the food they import is produced in compliance with applicable FDA regulatory requirements. The proposed regulation was intended to work in tandem with provisions of FSMA and the FD&C Act to create a more seamless system of food safety, applicable to both domestic and imported food, that provides appropriate layers of protection for U.S. consumers. At its core, FSMA establishes a preventive and risk-based approach that assigns to the food industry the primary responsibility for food safety. For example, FSMA requires food facilities that manufacture, process, pack, or hold food to implement risk-based preventive controls (in section 103 of FSMA, codified in section 418 of the FD&C Act (21 U.S.C. 350g)), with certain exceptions. FSMA also requires FDA to establish science-based, minimum standards for farms that grow, harvest, pack, and hold certain produce, also with certain exceptions (in section 105 of FSMA, codified in section 419 of the FD&C Act (21 U.S.C. 350h)). The intent of these requirements is to ensure that all segments of the food industry meet their responsibilities under the FD&C Act to produce safe food.

While FSMA grants FDA additional enforcement tools and directs the Agency to increase its inspections of food facilities, Congress determined that more was needed to adequately control the safety risks posed by imported food. Thus, FSMA creates new obligations for food importers. The FSVP proposed regulation was intended to ensure that importers take responsibility for the safety of the food they import into the United States so no food safety gaps exist between foreign producers and U.S. consumers.

Through this and other FSMA regulations, we are establishing a modern, risk-based food safety system designed to hold those in the food safety supply chain accountable for meeting their responsibilities. In doing so, we recognize the variability within the food industry of the size of operations and the type and volume of foods produced. Therefore, we have written regulations that provide a flexible approach to food

safety, taking into account the risk posed by the food and the size of the regulated businesses. While these regulations establish strong, risk-based food safety standards, they allow firms flexibility in determining how they will meet these standards, as appropriate.

In accordance with FSMA, the FSVP regulation we proposed would require food importers to adopt programs to ensure that the food they import: (1) Is produced in a manner that provides the same level of public health protection as required under section 418 or 419 of the FD&C Act, as appropriate; (2) is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning allergen labeling). The proposed rule would require importers to take the following actions as part of their FSVPs:

- Use a qualified individual to perform most FSVP activities;
- Analyze known or reasonably foreseeable hazards in foods they import to determine if the hazards are significant;
- Determine and perform verification activities for foods they import, based on the hazard analysis and an evaluation of supplier risks;
- Establish and follow procedures to ensure they import foods only from foreign suppliers they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis);
- Review complaints, conduct investigations of adulterated or misbranded food, take corrective actions when appropriate, and modify the FSVP when it is determined to be inadequate;
- Reassess the effectiveness of the FSVP;
- Ensure that information identifying the importer is submitted upon entry of a food into the United States; and
- Maintain records of FSVP procedures and activities.

In addition to these “standard” FSVP requirements that would apply to most food importers, the proposed rule included modified requirements for the following:

- Importers of dietary supplements and dietary supplement components;
- Very small importers and importers of food from very small suppliers; and
- Importers of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the U.S. food safety system.

D. Public Comments

We received more than 300 public submissions on the 2013 FSVP proposed rule and more than 100 public submissions on the 2014 Supplemental Notice, each containing one or more comments on various aspects of the proposal. We received submissions from diverse members of the public, including the following: Importers; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress; Federal, State, local, and tribal Government Agencies; foreign governments; and other organizations. The comments address virtually every provision of the FSVP proposed rule. In the remainder of this document, we describe these comments, respond to them, and explain any changes we made to the proposed regulation.

Some comments address issues that are outside the scope of this rulemaking. For example, we received comments asking that we increase the frequency and standardization of our inspection of foreign food facilities, improve our entry review procedures, and revise the Reportable Food Registry. We do not discuss such comments in this document.

II. Legal Authority

On January 4, 2011, FSMA was signed into law. Section 301 of FSMA added section 805 to the FD&C Act to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying the following: (1) The food is produced in compliance with section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are RACs) of the FD&C Act, as appropriate; (2) the food is not adulterated under section 402 of the FD&C Act; and (3) the food is not misbranded under section 403(w) of the FD&C Act (concerning food allergen labeling). Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of FSVPs. Section 805(c)(2)(A) states that these regulations must require that the FSVP of each importer is adequate to provide assurances that each of the importer’s foreign suppliers produces food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, as appropriate, and in

compliance with sections 402 and 403(w) of the FD&C Act. Section 805(c)(2)(B) states that these regulations must include such other requirements as FDA deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

Section 805(c)(3) of the FD&C Act directs FDA to, as appropriate, take into account differences among importers and types of imported food, including based on the level of risk posed by the imported food. Section 805(c)(4) states that verification activities under FSVPs may include monitoring records for shipments, lot-by-lot certification of compliance, annual onsite inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments of imported products. Section 805(d) states that records of an importer related to a foreign supplier verification program must be maintained for a period of not less than 2 years and must be made available promptly to a duly authorized representative of the Secretary of the Department of Health and Human Services (the Secretary) upon request. Section 805(g) directs FDA to publish and maintain a list of importers participating under section 805 on the Agency's Web site.

Section 301(b) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding section 301(zz), which designates as a prohibited act the importation or offering for importation of a food if the importer (as defined in section 805 of the FD&C Act) does not have in place an FSVP in compliance with section 805. In addition, section 301(c) of FSMA amends section 801(a) of the FD&C Act (21 U.S.C. 381(a)) by stating that an article of food being imported or offered for import into the United States must be refused admission if it appears from an examination of a sample of such an article or otherwise that the importer is in violation of section 805.

In addition to the authority specified in section 301 of FSMA to issue this regulation, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Also, some aspects of the FSVP regulation are supported by section 421(b) of the FD&C Act (21 U.S.C. 350j(b)).

In addition to the FD&C Act, FDA's legal authority for some aspects of the regulations derives from the Public Health Service Act (PHS Act) to the extent such measures are related to

communicable disease. Authority under the PHS Act is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act) (see section 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary).

III. Comments on the Proposed Rule and Supplemental Notice of Proposed Rulemaking

A. Definitions (§ 1.500)

We proposed to codify definitions of several terms that we use in the FSVP regulation. As discussed in the following paragraphs, we have revised several of the proposed definitions in response to comments we received. The definitions for terms used in the FSVP regulation are set forth in § 1.500.

1. Definitions Generally

(Comment 1) Some comments suggest that we use the same definition for terms used in different FSMA rulemakings.

(Response 1) We agree and have aligned the definitions used in the different regulations as much as possible. However, in some cases the definitions of terms differ because of differences in the applicable statutory provisions or in the scope or purpose of the regulations.

2. Audit

We proposed to define "audit" as the systematic, independent, and documented examination (through observation, investigation, records review, and, as appropriate, sampling and laboratory analysis) to assess a foreign supplier's food safety processes and procedures.

On our own initiative, we have changed the definition to refer to an "audited entity" rather than a "foreign supplier" because in some cases an importer might conduct (or rely on the results of) an onsite audit of an entity other than the foreign supplier (such as a foreign supplier's supplier) to meet FSVP requirements. In addition, consistent with auditing practice we have added discussions with employees of the audited entity to the list of activities that might be included in an audit.

(Comment 2) One comment recommends that we interpret an "independent" examination as including audits other than third-party audits, such as audits conducted by the importer or the importer's customer.

(Response 2) To the extent the comment is requesting that the definition of the term "audit" allow an importer to rely on an audit conducted by the importer itself, we agree. To the extent, however, the comment is requesting that there be no requirements for the independence of auditors, we disagree. Any qualified auditor conducting an audit relied upon by an importer would need to meet the requirements for independence set forth in § 1.506(e)(4), discussed in section III.G.7 of this document. Note, however, that under § 1.506(e)(2)(i) an importer cannot rely on a supplier's self-audit to fulfill the importer's requirement to conduct supplier verification under § 1.506 (because the supplier would have an inherent conflict of interest regarding the audit results).

(Comment 3) One comment requests that sampling and laboratory analysis not be specified as a potential component of an audit because they are separate verification activities.

(Response 3) While sampling and laboratory analysis might in some instances be conducted instead of an audit or other verification activities, we do not agree that sampling and laboratory analysis cannot also be included as a component of an audit. A qualified auditor might reasonably determine that it is appropriate to include some sampling and testing of a food or raw material or other ingredient as part of an onsite audit of a foreign supplier.

3. Environmental Pathogen

We proposed to define "environmental pathogen" as a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. The proposed definition also specified that environmental pathogens do not include the spores of pathogenic sporeformers. To provide additional clarity, the final rule specifies in the definition that examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella* spp.

(Comment 4) Some comments suggest that instead of a "pathogen," the definition of environmental pathogen

should refer to “pathogenic bacteria” because the latter term is considered more relevant to protecting food safety.

(Response 4) We do not agree.

Pathogens other than bacteria might be capable of surviving in a manufacturing environment, cause food to be contaminated, and result in foodborne illness.

4. Farm

We are adding a definition of “farm” to the final rule. A “farm” is a farm as defined in § 1.227 (21 CFR 1.227) in the regulation on registration of food facilities.

5. Farm Mixed-Type Facility

We are adding a definition of “farm mixed-type facility” to the final rule. A “farm mixed-type facility” is an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the FD&C Act (21 U.S.C. 350d).

6. Food

We proposed to define “food” as having the meaning given in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), except that food would not include pesticides as defined in 7 U.S.C. 136(u).

(Comment 5) Several comments request that we exclude food contact substances from the definition of food because facilities that manufacture, process, pack, or hold food contact substances are not required to register with FDA and therefore are not subject to the proposed regulations on preventive controls. One comment suggests that we either exclude food packaging from the FSVP regulation or establish modified requirements for packaging.

(Response 5) We do not agree that it is appropriate to exclude food contact substances (including food packaging), as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), from the definition of “food” for FSVP purposes. The definition of “food” in § 1.227, for the purposes of food facility registration, excludes food contact substances as defined in section 409(h)(6) of the FD&C Act. Consequently, a facility that manufactures/processes, packs, or holds food contact substances is not required to be registered. Because section 418 of the FD&C Act only applies to establishments that are required to register, facilities involved in the manufacturing/processing, packing, and holding of food contact substances are not subject to the preventive control regulations implementing section 418. Section 805 of the FD&C Act, however,

is not similarly limited to facilities that are required to register. Instead, section 805 applies to imports of “food.” The term “food” is defined in section 201(f)(3) of the FD&C Act to include articles used as components of food, and the case law interpreting the definition makes clear that many substances that meet the definition of food contact substances under section 409(h)(6) of the FD&C Act also meet the definition of food (see, e.g., *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food); *U.S. v. Articles of Food 688 Cases of Pottery (Cathy Rose)*, 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food)). Further, we do not believe there is any evidence that Congress intended to exclude food contact substances from being considered “food” for purposes of section 805 and the FSVP regulation.

(Comment 6) Several comments request that we add raw materials and other ingredients to the definition of food for clarity and for consistency with the definition of food in the preventive controls regulations.

(Response 6) We conclude that the suggested change is unnecessary because the definition of food in section 201(f) of the FD&C Act, which we are incorporating in the FSVP regulation, defines food as including articles used for components of any such food or drink for man or animals, which includes raw materials and other ingredients.

(Comment 7) One comment states that chemicals used in processing foods (e.g., hydrochloric acid in the production of cheese) that are declared as food-grade most likely will be used in food production but sometimes will not be used for such purposes. The comment asks that we provide guidance on how to address such imported chemicals.

(Response 7) As explained in section III.B.9 of this document, substances such as chemicals that are capable of food and non-food use are subject to the FSVP regulation if they are reasonably likely to be directed to a food use. In the example provided by the comment, the application of the FSVP regulation would not be based solely on whether a substance is declared as food-grade. However, we would consider the fact that the chemical is declared as food-grade in determining whether the chemical is reasonably likely to be directed to a food use.

7. Foreign Supplier

We proposed to define “foreign supplier” as, for an article of food, the establishment that manufactures/

processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

In the preamble to the proposed rule, we stated that the proposed definition of foreign supplier was generally consistent with the definition of a foreign facility under the preventive controls section (section 418) of the FD&C Act. However, we stated that the proposed definition of foreign supplier did not include firms that only pack or hold food, with no or de minimis manufacturing/processing (even if the firm is required to register with FDA under section 415 of the FD&C Act) because we tentatively concluded that Congress intended the importer to verify a single foreign supplier for a particular shipment of a food and, when several entities are required to register as foreign facilities with respect to this food, excluding a subsequent registered packer or holder who does not do any significant manufacturing/processing would be consistent with this intent. We also stated that the proposed exclusion from the definition of foreign supplier of any establishment engaging in further manufacturing/processing of a food that consists solely of the addition of labeling or any similar activity of a de minimis nature was consistent with FDA regulations on the registration of foreign food facilities in subpart H of part 1 (see 21 CFR 1.226(a)).

(Comment 8) Several comments oppose the proposed definition of foreign supplier because they believe it would require importers to go more than “one step back” in the supply chain to conduct supplier verification. The comments maintain this would be inconsistent with section 204(d)(1)(L) of FSMA and the section 414 of the FD&C Act (21 U.S.C. 350c)). The comments assert that, when foods are obtained from entities such as brokers, distributors, and consolidators, rather than the entity that manufactured/processed, raised, or harvested the food, it would be difficult for the importer to know the identity of the producer because the consolidator might refuse to reveal this information due to concern that the importer might decide to buy directly from the producer in the future. The comments also maintain that in these circumstances, particularly with consolidated or commingled RACs, it would be impractical and burdensome to have to conduct supplier verification of the original producer of the food and could result in multiple audits of the

same farm or manufacturer. Therefore, some comments request that we define the foreign supplier as the immediate previous source of an imported food. The comments assert that under this definition, importers would conduct verification activities to assess the supplier's ability to verify that its suppliers (growers or manufacturers) were producing food consistent with U.S. requirements.

(Response 8) Although we understand the concerns related to obtaining food from an entity that did not manufacture/process, raise, or harvest the food, such as distributors, warehouses, and consolidators of RACs, we decline to revise the definition of foreign supplier as suggested. The other FSMA and FD&C Act provisions noted by the comments were enacted to serve different purposes than the FSVP provisions. Section 805(c)(2)(A) of the FD&C Act specifically directs FDA to adopt regulations requiring that each importer's FSVP is adequate to provide assurances that "the foreign supplier to the importer *produces* the imported food" (emphasis added) in compliance with the applicable U.S. standards. Therefore, we conclude that Congress did not intend supplier verification to be conducted for entities that only perform activities of a de minimis nature with respect to the imported food. Consequently, we conclude that it would not be appropriate to define "foreign supplier" so that the importer would be conducting supplier verification of an entity in the supply chain that did not perform any significant processing step, such as distributors and some consolidators of RACs.

However, we understand that the requirement to perform supplier verification on the establishment that manufactures/processes, raises, or grows the imported food could impose a greater burden on importers when the foreign supplier is not the immediate source of the imported food, such as the case with consolidated RACs. To address this concern, we have revised the provisions on hazard analysis, evaluation for foreign supplier approval and verification, and supplier verification activities to allow an importer of a food to obtain information needed to meet certain FSVP requirements from other entities, such as a distributor or consolidator of that food. As discussed in sections III.E.5, III.F.4, and III.G.4 of this document, an importer may review and assess hazard analyses, evaluations of the risk posed by a food and the foreign supplier's performance, determinations of appropriate foreign supplier verification

activities, and results of such activities conducted by other entities for an imported food to meet its FSVP requirements in these areas. We anticipate that many importers will be able to rely on activities conducted by other entities, which will reduce the need for importers to directly verify the compliance of producers from which the importers did not directly purchase the imported food. We conclude that this approach to foreign supplier verification ensures that the FSVP requirements are consistent with FSMA while limiting the burden that otherwise might be imposed on importers when the foreign supplier of a food is not the importer's direct source for the food.

(Comment 9) One comment states that firms that pack or hold food products (other than of de minimis value) could introduce hazards during these operations. The comment maintains that the proposed definition of foreign supplier conflicts with the definition of facility in the FD&C Act and appears contrary to the intent of ensuring the safety of imported food. One comment asks that we revise the definition of foreign supplier to clarify that, in addition to an entity that harvests a food, a foreign supplier might be the establishment that owns (or owns and packs) a harvested food.

(Response 9) We decline to change the definition of foreign supplier to include entities that only own, pack, or hold food. We conclude that defining foreign supplier to include a firm that only owns or packs or holds a food would not be consistent with Congressional intent, because it would have the effect of requiring that importers verify the establishment that merely owns, packs, and/or holds a food—as opposed to the establishment that "produces" a food. As stated previously, in enacting section 805(c)(2)(A) of the FD&C Act, Congress specifically directed us to adopt regulations requiring that each importer's FSVP is adequate to provide assurances that "the foreign supplier to the importer *produces* the imported food" (emphasis added) in compliance with the applicable U.S. standards.

(Comment 10) Two comments request that we revise the definition of foreign supplier to include an exception for activities conducted on RACs that do not change the RAC into processed food. The comments maintain that farms that grow and harvest produce should not be regarded as foreign suppliers if the produce is sent to a packing operation that is not part of the farm before the produce is exported. The comments assert that because the packing operation is a separate entity from the farm, the activities performed at the

packing operation (such as washing and grading) should be considered manufacturing/processing by another establishment. The comments ask that we revise the definition of foreign supplier as follows:

- Specify that activities with RACs that do not change the RAC into processed food would not constitute further manufacturing/processing that would make an establishment a foreign supplier.
- State that when an entity aggregates a RAC from multiple farms without changing the RAC into processed food, the aggregator and the farm that produced the RAC will both be considered foreign suppliers.

(Response 10) We decline to revise the definition of foreign supplier as requested. In general, though not always, an entity between the farm and the importer that performs an activity that does not change a RAC into processed food would not be the foreign supplier of the RAC because, in most but not all cases, that entity would most likely not be manufacturing/processing the RAC but would only be packing or holding the RAC. For example, a packing operation that is a separate entity from a farm that only washes and grades produce RACs incidental to packing and holding the RACs is not manufacturing/processing the RACs but only packing and holding them.

We also conclude it would not be consistent with FSMA to designate multiple foreign suppliers of the same food, which would result by specifying that both the aggregator in the example and the farm that grew the RAC would be foreign suppliers of that RAC. If an aggregator is merely packing and/or holding RACs, and not performing manufacturing/processing (and no other foreign entity is doing more than de minimis manufacturing/processing of the food before export), then the farm that grew the RAC would be the foreign supplier of the RAC.

(Comment 11) One comment asks that we clarify whether food facilities required to register, such as off-farm packing houses, are foreign suppliers. This comment also asks whether farms that are not required to register and that have on-farm packing operations are foreign suppliers. Noting that RACs often are harvested by a contract harvest company, the comment also asks us to clarify what is meant by "establishment that harvests a food" and whether, in such circumstances, the foreign supplier of the RAC would be the contract harvest company or the establishment that owns the crop and sells it to an importer.

(Response 11) The foreign supplier of a crop that is grown and harvested would either be the establishment that grew the food or, if another foreign entity later manufactured/processed the food (performing an activity of a more than de minimis nature), the foreign supplier would be the last entity in a foreign country that performed such a manufacturing/processing activity. Because, as previously stated, the definition of foreign supplier does not include firms that only pack or hold food, off-farm packing houses that solely pack or hold food would not be foreign suppliers. In such cases, assuming that no other foreign entity manufactures/processes the food (performing an activity of more than a de minimis nature) after it is grown, the farm that grows the food is the foreign supplier. Similarly, provided that no foreign entity manufactures/processes the food (performing an activity of more than a de minimis nature) after it is grown, farms that grow food and also have on-farm packing operations are foreign suppliers of the food they grow because they grew the food.

Our consideration of the comment on contract harvesting, and of comments we received on the definition of “farm” in the rulemaking on preventive controls for human food, has led us to change the definition of foreign supplier as it relates to farming operations and to make other changes to clarify the importer’s responsibilities when multiple entities in its supply chain control different hazards in the same food. The definition of “farm” in the proposed rule on preventive controls for human food referred to an entity “devoted to the growing *and* harvesting of crops, the raising of animals (including seafood), or both” (78 FR 3646 at 3795, January 16, 2013) (emphasis added). However, as discussed in the preamble to the final rule on preventive controls for human food, farming operations can take diverse forms, including those in which multiple growers share ownership of a packinghouse and those in which separate operations grow and harvest a crop (80 FR 55908 at 55926 to 55927, September 17, 2015). Therefore, the definition of farm in § 1.227 (which is included in the definitions applicable to the FSVP regulation under § 1.500 of the final rule) refers to a “primary production farm” as an operation devoted to the “growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.” This change to the definition of farm accommodates business models in

which growing, harvesting, and packing operations—each of which requires the application of controls—are conducted by different business entities.

When we referred, in the FSVP proposed rule, to an establishment that “harvests the food” as being the foreign supplier, we assumed that the grower of a food was also the harvester, and because harvesting followed growing, it was appropriate to refer to the harvesting, rather than growing, of a food in the definition of foreign supplier. However, as noted by the comment and discussed in the previous paragraph, a food is not always grown and harvested by the same establishment. Given the possibility that the growing and harvesting of a food might be conducted by separate entities, we conclude that, for purposes of the definition of “foreign supplier,” it is appropriate to regard the grower of a food, rather than the harvester, as the foreign supplier of the food. Although there are some hazards that must be controlled during harvesting (*e.g.*, worker hygiene, water quality), we believe that most people would regard the farm that grows a crop as the producer of the food rather than the establishment that harvests the crop. Given the potential complexities associated with different harvesting contractual relationships, the grower of a crop may be more easily identifiable than the harvester. In addition, making the grower the foreign supplier facilitates onsite auditing of the supplier because there is a clearly defined physical location for the farm on which the crop is grown, while the entity conducting harvesting might not own or have control over the site at which harvesting occurs (*e.g.*, mobile harvesting operations).

This change in the definition of foreign supplier from the harvester of a food to the grower of the food means that, when food is harvested on a farm by a contract harvest company, even one that takes ownership of the food, the grower of the food would be the foreign supplier (provided that no other foreign entity manufactures/processes the food by performing an activity of more than a de minimis nature).

Although the final rule defines the grower of a food, rather than the harvester, as the foreign supplier, the importer still must obtain assurances that hazards associated with the harvesting and packing of food are being significantly minimized or prevented. Without such assurances, we conclude that an importer could not meet its obligation under section 805(a)(1) of the FD&C Act of verifying that imported food is produced in compliance with

sections 418 and 419, as applicable, and that such food is not adulterated under section 402 or misbranded with respect to allergen labeling under section 403(w). We address this issue further in the discussion of the determination of appropriate supplier verification activities in section III.G.4 of this document.

(Comment 12) One comment asks that we clarify how the definition of foreign supplier compares to the definitions of “grower” and “manufacturer” in the prior notice regulation. The comment asks whether the terms grower and manufacturer, collectively, equate to the term foreign supplier. The comment notes that “grower” is defined in the prior notice regulation (21 CFR part 1, subpart I) in 21 CFR 1.276(b)(7) as a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both; “manufacturer” is defined in § 1.276(b)(9) as the last facility (as defined in § 1.227) that manufactured/processed the food. Under § 1.227, a facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature.

(Response 12) As previously stated, the final rule defines the foreign supplier of a crop as the grower of the food rather than the harvester. Consequently, with respect to food that is grown, the definition of “foreign supplier” for FSVP purposes differs from the definition of “grower” under § 1.276(b)(7), which includes both growing and harvesting. Regardless, definitions used in the prior notice regulation do not apply to words or phrases in the FSVP regulation, and vice versa.

(Comment 13) One comment asks that the definition of foreign supplier exclude farms that grow non-produce botanical, algal, or fungal RACs. The comment asserts that these products have a complicated supply chain that makes it difficult to identify the farms that grow them, there are no public health reasons to identify these farms, and there are no regulations governing the production of these products.

(Response 13) We decline to adopt a different approach for these particular types of RACs compared to the previously stated approach to defining the foreign supplier of a RAC. Provided these products are being imported for use as food as defined in 201(f) of the FD&C Act, importers of these products are subject to FSVP. However, the FSVP regulation does not require that the importer be the entity to gather

information about the farms. Rather, the regulation allows importers of such RACs to obtain information from other entities in the supply chain for the RAC to meet the importers' FSVP requirements for these products, provided the importer reviews and assesses the information and documents the review and assessment.

(Comment 14) Several comments request that we clarify whether certain activities are "de minimis" activities and therefore would mean the entity performing these activities for a food would not be the foreign supplier of the food. Some comments ask whether waxing, cooling, washing, and repacking are de minimis activities. Some comments maintain that sorting, packing, cooling, and holding of produce by packing houses should be regarded as de minimis activities, as should farm activities such as waxing, sorting, culling, conveying, storing, labeling, packing, packaging, and shipping of RACs.

(Response 14) The foreign supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing except for the addition of labeling or any similar activity of de minimis nature. This means that a foreign supplier is not an entity that merely performs de minimis manufacturing/processing activities, but, importantly, a foreign supplier also is not an entity that only packs or holds a food.

Whether an activity is harvesting, manufacturing/processing, packing, or holding can depend on the circumstances. For example, packing, cooling, and holding performed by an off-farm packing house (that only packs and holds produce and cools the produce incidental to packing and holding) would not make the packing house the foreign supplier, because these activities would not be considered manufacturing/processing but only packing and holding. Waxing, sorting, culling, conveying, storing, packing, and shipping of RACs when conducted on a farm would generally be considered harvesting, packing, or holding. Assuming the farm conducting these activities grows the RACs and no other entity manufactures/processes the food (except de minimis manufacturing/processing) before it enters the United States, the farm would be the foreign supplier.

With regard to the packaging of RACs, packaging is a manufacturing/processing activity but is specifically included within the farm definition. A farm that raises an animal or grows a

crop and performs packaging operations would be the foreign supplier (assuming that no other entity manufactures/processes the food except for de minimis manufacturing/processing).

Concerning the comment's reference to re-packing, re-packing is a packing activity (*i.e.*, the definition of packing includes re-packing), not a manufacturing/processing activity. We regard waxing and cooling RACs, when done by a packing operation for purposes of storage or transport, to be packing activities rather than manufacturing/processing activities.

To help explain FDA's current thinking on the classification of activities as "harvesting," "packing," "holding," or "manufacturing/processing," we will issue a draft guidance for industry on preventive controls for human food. We intend for this guidance, when finalized, to provide sufficient examples of activities within each of these definitions to inform both industry and regulators of those activities we consider to be within those definitions. The draft guidance will be available for public comment in accordance with our regulation on good guidance practices (see 21 CFR 10.115(g)(1)). We will consider comments we receive on the draft guidance in developing the final guidance.

(Comment 15) One comment, noting that coffee beans are extracted from the cherry surrounding the bean by fermentation, washing, and/or drying at a mill, asserts that because these activities are more than de minimis in nature, the mill should be regarded as the foreign supplier of the coffee beans.

(Response 15) We agree that fermentation, washing, and/or drying of raw coffee cherries (or "berries") would constitute manufacturing/processing that is not of a de minimis nature and would make the mill the foreign supplier of the coffee beans (provided no subsequent entity conducted additional manufacturing/processing that is not of a de minimis nature before export to the United States). We note, however, that under § 1.507(a)(1) of the final rule, importers of foods that cannot be consumed without the application of an appropriate control, including RACs like coffee beans, are not subject to the full requirements of the FSVP regulation (see the discussion in section III.H.1 of this document).

(Comment 16) One comment asks that we distinguish "further manufacturing/processing by another establishment" under the proposed definition of foreign supplier from the concept of substantial transformation applied by U.S. Customs and Border Protection (CBP).

(Response 16) The concept of "further manufacturing/processing by another establishment" in the definition of "foreign supplier" under the FSVP regulation and the definition of "substantial transformation" as used by CBP (*i.e.*, the emergence of an article from manufacturing processes as a new and different article, with a distinctive name, character, or use) are used for different purposes and do not necessarily refer to the same processes. Further manufacturing/processing in the context of FSVP involves direct manipulation of a food, but it need not result in a new and different article, as it can include activities such as washing and freezing.

8. Good Compliance Standing With a Foreign Food Safety Authority

We proposed to define "good compliance standing with a foreign food safety authority" as meaning the foreign supplier (1) appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food manufacturers and processors that are in good compliance standing with the food safety authority, or (2) has otherwise been designated by such food safety authority as being in good compliance standing. Under § 1.513 of the final rule (discussed in section III.N of this document), modified FSVP requirements apply, subject to certain conditions and requirements, to importers of certain types of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the U.S. system. One of the requirements for eligibility for the modified requirements is that the foreign supplier must be in good compliance standing with the food safety authority of a country with a comparable or equivalent food safety system.

On our own initiative, we revised the definition to reference to "food producers" instead of "food manufacturers and processors" because farms might be included among food producers designated as being in good compliance standing by a foreign food safety authority.

(Comment 17) One comment questions the need for this term in the FSVP regulation given that all U.S. importers of food must ensure the safety of the food they import. The comment maintains that it is unclear whether or to what extent a foreign supplier's inclusion on a list maintained by a foreign food safety authority will

facilitate an importer's access to a foreign-supplied food. The comment also asserts that it is unclear whether any country's food safety authority can be required to develop and maintain such a list and suggests that there will be disparity among countries regarding whether such a list can and will be developed.

(Response 17) The term good compliance standing with a foreign food safety authority is used to describe one of the conditions under which an importer is eligible to import certain types of food under the modified requirements in § 1.513 of the final rule. We conclude it is appropriate to condition the use of these modified requirements on the foreign supplier of the food being in good compliance standing with the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States. If the foreign supplier is not in good compliance standing, we conclude that the importer would lack adequate assurances that the foreign supplier is producing the food consistent with U.S. requirements. Although foreign authorities will not be required to designate food producers as being in good compliance standing, we believe that it is likely that some authorities will decide to do so.

(Comment 18) One comment suggests that the official registration or approval of an establishment by the relevant competent authority should be considered sufficient to meet the requirement of good compliance standing. The comment asserts that because all food establishments in the European Union (EU) are either registered with, or approved by, the national authorities, the existence of the records of these actions should be taken into account to avoid unnecessary or duplicative work.

(Response 18) We do not agree. We conclude that the fact that a foreign supplier is registered with, or approved to operate by, the food safety authority of the country in which it is located would generally not constitute a designation that the foreign supplier was in good compliance standing with that authority, absent a determination or designation by a food safety authority indicating that the supplier is in good compliance standing within the meaning in § 1.500. We believe it is possible a foreign supplier might maintain its registration or approval to operate even while it is the subject of an ongoing enforcement action due to significant non-compliance. Therefore, a foreign supplier cannot be regarded as

in good compliance standing with a food safety authority unless that authority has affirmatively designated that supplier as being in good compliance standing, either through the supplier's inclusion on a list of such suppliers, a company-specific certification, or some other manner of designation.

9. Harvesting

For clarity and consistency, we are adding a definition of "harvesting" that is consistent with the definition in the preventive controls regulations. Our new definition states that harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on RACs on a farm. Harvesting does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of a RAC from the crop plant and removing or trimming part of the RAC (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming outer leaves of, and washing RACs grown on a farm.

10. Hazard

We proposed to define "hazard" as any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

On our own initiative, we have deleted "in the absence of its control" from the definition, consistent with a corresponding change to the definition of hazard in the preventive controls regulations, because the aspect of control of a hazard is addressed under the definition of "hazard requiring a control."

(Comment 19) One comment suggests limiting the definition of hazard by referring to an agent that is reasonably likely to cause illness or injury "in the intended species" in the absence of its control.

(Response 19) We do not believe that the suggested change to the definition of hazard is necessary. We note that under § 1.504(c)(3) of the final rule, in determining whether a hazard is a "hazard requiring a control," an importer must consider, among other factors, the intended or reasonably foreseeable use of the food, including

the species for which the food was intended.

11. Hazard Requiring a Control

In the Supplemental Notice, we proposed to adopt the term "significant hazard" and to define it as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

(Comment 20) Some comments request that we use a term other than "significant hazard" to refer to a known or reasonably foreseeable hazard for which a knowledgeable person would establish a control. One comment maintains that use of the term "significant hazard" could be confusing because the term is used to refer to hazards addressed in a HACCP plan through critical control points. One comment recommends using the definition of "significant hazard" instead of the term itself. Some comments recommend using the term "food safety hazard" because it has no association with HACCP principles. Some comments recommend using the term "hazard requiring control."

(Response 20) To provide more clarity, we agree that the FSVP regulation should use a term other than "significant hazard." We conclude it is appropriate to refer to such a hazard as a "hazard requiring a control." The definition states, in pertinent part, that a "hazard requiring a control" is a known or reasonably foreseeable hazard for which a knowledgeable person would establish one or more "controls or measures" to significantly minimize or prevent the hazard. The definition refers to controls or measures because the FSVP requirements apply to food that is subject to the preventive controls regulations (which require the establishment of preventive "controls"), food that is subject to the produce safety regulation (which refers to safety "measures"), and food that is subject to other FDA regulations (e.g., dietary supplement CGMPs).

(Comment 21) Some comments recommend replacing the reference to "a person knowledgeable about safe manufacturing, processing, packing, or holding food" with "a qualified individual" because a qualified individual will be responsible for conducting a hazard analysis.

(Response 21) Although a qualified individual must conduct a hazard analysis for a food, we decline to make this change to the definition of “hazard requiring a control” because we believe it is appropriate to specify that a person determining whether a known or reasonably foreseeable hazard is one for which one or more controls or measures are needed must be knowledgeable about the safe manufacturing, processing, packing, or holding of food. This is consistent with the revised definition of “hazard requiring a preventive control” in the preventive controls regulations.

(Comment 22) Some comments recommend stating in the definition of “significant hazard” (or its replacement term) that a determination of a significant hazard is based on a hazard analysis that assesses the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of a control, because severity and probability are integral to determining whether a hazard is significant.

(Response 22) We agree with the comments that this additional language is helpful. Consistent with the revised definition of “hazard requiring a preventive control” in the preventive controls regulations, this change is incorporated in the definition of “hazard requiring a control,” which under the final rule means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility’s food safety system.

(Comment 23) Some comments recommend that the definition of significant hazard reflect that components to manage controls should be appropriate not just to the food, the facility, and the control, but also to the intended use of the food.

(Response 23) We do not think this change to the definition of hazard requiring control is necessary because an importer already must consider the

intended or reasonably foreseeable use of a food in evaluating the hazards in the food under § 1.504(c)(3) of the final rule.

12. Holding

On our own initiative, we are adding a definition of “holding” that is consistent with the preventive controls regulations. Our new definition states that holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets), but does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

13. Importer

We proposed to define “importer” as the person in the United States who has purchased an article of food that is being offered for import into the United States. The proposed definition further stated that:

- If the article of food has not been sold to a person in the United States at the time of U.S. entry, the importer is the person in the United States to whom the article has been consigned at the time of entry; and
- If the article of food has not been sold or consigned to a person in the United States at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry.

We proposed this definition of importer based on the statutory definition of importer in section 805(a)(2) of the FD&C Act, which states that the importer is the U.S. owner or consignee of an article of food at the time of entry of the article into the United States, or if at that time there is no U.S. owner or consignee, the importer is the U.S. agent or representative of the foreign owner or consignee.

On our own initiative, we are revising the definition of “importer” to mean the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S.

entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulations. We conclude that this revised definition is more consistent with the statutory definition in section 805(a)(2). For the reasons explained in the following paragraphs, we also conclude that this change, along with a new definition we are adding for “U.S. owner or consignee,” better ensures that the FSVP importer is a person who has a financial interest in the food and has knowledge and control over the food’s supply chain. We are defining “U.S. owner or consignee” to mean the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

a. General

(Comment 24) Some comments ask that we either define or clarify the term “purchased.” One comment states that CBP defines the terms owner and purchaser to include any party with a financial interest in a transaction, including, but not limited to, the actual owner of the goods, the actual purchaser of the goods, a buying or selling agent, a person or firm who imports for exhibition at a trade fair, or a person or firm who imports foods for repair or alteration. One comment maintains that in contrast to the proposed rule, the statute does not create different rules for U.S. owners and their consignees regarding their FSVP responsibilities and does not define the importer as the person who purchased an article of food. The comment asserts that because neither the statute nor the proposed rule defines “purchased,” it is unclear who is responsible for ensuring FSVP compliance.

(Response 24) We do not agree that the proposed definition would create different FSVP regulations for U.S. owners and consignees, as the proposed rule contained no requirements that differed on that basis. However, to prevent possible confusion regarding the definition of importer and to align more closely with the statutory text, we have revised the definition of importer to mean the U.S. owner or consignee of an article of food that is being offered for import into the United States. We are further defining “U.S. owner or consignee” as the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. Thus, the final rule explicitly refers to

a U.S. “owner” of a food. Because there is a wide range of commercial arrangements between foreign owners and U.S. persons, there may be situations in which ownership of imported food has not transferred from the foreign owner at the time of entry to the United States, but a person in the United States has nevertheless purchased or agreed in writing to purchase the goods. We do not agree it is necessary to define the terms “purchased” or “purchase,” but we understand the terms to mean obtain by paying money or its equivalent.

(Comment 25) Some comments request that we clarify that the FSVP importer of a food is not necessarily the importer of record for the food as defined by CBP. However, some comments suggest that instead of creating a new definition of importer, we should adopt a definition that parallels CBP’s definition of importer of record. The comments note that under 19 U.S.C. 1484(2)(B), an “importer of record” is defined as the owner or purchaser of the merchandise or, when appropriately designated by the owner, purchaser, or consignee of the merchandise, a person holding a valid customs broker license. The comments maintain that this definition of importer of record is substantially similar to the statutory definition of importer under FSMA. (The comments also note that CBP regulations (19 CFR 101.1) define “importer” as the person primarily liable for the payment of any duties on the merchandise or an authorized agent.) The comments maintain that CBP’s definition of importer has been effective in ensuring proper enforcement of collection of customs duties and provides certainty by defining a single party responsible for entry of a product.

(Response 25) We do not agree that it is appropriate to define “importer” for FSVP purposes to match CBP’s definition of “importer” or “importer of record.” As we stated in the preamble to the proposed rule, the importer of a food for FSVP purposes might be, but would not necessarily be, the importer of record of the food under CBP provisions (*i.e.*, the individual or firm responsible for making entry and payment of import duties). We conclude that, in section 805(a)(2) of the FD&C Act, Congress adopted a definition of importer that suits the purposes of the FSVP regulation because:

- It clearly specifies the person who will be responsible for ensuring that supplier verification activities are conducted for each food imported into the United States; and

- By specifying the U.S. owner or consignee, the definition helps to ensure that the person responsible for meeting the FSVP requirements has a financial interest in the food and has knowledge and control over the food’s supply chain.

The “U.S. owner or consignee” of a food, as we have defined the term, is more likely to have knowledge of food safety practices and control over the supply chain of an imported food than a customs broker, who often is the importer of record of a food for CBP purposes. Although the CBP definition of importer may be effective in ensuring collection of customs duties and otherwise meeting CBP requirements, that is not the purpose of the FSVP regulation. Consequently, the final rule adopts a definition of importer that best serves the purposes of the FSVP requirements, consistent with the statutory provisions the FSVP regulation must implement.

(Comment 26) Some comments maintain that the importer should be the person who has a direct financial interest in the imported food or, alternatively, the last known exporter. The comments assert that the only parties who can ensure the safety of the food supply chain are entities who are directly and financially involved in the manufacture, growth, sale, receipt, or purchase of the imported food.

(Response 26) As previously stated, the definition of importer is intended in part to ensure that someone with a financial interest in the imported food, as well as knowledge and control over the food’s supply chain, is responsible for meeting the FSVP requirements. In most cases, this will be the U.S. owner or consignee of the food. However, under section 805(a)(2) of the FD&C Act and § 1.500 of the final rule, the importer for FSVP purposes could not be the exporter in the foreign country in which the food was produced. If there is no U.S. owner or consignee of a food at the time of the food’s entry into the United States, the foreign owner or consignee of the food must have validly designated a U.S. agent or representative (in accordance with § 1.509(b) of the final rule) to serve as the U.S. importer of the food for purposes of FSVP compliance. We do not agree that the last known exporter is an appropriate person to serve as the FSVP “importer” because such a person exports—as opposed to imports—the food.

(Comment 27) One comment states that retailers may contract with foreign manufacturers to produce private label products bearing the retailer’s name and purchase the products from a U.S. firm after the products have entered the

United States. The comment asks us to clarify that in this situation, the retailer would not be the importer of the food for FSVP purposes.

(Response 27) We agree that provided a U.S. entity other than the retailer owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry (*i.e.*, is the “U.S. owner or consignee”), the retailer would not be the FSVP importer of the food. In this situation, the importer is the U.S. firm that owns the product, has purchased the product, or has agreed in writing to purchase the product when it is offered for import into the United States and the entry documentation is submitted or presented. It would not be relevant that the retailer was the entity that entered into a contract with the foreign manufacturer (as long as the retailer is not the person in the United States that owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry). If, on the other hand, the retailer owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry (and thus is the U.S. owner or consignee), the retailer would be the FSVP “importer.”

(Comment 28) One comment asks that we clarify that a restaurant owner is not an “importer” for FSVP purposes unless it directly imports a food for its use and chooses to accept the responsibilities of the importer. The comment asserts that failing to do this would place an added burden on restaurant owners and operators who will have to make clear to their suppliers of foreign materials that the suppliers are responsible for compliance with FSVP requirements. The comment maintains that adoption of the FSVP regulation might result in a loss of U.S. importers of foreign products due to their unwillingness to assume responsibility for FSVP compliance.

(Response 28) A restaurant located in the United States must comply with the FSVP requirements only if it meets the definition of importer under § 1.500 (*e.g.*, because it is the “U.S. owner or consignee” of the food at the time of entry or, if there is no U.S. owner or consignee at the time of entry, the foreign owner or consignee designates the restaurant as a U.S. agent or representative for purposes of serving as the FSVP “importer”). If the restaurant purchases the food from another U.S. entity, the restaurant would not meet that definition and would not be responsible for meeting the FSVP requirements. However, we have added flexibility in the final rule to allow importers, including restaurants, to

meet their FSVP obligations by relying on analyses, evaluations, and activities performed by certain other entities, provided those importers review and assess the corresponding documentation (see sections III.E.5, III.F.4, and III.G.4 of this document).

(Comment 29) One comment asks that we define the phrase “time of U.S. entry” as used in the proposed definition of importer.

(Response 29) Section 805(a)(2)(A) of the FD&C Act provides that for purposes of the FSVP regulation, the term “importer” means the United States owner or consignee of the article of food “at the time of entry of such article into the United States.” The meaning of the phrase “at the time of entry of such article into the United States” is ambiguous. It could mean that the importer is the U.S. owner or consignee at the time of submission of an entry or at the time that the article of food physically enters U.S. territory. Given it might not always be clear when an imported item physically enters U.S. territory, we conclude that Congress intended that the importer be the U.S. owner or consignee at the time of submission of entry documents. Therefore, “time of U.S. entry,” as used in § 1.500, is the time when an import entry is submitted to CBP either electronically or in paper form. Because we believe that entities engaged in the import of food into the United States will understand this term, we do not think it is necessary to include a definition for “time of entry” in these regulations.

(Comment 30) One comment expresses concern that the proposed definition of importer will create a new layer of middlemen who would assume ownership of food at the time of entry into the United States and charge fees for ensuring compliance with the FSVP requirements. The comment contends this might result in duplicative foreign supplier verifications.

(Response 30) We do not agree. We believe it is unlikely that many entities currently not food importers will enter the food importing business because of the need to adopt and implement the procedures required under the FSVP regulation. Some importers may choose to hire employees or outside consultants to assist them in meeting the FSVP requirements, but this would not need to involve third parties assuming ownership of imported food or otherwise serving in an importer role solely for the purpose of providing supplier verification services. Even if new, FSVP-oriented businesses are created to conduct supplier verification activities on behalf of some importers,

we do not see how this would result in duplicative supplier verification. Regardless, the definition of “importer” is consistent with the definition established by Congress in section 805(a)(2) of the FD&C Act.

(Comment 31) Some comments request that we define the term “consignee” because it might be confused with a similar term used by CBP. In addition, some comments suggest that the term “consignee” be restricted to persons with a direct ownership interest in the product.

(Response 31) We agree with the comments to the extent they are premised on a claim that the proposed rule did not clarify the meaning of “consignee.” Instead of defining the term “consignee,” however, we have revised the definition of “importer” so the FSVP importer is not, first, a U.S. owner, and, second, a U.S. consignee. There is no separate “consignee” category of persons who meet the definition of “importer.” Instead, under the revised definition, the “importer” is the “U.S. owner or consignee” of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulation.

At the same time, we are defining “U.S. owner or consignee” to mean the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. Under the previously proposed definition of “importer,” the “consignee” category could have caused proprietors of the U.S. premises to which imported food is to be delivered to be designated as FSVP “importers,” even when such proprietors have no connection to the imported food other than the physical receipt—even temporary receipt—of the food. Under section 805(a)(2)(B) of the FD&C Act, Congress provided that when there is no U.S. owner or consignee, the FSVP importer should be the U.S. agent or representative of a foreign owner or consignee at the time of entry into the United States. If the consignee for purposes of FSVP included the proprietor of the U.S. premises to which the merchandise is to be delivered, we believe it would be unlikely an FSVP importer would ever be the U.S. agent or representative of a foreign owner or consignee, as contemplated by section 805(a)(2)(B), because the role of FSVP importer would fall to the proprietor of

the premises before it would fall to the U.S. agent or representative. Moreover, we believe that a U.S. agent or representative of a foreign owner or consignee is more likely to have knowledge and control over the product’s supply chain, and is therefore more likely to be able to perform supplier verification activities, than the proprietor of the U.S. premises to which the merchandise is delivered (in cases where the proprietor of the U.S. premises has no connection to the food other than physical receipt).

The effect of our change to the definition of “importer,” in conjunction with the new definition of “U.S. owner or consignee,” likely will result in different entities serving as the FSVP importer in some circumstances than those who might have served as the importer under the proposed definition. For instance, in the case of a Canadian company that ships a food product to a Montana warehouse and for which delivery is made to the Montana facility in anticipation of possible orders from customers in the United States, it is possible, under the proposed rule, that the warehouse would have been the FSVP “importer” because the food might be considered to be consigned to the warehouse at the time of entry and no one in the United States at the time of entry either owned or had purchased the food. Under the final rule, however, the warehouse would not necessarily be the FSVP importer. Because there is no person in the United States at the time of entry who owns the food, purchased the food, or promised to purchase the food, there is no “U.S. owner or consignee.” Therefore, the FSVP “importer” would have to be a properly designated U.S. agent or representative.

As for those comments suggesting that a consignee needs to be a person with a direct ownership in the product, we do not agree. Section 805(a)(2)(A) of the FD&C Act provides that “importer” for purposes of section 805 means the “United States owner or consignee” (emphasis added). Because Congress used the word “or” between “owner” and “consignee,” we believe Congress intended the “United States owner or consignee” to include persons other than owners. Requiring a U.S. owner or consignee to have direct ownership over the product would be inconsistent with that intent. We also understand it is possible for U.S. persons to purchase or agree in writing to purchase food at the time of entry to the United States, even if they do not yet own the products at that time. Requiring a U.S. owner or consignee to have direct ownership in the product at the time of entry would

not account for these types of commercial arrangements.

b. U.S. Agent or Representative

(Comment 32) Several comments maintain that the U.S. agent or representative for FSVP purposes should not necessarily be the same person as the U.S. agent for a foreign food facility under the FDA food facility registration regulation (§ 1.227) and section 415(a) of the FD&C Act. The comments note that while section 805(a)(2) of the FD&C Act describes an agent acting for the foreign owner or consignee of an article of imported food at the time of entry, section 415(a) describes an agent acting for a food facility. The comments assert that Congress did not require that the U.S. agent for a foreign food facility also act as the U.S. agent for FSVP purposes, and many persons who serve as U.S. agents for facility registration purposes might not have the knowledge or ability to meet the FSVP requirements. The comments request that the FSVP regulation clarify this distinction by referring to the “U.S. FSVP agent or representative.”

(Response 32) FDA agrees in part and disagrees in part. Section 805(a)(2)(B) provides that when there is no U.S. owner or consignee with respect to an article of food, the term “importer” for FSVP means “the *United States agent* or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States” (emphasis added). Section 805 does not further define the term “United States agent.” In addition, section 415(a)(1)(B) of the FD&C Act provides that foreign food facilities must submit the name of the “United States agent” for the facility as part of the facility’s registration under that section. FDA’s regulation implementing the food facility registration requirements in section 415 of the FD&C Act specifies that the registration for foreign facilities must include the name of the U.S. agent for the facility (21 CFR 1.232(d)). The facility registration regulation also defines the term U.S. agent to mean a person (as defined in section 201(e) of the FD&C Act) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of food facility registration (§ 1.227). The regulation further specifies that the U.S. agent “acts as a communications link between FDA and the foreign facility for both emergency and routine communications”.

Although Congress used the term “United States agent” in both section 805(a)(2)(B) and section 415(a)(1)(B) of

the FD&C Act, we do not interpret the use of the term “United States agent” in section 805(a)(2)(B) to mean the U.S. agent for a foreign facility under section 415(a)(1)(B). U.S. agents that foreign food facilities must designate for purposes of food facility registration perform a very different role than the “United States agent” that a foreign owner or consignee may designate under section 805(a)(2)(B) of the FD&C Act to serve as the “importer” for purposes of the FSVP regulations. For food facility registration, the “U.S. agent” acts as a communications link. For FSVP, however, an importer (whether a “United States agent” or otherwise) is responsible for the full breadth of supplier verification activities required under the FSVP regulation. These activities involve ensuring the safety of imported food, which is qualitatively different from serving as a communications link. Thus, we agree with the comments that urge us to not interpret the use of the term “United States agent” under section 805(a)(2)(B) to have the same meaning as the U.S. agent that food facilities are required to designate under section 415(a)(1)(B) and FDA’s food facility registration regulation.

We note, however, that this interpretation does not prohibit a foreign owner or consignee from designating a person who serves as a U.S. agent under the food facility regulation as the “importer” for purposes of FSVP. To the contrary, under the definition of “importer” in § 1.500, in cases in which there is no U.S. owner or consignee, it is up to the foreign owner or consignee to determine which U.S. agent or other U.S. representative will serve as the FSVP “importer.” Whomever the foreign owner or consignee designates also may be listed as a foreign facility’s U.S. agent for food facility registration purposes. We decline to adopt the term “U.S. FSVP agent or representative” because doing so is not necessary to prevent the kind of inadvertent or otherwise improper designation of FSVP importers contemplated by the comments.

(Comment 33) Some comments ask that we revise the definition of importer to specify that a person acting as a U.S. agent or representative of a foreign owner or consignee must knowingly and explicitly consent to serve as the U.S. agent or representative.

(Response 33) For cases in which a food has not been sold or consigned to a person in the United States at the time of entry, we proposed to require that, before an article of food is imported or offered for import into the United States, the foreign owner or consignee of

the article must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer.” The final rule retains this requirement. Because we agree a U.S. agent or representative cannot truly function as the FSVP importer without having consented to do so, we are adding a clarification to the definition of “importer” explaining that in order for the foreign owner or consignee of the article to validly designate a U.S. agent or representative (when there is no U.S. owner or consignee) for purposes of the definition of “importer,” the U.S. agent or representative’s role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. Because a signed statement is an explicit acknowledgment of consent, we conclude that a signed statement is an effective way of ensuring the consent of U.S. agents and representatives. In addition, we will be able to inspect the signed statements, should the need arise, allowing us to verify the accuracy of “importer” designations under the FSVP regulation. Being able to verify the accuracy of such designations will allow us to more efficiently and effectively monitor compliance with, and enforce, section 805 of the FD&C Act.

(Comment 34) Several comments express concern about the manner in which a foreign owner or consignee would designate its U.S. agent or representative. The comments state that a foreign supplier might designate a party in the United States, such as the warehouse where the imported food will be stored, without seeking an affirmative acceptance from that party, or the foreign supplier of the food might assume the agent listed on its facility registration is also the U.S. agent for FSVP purposes. Some comments note concerns regarding the process for verification of U.S. agents of foreign facilities, including the absence of a requirement to obtain formal consent from a person to serve as the agent and FDA’s failure to obtain confirmation of consent. Several comments suggest that, because the U.S. agent’s responsibilities as the importer of a food under the FSVP regulation will be substantial, the regulation should require affirmative written acceptance by the designated firm for valid designation of a foreign owner or consignee’s U.S. agent or representative.

(Response 34) We agree that a person should not be required to serve as the U.S. agent or representative of a foreign owner or consignee unless the person has agreed to serve in this capacity. As

explained in Response 33, we therefore are adding a clarification to the definition of “importer” stating that when the foreign owner or consignee of the article must designate a U.S. agent or representative (when there is no U.S. owner or consignee) for the purposes of the definition of “importer,” the U.S. agent or representative’s role should be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. In accordance with these changes, we also have revised the provisions regarding refusal of admission in proposed § 1.514(a) to specify that if there is no U.S. owner or consignee at the time an article of food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(Comment 35) One comment states that the requirement for foreign producers to obtain a U.S. agent in order for their product to be imported into the United States could be considered a technical barrier to trade according to the World Trade Organization (WTO).

(Response 35) We do not agree that the regulation requires that foreign producers obtain U.S. agents or otherwise imposes a barrier to trade. To the extent that the comment’s reference to U.S. agents relates to who may be an FSVP “importer,” the definition of importer in § 1.500 is flexible and does not require that the importer be a U.S. agent. Instead, the FSVP importer is the U.S. owner or consignee of the imported food. A U.S. agent or representative functions as the FSVP importer of a food only if there is no U.S. owner or consignee of the food at the time of entry. Notably, the importer can be a foreign national residing in the United States and need not be a U.S. citizen. The definition of importer thus serves to identify persons with financial interests in the imported food who are likely to be able to ensure the safety of the food, while also providing flexibility that does not unduly burden trade.

(Comment 36) One comment states that FDA’s explanation of the proposed definition of “importer” indicates the rule implies a regulatory pressure for foreign producers to sell or distribute products through U.S. persons in a manner inconsistent with U.S. obligations under the U.S.-Korea Free Trade Agreement (KORUS).

(Response 36) We do not agree that the definition of “importer” in § 1.500 is

inconsistent with U.S. obligations under the KORUS. Under National Treatment and Market Access for Goods, Article 2.8.6 to 2.8.8, neither party may, as a condition for engaging in importation or for the importation of a good, require a person of the other party to establish or maintain a contractual or other relationship with a “distributor” in its territory. The term “distributor” under the KORUS is defined as a “person of a party” who is responsible for the commercial distribution, agency, concession, or representation in the territory of that party of goods of the other party. The term “person of a party” is defined as a national or an enterprise of a party to the agreement. The term “enterprise” means any entity constituted or organized under applicable law, whether or not for profit, and whether privately or governmentally owned or controlled, including any corporation, trust, partnership, sole proprietorship, joint venture, association, or similar organization.

The U.S. owner or consignee need not be a United States “distributor” within the meaning of the KORUS because it need not be a U.S. national or U.S. enterprise constituted or organized under U.S. law responsible for commercial distribution, agency, concession, or representation in the United States. For example, the U.S. owner or consignee could be a Korean national or enterprise residing or maintaining a place of business in the United States. Alternatively, if there is no U.S. owner or consignee of a food at the time of entry, the foreign owner or consignee could designate a U.S. agent or representative who is a Korean national (or a national of another country) but who resides or maintains a place of business in the United States. Under those circumstances, such a Korean national or enterprise would be the FSVP “importer.” Consequently, we are not requiring any person whose imports fall within the scope of the KORUS to establish or maintain a contractual or other relationship with a “distributor” or other entity in its territory. Therefore, the definition of “importer” is not inconsistent with U.S. obligations under the KORUS, and we do not believe the rule exerts any pressure on foreign producers to rely on U.S. persons to distribute food in a manner that is inconsistent with the KORUS.

14. Known or Reasonably Foreseeable Hazard

In the Supplemental Notice, we deleted the proposed term “hazard reasonably likely to occur” and replaced

it with the term “known or reasonably foreseeable hazard.” We proposed to define “known or reasonably foreseeable hazard” as a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

(Comment 37) One comment suggests that we use the term “reasonably anticipated contaminants” as a phrase that clearly defines all hazards, whether deliberate or accidental, that can cause adulteration in the food supply.

(Response 37) We decline to make this change because “hazard” is a widely understood term in food safety and the word “contaminant” might suggest a substance that comes into contact with or is added to a food, but not all hazards arise from such contaminants. As discussed in section III.E.3.b of this document, importers are required to consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced for economic gain.

(Comment 38) One comment asks that we delete the reference to “potential” hazards as redundant because the proposed definition of “hazard” refers to agents “reasonably likely” to cause illness or injury.

(Response 38) We are deleting the word “potential” before the phrase “biological, chemical (including radiological), or physical hazard” because we agree the use of that word is redundant. The remaining portion of the definition of “known or reasonably foreseeable hazard” includes both a hazard that is known to be associated with a food or the facility in which it is manufactured/processed, as well as a hazard that “has the potential to be” associated with a food or facility.

(Comment 39) One comment requests that the definition of “known or reasonably foreseeable hazard” also refer to hazards that might be associated with the location or type of farm on which a food is grown or raised. The comment cites as an example the potential effect on a food of the agricultural methods used on the farm that produced the food.

(Response 39) We conclude this change is unnecessary because the potential effect of the location or type of farm on which a food is grown or raised on whether a hazard requires a control will be addressed as part of the hazard evaluation conducted under § 1.504(c) of the final rule, which considers factors such as those related to the harvesting and raising of the food.

15. Lot

We proposed to define “lot” as the food produced during a period of time indicated by a specific code.

(Comment 40) Several comments request that “lot” be defined by criteria other than time. Some comments assert that the proposed definition appears to ignore other factors such as common characteristics (e.g., origin, variety, type of packing) and maintain that multiple lots can be produced during the same time but with different lot designations. These comments suggest that lot be defined as a body of food designated with common characteristics that is separable by such characteristics from other bodies of food. One comment asserts that growers and processors define lot differently based on their company practices and the specific characteristics of the process and product. As examples of such definitions, the comment lists the following:

- A specific planting block of specified size prepared and planted on a given day, raised with common agricultural inputs, and scheduled for harvest on a selected date.
- A quantity of finished product that passes over a processing line during a given period of time.

This comment requests that importers be permitted to independently define lot and make the definition available to FDA during an inspection.

One comment suggests that lot be defined as a batch, or a specified identified portion of a batch or, in the case of food produced by a continuous process, a specific identified amount of food produced during a specified period of time, or in a specified quantity, on a specified equipment line. This comment would define “batch” as a specific quantity of a food produced during a specified time period during a single cycle of manufacture, and it would define “code” as a unique and distinctive group of letters, numbers and/or symbols from which the manufacturing and packaging history of the associated lot or batch of food can be determined.

(Response 40) We agree that a change to the definition of lot is appropriate, as we believe the reference to a period of time indicated by a specific code might be misinterpreted to mean that the “specific code” must be based on time (such as a date), which was not our intent. Although the term “lot” is associated with a period of time, the establishment that produces a food has the flexibility to develop its own coding system for lots, with or without any indication of time in the code. For

example, a lot code could be based on a date, time of day, production characteristic (such as those mentioned in the comments), combination of date/time/production characteristic, or any other characteristics the establishment finds appropriate. To clarify that the definition of lot would not require that the time of production be “indicated” by the lot code and acknowledge the establishment’s flexibility to determine the code, we have revised “period of time indicated by a specific code” to “period of time and identified by an establishment’s specific code.”

16. Manufacturing/Processing

We proposed to define “manufacturing/processing” as making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities the definition provided include cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. The proposed definition stated that for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding.

We are finalizing the definition of “manufacturing/processing” largely as proposed. However, we are adding “boiling”, “canning”, and “evaporating”, and “treating to manipulate ripening” to the list of activities that we classify as manufacturing/processing, as well as drying/dehydrating RACs to create a distinct commodity. We are also adding “extruding” and “pelleting” but limiting the applicability of these activities to the manufacture/processing of animal food. We are making these changes so that the definition of manufacturing/processing in this regulation aligns with the definitions in the regulations on preventive controls for human food and animal food. For a discussion of the classification of these and other activities, see section IV of the preamble to the final rule on preventive controls for human food (80 FR 55908 at 55924 through 55936).

(Comment 41) Several comments express concern regarding the proposed definition of “manufacturing/processing” and what may constitute activities that are a part of harvesting, packing, or holding. One comment asks that we classify the following activities, whether they occur on or off the farm,

as part of harvesting/post-harvest handling operations because there is no substantial transformation of the produce item into a different product in commerce: cutting, trimming, washing, waxing, cooling, mixing, labeling, and packaging of fresh produce RACs. One comment requests that coring, artificial ripening, waxing, cutting, labeling, stickering, packaging, and fumigation be included in the definition of “harvesting” and not “manufacturing/processing.”

(Response 41) We conclude that the definition of “manufacturing/processing” in § 1.500 is appropriate because it is consistent with the definition of the term in the regulations on preventive controls for human food and for animal food. With respect to the comments regarding whether particular activities involving produce should be classified as manufacturing/processing, as previously stated, the final rule on preventive controls for human food addresses the scope of manufacturing/processing (80 FR 55908 at 55924 through 55936).

(Comment 42) One comment suggests that the definition of “manufacturing/processing” refer to making food from one or more “raw materials and/or ingredients” rather than “ingredients.”

(Response 42) We do not believe the change is necessary because raw materials in the context of the definition of “manufacturing/processing” are food ingredients.

17. Pathogen

We proposed to define “pathogen” as a microorganism of public health significance.

(Comment 43) Some comments assert that, because the significance of a pathogen for public health depends on an organism’s severity and exposure, “pathogen” should be defined as a microorganism of such severity and exposure that it would be deemed of public health significance. Some comments suggest that the definition refer to “human or animal” public health significance.

(Response 43) We decline to make these changes because the definition already addresses the public health significance of a pathogen and it is unnecessary to indicate that a pathogen might affect humans or animals. The definition’s reference to microorganisms “of public health significance” takes into account factors such as the severity of illness and the route of exposure. In addition, the term “microorganism of public health significance” is broad enough to address both humans and animals.

18. Qualified Auditor

In the Supplemental Notice, we proposed to add a definition for “qualified auditor,” which we proposed to define as a person who is a qualified individual and has technical expertise obtained by a combination of training and experience appropriate to perform onsite audits. We further stated that a foreign government employee could be a qualified auditor.

(Comment 44) Some comments ask that we revise the definition of qualified auditor to include persons who have technical expertise obtained by a combination of training, experience, or education appropriate to perform audits. Some comments ask us to recognize that training and/or experience can make a person a qualified auditor; the comments state that people with experience performing audits likely have applicable training but might not have completed a specific regimen of courses. Some comments maintain that a person might be sufficiently qualified to conduct an audit through experience only and allowing an individual to be deemed qualified through training and/or experience is critical for food additive and generally recognized as safe (GRAS) substance facilities. Some comments maintain that we should recognize the role of the education of a potential qualified auditor as well as training and experience to meet the criteria.

(Response 44) We agree a qualified auditor might obtain the necessary auditing expertise through education, training, or experience, or some combination of those sources of expertise, and we have revised the definition of qualified auditor accordingly. (As discussed in section III.D of this document, the requirement that a qualified auditor have such education, training, and/or experience is separately set forth in § 1.503(b) of the final rule.) However, we believe it is likely that a person would need at least some actual experience in auditing (including by assisting or observing others in the performance of an audit) to meet the definition of a qualified auditor, *i.e.*, it would be difficult to obtain the necessary technical expertise solely through education and/or training that does not involve assisting or observing others in the performance of an audit.

(Comment 45) Some comments object to the proposed requirement that a qualified auditor must be a qualified individual with certain technical auditing expertise. One comment asserts that a qualified auditor should not be required to have the broader skills of a

qualified individual. One comment maintains that a qualified auditor should not be required to have knowledge, skills, and abilities beyond those of a qualified individual; instead, the definition should give a qualified individual the discretion to conduct an audit himself/herself or identify someone to perform this function.

(Response 45) We do not agree with the comments. For purposes of FSVP, the final rule defines a qualified individual as a person with the education, training, or experience (or a combination thereof) necessary to perform the activities needed to perform an activity required under the FSVP regulations. (We did not intend that every qualified individual who performs an FSVP activity would need to have the education, training, or experience needed to perform *all* FSVP activities—only the activity or activities the person is performing; therefore, we have revised the definition of “qualified individual” to refer to the performance of “an activity required under this subpart”.) Thus, whatever FSVP activity is being conducted, including onsite auditing, the individual conducting the activity must have adequate education, training, or experience (or some combination thereof) to properly conduct the activity. However, in the case of onsite auditing, the qualified individual conducting the auditing must have additional expertise—specifically, technical expertise that is needed to adequately perform the auditing function.

Further, we conclude that the person conducting an audit must not only have expertise in conducting audits but also a broader understanding of food safety processes and procedures. The scope of an audit can be a review of an entire range of food safety processes or procedures or a component of an overall system of such processes and procedures. It is therefore critical that the auditor has education, training or experience required of qualified individuals, as well as education, training, or experience specific to conducting audits. The definition of qualified auditor does not require or prohibit a qualified individual working on the importer’s behalf from selecting the person who will conduct an onsite audit. However, the person selected to conduct an onsite audit must meet the definition of a qualified auditor.

(Comment 46) One comment asks that we define qualified auditor under the FSVP regulation the same way we define qualified auditor under the regulation on preventive controls for animal food.

(Response 46) The definitions of qualified auditor in the FSVP and preventive controls for animal food regulations are essentially the same. Therefore, no changes are needed.

(Comment 47) Some comments ask that we define or provide guidance on the criteria for the technical expertise required under the definition of qualified auditor. One comment asks that we consider training courses that would certify individuals similar to the courses being developed to become a qualified individual.

(Response 47) A qualified auditor might acquire the appropriate technical expertise through education, training (including training that results in accreditation under a recognized facility auditing or certification scheme), or experience, or some combination of those criteria. We intend to provide more information in the FSVP draft guidance on how persons might obtain the necessary expertise to be qualified auditors for FSVP purposes.

(Comment 48) One comment asks how an importer can determine whether a foreign government employee has sufficient knowledge of U.S. regulations to serve as a qualified auditor, given that such officials often inspect and certify firms according to national requirements. One comment requests guidance on how an importer may rely on audits performed by unaccredited foreign government employees and how foreign governments can create audit programs to assist firms that export food to the United States. One comment suggests that we recognize foreign government employees as qualified auditors after they receive training and pass an assessment organized by the foreign government according to U.S. regulations.

(Response 48) The standard for being a qualified auditor does not differ when the audit is performed by a foreign government employee. Auditors often audit against multiple schemes, and we see no reason why a foreign government employee with appropriate technical expertise obtained by a combination of education, training, and/or experience could not audit against FDA’s standards. There also is no requirement that audits be performed by accredited auditors for the purpose of the FSVP regulation. We currently do not envision establishing a program to recognize individuals as meeting the definition of qualified auditor for the purposes of FSVP. However, we do intend to conduct outreach, develop training modules, and provide technical assistance to facilitate compliance with this rule.

(Comment 49) Some comments ask that we include in the definition of

qualified auditor properly trained Federal auditors and what the comments described as State and private auditors operating under contract with the Federal government.

(Response 49) We agree that government employees of different levels of government may be qualified auditors (provided they otherwise meet the definition of qualified auditor). We therefore have revised the definition of qualified auditor to state in part that a government employee, including, but not limited to, a foreign government employee, may be a qualified auditor. As for the comment suggesting that private auditors operating under contract with the Federal government may be qualified auditors, we note that nothing in the definition of qualified auditor prevents private auditors from serving as qualified auditors (provided they otherwise meet the definition of qualified auditor).

(Comment 50) One comment suggests that the definition of qualified auditor should include third-party auditors accredited under FDA's third-party auditing regulations.

(Response 50) We agree and have revised the definition of qualified auditor to state that a qualified auditor could be an audit agent of a certification body accredited in accordance with subpart M of part 1 (the regulations implementing section 808 of the FD&C Act (21 U.S.C. 384d)). (The final rule on the accreditation of third-party certification bodies, published elsewhere in this issue of the **Federal Register**, refers to third-party auditors also as "certification bodies.") As a result of making this change, it is no longer necessary to specify in the definition of "qualified individual" that a qualified individual includes, but is not limited to, a third-party auditor (certification body) that has been accredited in accordance with section 808 of the FD&C Act, as we previously proposed (because a qualified auditor must also be a qualified individual).

(Comment 51) One comment maintains that in addition to auditors accredited under FDA's third-party certification regulations, a qualified auditor could be a qualified individual who is not a third-party auditor accredited under those regulations. However, one comment asserts that not requiring the use of accredited auditors or an accredited system is not a good idea from a food safety perspective, particularly for RACs originating in a part of the world that has a history of shipping microbiologically contaminated products to the United States.

(Response 51) We believe that a person need not be an auditor formally accredited under the third-party certification regulations or any other accreditation system to have the technical expertise needed to appropriately perform an onsite audit. Under the definition of qualified auditor, a person may obtain the necessary technical expertise through a combination of education, training (including training that is rigorous but does not lead to formal "accreditation"), and/or experience. For example, a government employee might be less likely than a private sector auditor to be accredited, but the government employee might still be a qualified auditor and be appropriately suited to conduct onsite audits of foreign suppliers. However, importers have the responsibility to choose qualified auditors even though we are not requiring that auditors be formally accredited.

(Comment 52) One comment, stating that it uses its internal auditors to conduct onsite audits of its foreign suppliers, suggests that the definition of qualified auditor be revised to allow the use of internal auditors when they have no direct financial interest in the foreign supplier.

(Response 52) Although we agree with the comment, we do not believe that it is necessary to change the definition as suggested. An importer's employee could be a qualified auditor if he or she has the expertise required under the definition. In addition, the final rule does not prohibit an importer or one of its employees from conducting verification of the supplier.

19. Qualified Individual

We proposed to define "qualified individual" as a person who has the necessary education, training, and experience to perform the activities needed to meet the FSVP requirements. The proposed definition states that a qualified individual may be, but is not required to be, an employee of the importer. The proposed definition further states that, regarding the performance of verification activities related to preventive controls implemented by the foreign supplier in accordance with section 418 of the FD&C Act, a qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety

system. The proposed definition also states that:

- A qualified individual includes, but is not limited to, a third-party auditor that has been accredited in accordance with section 808 of the FD&C Act; and
- A foreign government employee could be a qualified individual.

(Comment 53) One comment asks that we clarify in the definition that a qualified individual could have the necessary education, training and experience to perform FSVP activities "or a combination thereof."

(Response 53) We agree and have changed the definition to state that a qualified individual must have education, training, or experience (or a combination thereof) necessary to perform an FSVP activity. (We have separately set forth the requirement that a qualified individual have such education, training, and/or experience in § 1.503(a) of the final rule.)

(Comment 54) One comment asserts that the term "necessary education" in the proposed definition is misleading and suggests that the definition require a qualified individual to have "skills consistent with the requirements."

(Response 54) We have changed the definition of qualified individual so the term "necessary education" is not included. However, we do not agree that the use of the term "necessary" in the revised definition is misleading. The definition of qualified individual makes clear that the required education, training, or experience is that which is needed to conduct the FSVP activity or activities the person is performing.

(Comment 55) One comment, noting "qualified individual" is defined differently in the proposed regulations on preventive controls, asserts that using the same term with different meanings in different regulations could lead to confusion. The comment suggests that the FSVP regulation use the term "FSVP qualified individual."

(Response 55) We decline to make this change. The definition of "qualified individual" in the FSVP regulation makes clear that the necessary qualifications are specific to FSVP activities performed by the individual, and the definition of "qualified individual" in the preventive controls regulations likewise makes clear that the necessary qualifications are specific to the activities required under those regulations. To the extent the comment objects to the differences in the definitions for "qualified individual" across the different regulations, we disagree. Fundamentally, the definition of "qualified individual" in the FSVP regulation is aligned with the definition of qualified individual in the preventive

controls regulations. In each case, a qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform activities required under the regulations. However, the definitions vary as a result of the different activities a qualified individual must perform under each rule.

(Comment 56) Some comments suggest that we establish specific standards or minimum qualifications for qualified individuals. One comment maintains that the definition should require an understanding of FDA regulations. Some comments ask that we provide examples of, or guidance regarding, necessary education, training, and experience so that importers can determine whether their employees meet the standard. One comment asks that qualifications not be restricted to a certain type of course or program as this would unnecessarily raise the cost of compliance and disqualify well-suited individuals from compliance roles.

(Response 56) We intend to address in guidance what appropriate education, training, and experience qualified individuals should have to conduct FSVP activities. To maximize flexibility, persons will not be required to complete a particular course or program to become a qualified individual under the FSVP regulations; rather, persons will be able to obtain the necessary education, training, and/or experience through a variety of methods and experiences. The principal concern is that the education, training, and experience equip them to conduct the FSVP activity or activities they are performing.

(Comment 57) One comment requests that we include a requirement for certification with specific criteria for competence for performing FSVP activities because merely requiring that an individual be knowledgeable in the food process would not adequately ensure the individual is qualified to perform FSVP activities.

(Response 57) We decline to require that a person obtain a particular certification to act as a qualified individual on behalf of an importer. As stated previously, we want to provide flexibility as to how a person can obtain the necessary education, training, and/or experience.

(Comment 58) One comment stresses that the determination as to whether an individual is qualified to develop and oversee an importer's FSVP should be a performance-based evaluation, not a paperwork exercise.

(Response 58) We agree with the comment to the extent that the comment suggests that an importer should only

use a person to conduct FSVP activities who the importer has determined has the education, training, or experience (or a combination thereof) necessary to perform those activities. Whether a person is qualified to perform those activities should be determined by the importer on a case-by-case basis.

(Comment 59) One comment suggests that we add to the definition a requirement that the qualified individual understands the language of the country in which the foreign supplier is located.

(Response 59) We agree a qualified individual must be able to read and understand the language of any records that the individual must review in performing FSVP activities. This would ensure the individual responsible for performing FSVP activities is able to provide meaningful supplier verification, and is especially important in the imports context in which individuals in the United States must verify suppliers in countries where records may be kept in languages other than English. We therefore have revised the definition of "qualified individual" to specify that a qualified individual must have the ability to read and understand the language of any records the person must review in performing FSVP activities (this requirement is separately set forth in § 1.503(a) of the final rule). As discussed more fully in section III.K.3.a of this document, we have deleted the proposed requirement in § 1.510(b) of the proposed rule that all FSVP records be maintained in English, and we have added a requirement that, upon Agency request, the importer must provide an English translation of a record in another language in a reasonable period of time.

(Comment 60) One comment requests that we clarify the statement in the proposed definition of qualified individual regarding the "standard curriculum" for training in the development and application of risk-based preventive controls recognized by FDA as adequate. The comment also asks that we explain how a qualified individual could be qualified through job experience to develop and implement a food safety system and state whether and how the Agency will recognize industry providers of training programs. One comment requests that we provide a process by which foreign training in risk-based preventive controls can be recognized as equivalent or adequate. The comment asserts that it would be unreasonable to expect FDA-recognized training to be available in all languages and in all countries exporting food to the United States, and it also would be unreasonable to require

foreign suppliers to travel to the United States to obtain the required training.

(Response 60) As discussed in the preamble to the final rule on preventive controls for human food, we are working to develop general guidance on hazard analysis and preventive controls. We also intend to work with the Food Safety Preventive Controls Alliance (FSPCA) to develop selected sections of model food safety plans for several food types that will provide instructional examples. In addition to the preventive controls curriculum, we intend to develop a curriculum regarding FSVP that will be available as an option for importers and other stakeholders. It will be the responsibility of a person providing training in preventive controls to ensure the training is at least equivalent to that provided under a standardized curriculum recognized as adequate by FDA. Training providers will not need to obtain express approval from the Agency to use any particular curriculum. In addition, the qualified individuals used by importers to perform FSVP activities related to preventive controls will not be required to obtain training in the United States.

However, we have concluded it is not necessary to include in the regulation a requirement that qualified individuals performing FSVP activities related to a foreign supplier's preventive controls complete a specified training in preventive controls. Instead, the draft guidance on FSVPs will provide recommendations on the type of training that qualified individuals should have, including, for persons who assess foreign suppliers' preventive controls, training in the development and application of preventive controls available in (or comparable to) the curriculum that FDA is developing with the FSPCA. The draft guidance also will provide recommendations for training for individuals who will be conducting verification activities regarding suppliers of food that is subject to the produce safety regulations or other FDA food safety regulations.

(Comment 61) One comment suggests that we revise the definition of qualified individual to refer to a person being qualified to "develop and apply" a food safety program rather than "develop and implement" such a program to be consistent with the proposed regulations on preventive controls for human food.

(Response 61) Although we agree that this change would be appropriate, we have deleted the reference to specialized training in preventive controls from the definition of qualified individual. However we will take this suggestion into consideration in developing our

guidance on appropriate training for qualified individuals.

(Comment 62) One comment suggests that we consider including requirements for ongoing training to ensure qualified individuals stay current in the latest developments relevant to their credentials.

(Response 62) Because the definition for “qualified individual” already requires that such individuals be qualified to perform FSVP activities, we do not believe it is necessary to establish specific requirements for ongoing training. If developments over time cause a person’s education, training, and experience to be inadequate to perform FSVP activities, that person would no longer be a qualified individual and the individual might need to obtain additional education, training, or experience.

(Comment 63) One comment requests that we specify that to be considered a qualified individual, a foreign government employee should meet the same stringent requirements as those who are privately employed.

(Response 63) All persons acting as qualified individuals for an importer—whether located in the United States or another country, whether a government official or privately employed—will be required to have the education, training, or experience (or a combination thereof) necessary to perform their FSVP activities. Thus, the standard for being a qualified individual does not vary depending on whether an individual is a foreign government employee.

20. Ready-To-Eat Food

On our own initiative, we are adding a definition of “ready-to-eat food” that is consistent with the preventive controls regulations. The definition states that ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

21. Receiving Facility

Also on our own initiative, we are adding a definition of “receiving facility” that is consistent with the preventive controls regulations. The definition states that a receiving facility means a facility that is subject to subparts C and G of part 117 (21 CFR part 117) (the regulations on hazard analysis and risk-based preventive controls and supply-chain programs for human food) or subparts C and E of part 507 (21 CFR part 507) (the corresponding regulations for animal

food) and that manufactures/processes a raw material or other ingredient it receives from a supplier. In accordance with the language used in the final regulations on preventive controls, we refer to the supplier provisions in those regulations as provisions on “supply-chain programs” instead of “supplier programs.”

22. Very Small Foreign Supplier

In the Supplemental Notice, we proposed to define “very small foreign supplier” as a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$1 million, adjusted for inflation.

(Comment 64) We received many comments on the proposed definition of very small foreign supplier. Some comments support the definition while others question the breadth of the definition and the percentage of imported food it would exclude from full FSVP requirements. Some comments suggest different eligibility criteria, such as number of employees. Some comments assert that basing the definition on the U.S. dollar value of sales would provide an unfair advantage to foreign firms compared to American firms of comparable size because many foreign suppliers are located in countries with currencies valued much lower than the U.S. dollar. Some comments assert that using a monetary criterion for very small status is impractical because of fluctuations in foreign exchange rates and because those rates are not related to any risk in food; the comments maintain that using this criterion would jeopardize a foreign supplier’s predictability of business and have negative effects on international trade.

Some comments assert that “very small” status should be based on the foreign supplier’s sales of food exports to the United States rather than its total food sales. One comment suggests that it might be difficult for foreign suppliers to determine their average annual monetary value of food sales because many crops can be used for both food and non-food purposes (such as soil improvement, planting seed, and biofuels). Some comments suggest that the reference to food “sales” include returns received by members of cooperatives for the crops the members provide.

One comment states that if a very small foreign supplier is defined on the basis of dollar revenues, we should

clarify whether the adjustment for inflation is to be based on the U.S. inflation rate or the rate in the supplier’s country. The comment also suggests that a neutral outside source such as the World Bank be used to determine the inflation rate rather than using rates estimated by individual governments.

(Response 64) As discussed more fully in section III.M.1 of this document, in response to these comments and other comments related to the modified requirements we proposed for very small foreign suppliers, we have deleted the proposed provisions applicable to food imported from “very small foreign suppliers.” Instead, in alignment with the supply-chain program provisions of the preventive controls regulations, § 1.512 of the final rule includes modified requirements for importers of food from certain small foreign manufacturers/processors and farms. The modified requirements include, among other things, the following:

- Annually obtaining written assurance from the importer’s foreign supplier that the supplier meets the specified criteria as a certain type of small facility or farm under FDA regulations on preventive controls, produce safety, or shell egg production, storage, and transportation;
- Obtaining written assurance at least every 2 years that the small supplier is in compliance with applicable regulations or (for some small suppliers) that it acknowledges it is subject to the adulteration provisions of the FD&C Act;
- Evaluating the foreign supplier’s compliance history and approving suppliers; and
- Establishing procedures to ensure the use of approved suppliers.

As discussed in section III.M.1 of this document, we conclude that these modified requirements for food from certain small foreign suppliers are appropriate to align the FSVP and preventive controls provisions to help provide parity in supplier verification requirements for domestic and foreign food producers. We further conclude that basing eligibility for the modified requirements on different criteria, such as the supplier’s sales of food to the United States, would not be consistent with this approach. We believe it is appropriate for these modified verification requirements to be based on the underlying food safety regulations (*i.e.*, the regulations on preventive controls, produce safety, and shell egg production) because those regulations themselves provide for modified requirements or exemptions for these food producers. Because the modified verification provisions for certain small

foreign suppliers are based on the underlying food safety regulations, a foreign supplier's qualification for these modified requirements or exemptions depends on the eligibility criteria specified in those regulations. Concerns regarding the appropriateness of these eligibility criteria are beyond the scope of this rulemaking.

23. Very Small Importer

In the Supplemental Notice, we proposed to define "very small importer" as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$1 million, adjusted for inflation. We stated that the proposed annual sales ceiling of \$1 million was consistent with the definition of "very small business" in the proposed rule on preventive controls for human food. However, we noted that the definition of "very small business" in the proposed rule on preventive controls for animal food included an annual sales ceiling of \$2,500,000 and different sales ceilings applied to smaller entities subject to (or not covered under) the proposed produce safety regulations (*i.e.*, \$500,000 in annual produce sales for "small businesses," \$250,000 in annual produce sales for "very small businesses," and \$25,000 in annual produce sales for certain farms not covered under the produce safety regulations), and we sought comment on whether and, if so, how we should take these definitions into account in defining very small importers and very small foreign suppliers.

(Comment 65) Some comments support defining "very small importer" consistently with the definition of "very small business" in the regulation on preventive controls for human food. Other comments support a definition of very small importer for animal food that is consistent with the proposed definition of very small business in the preventive controls for animal food regulation. Some comments asserting that our proposed definition is inconsistent with some other FSMA definitions of small entities nevertheless also express concern about practical challenges of having different annual sales ceilings for different types of imported food. Some comments support using an annual food sales ceiling of \$500,000 as originally proposed.

(Response 65) We agree with the comments that the definition of very small importer should be consistent

with the definitions of very small business in the preventive controls regulations. This is particularly important for importers that are also subject to those regulations. We believe that defining the terms consistently will contribute to a level playing field between domestic and imported food and will help avoid a situation in which a facility would be a very small business under the preventive controls regulations but not a very small importer under FSVP, or vice versa.

Given that our very small importer definition was already designed to track the definition of very small business in the preventive controls for human food regulation, we are only adding new language to address the inconsistency between the very small importer definition and the very small business definition in the regulation on preventive controls for animal food. Therefore, the final rule states that, with respect to animal food, a very small importer means an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale—as discussed in the following paragraphs). For importers that import both human and animal food, the \$1 million ceiling applies to the human food imported and the \$2.5 million ceiling applies to the animal food imported. For example, if an importer imports \$1.5 million of human food and \$1 million of animal food, the importer would be a very small importer for the purposes of its animal food (*i.e.*, the importer would be subject to modified requirements for this food) but would not be a very small importer for the purposes of its human food (*i.e.*, the importer would be subject to the standard supplier verification requirements for this food). This is consistent with the way facilities that produce both human and animal food domestically are treated under the preventive controls regulations.

Another change we are making to the very small importer definition to make it more consistent with the very small business definitions in the preventive controls regulations is to address the circumstances in which an importer charges fees for importing food. Because the definition in the Supplemental Notice concerned "sales of food," it was unclear how entities that charge fees but do not "sell" food would be treated. As discussed more fully in section III.M of this document, a principal reason that we are comfortable with modified

requirements for food imported by very small importers is that these firms are likely to be importing a relatively low volume of food into the United States. As we stated in the preamble to the proposed rule, sales of food is a proxy for volume. We need a different proxy for importers of food that do not have food sales, such as certain warehouses and repacking facilities. Therefore, we are clarifying that importers that do not have sales of food, per se, should calculate the U.S. market value of the food they import to determine whether they do not exceed the monetary ceiling for being a very small importer. If an importer has some sales of food and conducts some of its food importation business in exchange for fees, the importer must add the sales of food and the U.S. market value of the food imported without sale to determine whether it is a very small importer.

(Comment 66) One comment finds the phrase "on a rolling basis" in the definition of very small importer to be confusing.

(Response 66) In response to this comment and to be consistent with the very small business definitions in the preventive controls regulations, we are removing the phrase "on a rolling basis" from the definition. Instead, we are specifying that the average annual sales must be calculated, adjusted for inflation, during the 3-year period preceding the applicable calendar year.

(Comment 67) Some comments request that we base annual sales on different criteria. Several comments request that the annual sales ceiling be based on sales to the United States rather than worldwide. Some comments similarly request that the ceiling apply only to the value of food imported into the United States rather than an importer's total annual food sales. Some comments assert that it would be difficult for FDA to determine which products are intended for export and which are for domestic consumption. One comment supports an annual sales ceiling of \$2 million if we decide to base the number on worldwide sales.

(Response 67) We disagree that the annual sales ceiling should be based on sales to the United States rather than worldwide or only to the value of food imported as opposed to an importer's total annual food sales. By establishing modified requirements for very small importers, we are providing practical allowances for entities we believe pose a relatively low risk of causing harm to consumers. An importer that sells more than the ceiling dollar amount poses more risk. We also affirm our tentative conclusion from the proposed rule that, given the risk to overall public health,

the modified requirements we put in place are adequate to provide assurances that the foreign suppliers to these importers produce food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act (as applicable) and in compliance with sections 402 and 403(w) of the FD&C Act (as applicable). This approach is consistent with the approach we are taking with respect to very small businesses under the preventive controls regulations.

B. Applicability and Exemptions (§ 1.501)

We proposed to specify (in § 1.501(a)) that the FSVP regulations would apply to all food imported or offered for import into the United States and to the importers of such food, except to the extent that we set forth proposed exemptions in § 1.501. In response to comments, we have made some changes to the exemptions and added certain exemptions.

1. Exemption for Certain Juice and Seafood Products

In accordance with section 805(e) of the FD&C Act, we proposed to exempt from the FSVP regulation juice, fish, and fishery products imported from a foreign supplier that is required to comply with, and is in compliance with, the regulation on juice in part 120 (21 CFR part 120) or the regulation on fish and fishery products in part 123 (21 CFR part 123) (proposed § 1.501(b)). We further proposed to specify that importers of juice or fish and fishery products that are subject to the requirements applicable to importers of those products under § 120.14 or § 123.12, respectively (the “HACCP importer regulations”), must comply with those requirements.

(Comment 68) One comment expresses concern about the proposed exemption for seafood products. The comment maintains that because the seafood HACCP regulation does not require onsite auditing to verify the foreign supplier’s compliance with that regulation, there is no assurance of compliance. The comment contends that the exemption for seafood products is not consistent with congressional direction and the stated intent of the FSVP regulation.

(Response 68) We do not agree. The exemption for fish and fishery products in § 1.501(b)(1) of the final rule provides that the FSVP regulation does not apply to products imported from a foreign supplier that is required to comply with, and is in compliance with, the

regulation on fish and fishery products in part 123. Among other things, part 123 requires importers to comply with requirements for imported fish and fishery products, which may include implementing written procedures for ensuring that imported products were processed in accordance with the HACCP regulation, including the use of “affirmative steps” such as obtaining continuing lot-specific certificates from an appropriate foreign government inspection authority or competent third party, or regularly inspecting foreign processor facilities (see § 123.12). Thus, § 1.501(b)(1) makes clear that importers of fish and fishery products are responsible for verification, but must do so under the regulation specific to fish and fishery products in part 123. As for the comment that the seafood HACCP exemption is inconsistent with congressional intent, we do not agree. Section 805(e) of the FD&C Act states that the FSVP requirements “shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with,” the HACCP regulation for seafood (as well as juice). Thus, Congress specifically exempted facilities that are required to comply with, and are in compliance with, the seafood HACCP regulation from the scope of the FSVP regulation. We therefore conclude that it is consistent with congressional intent to exempt from the FSVP regulation the importation of seafood that is required to comply with, and is in compliance with, the seafood HACCP regulation in part 123.

(Comment 69) One comment asserts that the proposed exemption for juice is narrower than the statutory exemption because it applies to imported juice products but not ingredients. The comment requests that the exemption be applied to all ingredients and raw materials used in a facility that is subject to and in compliance with the juice HACCP regulation provided those ingredients will be used in the production of juice products subject to the HACCP regulation.

(Response 69) We agree with the comment that we should broaden this exemption. As we stated in the preamble to the FSVP proposed rule, the meaning of the reference to a juice or seafood “facility” in section 805(e)(1) and (e)(2) of the FD&C Act is subject to multiple interpretations (78 FR 45730 at 45745). We discussed the possibility that the reference to “facility” might be intended to apply to a foreign supplier of juice or seafood or to an importer of such food. We tentatively concluded that Congress intended that section

805(e)(1) and (e)(2) apply to food being imported from foreign suppliers in compliance with FDA requirements for juice or seafood HACCP.

However, as the comment notes, applying section 805(e)(1) and (e)(2) only to food being imported from HACCP-compliant foreign facilities would mean that importers that are also juice or seafood facilities would need to conduct supplier verification for the raw materials and other ingredients they import for use in juice and seafood products that are processed in accordance with the HACCP regulations. However, in enacting section 805(e)(1) and (e)(2), we believe that Congress intended to exclude food covered by and in compliance with the HACCP requirements from section 805 of the FD&C Act. This exclusion likely reflects a determination that the HACCP regulations in parts 120 and 123 make application of section 805 unnecessary because those regulations require processors to adequately address applicable hazards.

We therefore conclude that a more reasonable interpretation is that Congress intended to exempt from the FSVP requirements the activities of a facility that are subject to the juice or seafood HACCP regulations in part 120 or 123. Under this interpretation, the exemption applies not only to the importation of food produced by a foreign supplier subject to and in compliance with those regulations, but also to the importation of raw materials or other ingredients by U.S. facilities for use in processing juice and seafood products in accordance with the regulations. We conclude that this interpretation would fulfill the apparent goal of section 805(e)(1) and (e)(2) because importers that manufacture/process juice or seafood under the HACCP regulations will be addressing all the hazards in the raw materials or other ingredients they import in accordance with those regulations. Accordingly, § 1.501(b)(2) of the final rule states the FSVP regulation does not apply with respect to raw materials or other ingredients an importer uses in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided the importer complies with the relevant regulation when manufacturing or processing the juice or seafood product.

(Comment 70) Some comments express concern regarding the statement in the preamble to the proposed rule that we are considering whether in the future we should initiate a rulemaking to revise the HACCP importer regulations in light of the FSVP regulation and FSMA’s increased

emphasis on importers' role in ensuring the safety of imported food. The comments assert that although the HACCP importer regulations do not require onsite audits of foreign suppliers, other requirements under the HACCP regulations ensure food safety. One comment questions whether revising the juice HACCP regulation would result in additional safety because juice producers must process juice to achieve a 5-log reduction in the pertinent microorganisms for juice, a requirement that is not mandated in the FSMA proposed rules.

(Response 70) We agree that the juice and seafood HACCP regulations have requirements applicable to importers in §§ 120.14 and 123.12, respectively. At the same time, we recognize that section 805 of the FD&C Act and the implementing regulation in this final rule set forth a more comprehensive approach to verification than the existing juice and seafood HACCP regulations. Consistent with the statement in the preamble to the proposed rule, we therefore think it is appropriate to consider whether the Agency should in the future initiate a rulemaking to revise the regulations applicable to importers of juice and seafood. We believe that the comment on the juice HACCP processing requirements is misplaced because the FSVP regulation concerns verification that the food safety requirements applicable to the manufacturing/processing, growing, or raising of food are met, not the establishment of the food safety requirements themselves.

2. Exemption for Food Imported for Research or Evaluation

In proposed § 1.501(c), we proposed to exempt from the FSVP regulation food that is imported for research or evaluation use, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled with the statement "Food for research or evaluation use"; and
- When filing entry with CBP, the customs broker or filer for the food provides an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

We further proposed to specify that food is imported for research or evaluation purposes only if it is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose and the entire quantity is used for this purpose. We proposed this exemption from the FSVP

requirements consistent with section 805(f) of the FD&C Act.

(Comment 71) One comment asks that we require that the statement "Food for research or evaluation use" be placed on a permanently affixed label.

(Response 71) We do not believe that it is necessary to specify that the label be permanently affixed to the food covered by this exemption. However, in proposing to require that the food eligible for this exemption be labeled with the statement "Food for research or evaluation use," we stated that this requirement was intended to help ensure that the food is, in fact, not intended for retail sale and is not sold or distributed to the public. We therefore expect that such labels will be securely attached to the food so they remain on the food until the food is used for research or evaluation to ensure that it is not sold or distributed to the public.

(Comment 72) One comment maintains that the regulation should not require the importer to declare electronically that a food will be used for research and evaluation purposes, asserting that the requirement to label the food should be sufficient.

(Response 72) We do not agree. We stated in the preamble to the proposed rule that the intent of requiring this declaration at entry was to help ensure that the food is, in fact, not intended for retail sale and is not sold or distributed to the public. The electronic declaration requirement also provides an efficient and effective means of determining whether a food is exempt under § 1.501(c). For example, the electronic declaration will mean that the designation for research and evaluation use is readily available to FDA during entry review of the food. We believe that the electronic declaration requirement will allow us to efficiently enforce this exemption and thus efficiently enforce section 805(f) of the FD&C Act.

(Comment 73) Some comments request that we interpret "small quantity" flexibly to allow for variance based on the type of food product, the purpose of the research or evaluation, and other factors. Some comments suggest that we interpret research and evaluation use on a case-by-case basis. One comment asserts that the amount of food needed for research or evaluation varies and is not always a small quantity; therefore, the comment suggests that we remove the term "small quantity" or replace it with a phrase such as "amounts not to exceed the amount reasonably sufficient to conduct" the research or evaluation. Some comments maintain that the quantity should not matter as long as

the imported food will be used exclusively for research or evaluation and will not enter commerce.

(Response 73) We do not agree that we should remove or replace the term "small quantity" in § 1.501(c). In drafting section 805(f) of the FD&C Act, Congress specified that the exemption for research and evaluation purposes is for "small quantities" of food. Thus, it would not be consistent with the intent of the exemption if we removed the specification that the exemption applies to small quantities of food. As for replacing the term "small quantity" with a term such as "amounts not to exceed the amount reasonably sufficient to conduct" the research or evaluation, we decline this request for the same reason; the limitation regarding "small quantities" is consistent with congressional intent. To the extent the comments take the position that some flexibility is needed in administering the "small quantities" limitation, we agree. Because we understand that the amount of food used in research can vary based on the type of food, the nature of the research, and other factors, we intend to address in the FSVP draft guidance the quantity of food that is consistent with the "small quantities" limitation under different circumstances.

(Comment 74) One comment suggests that we modify the exemption for food imported for research or evaluation to require unused amounts to be properly managed to ensure they do not enter commerce.

(Response 74) We agree and have revised the exemption to specify that any unused amounts must be properly disposed of. This requirement will help ensure that all food imported under this exemption is in fact used for the intended purpose of the exemption: research or evaluation. As such, this requirement will assist us in meeting our statutory obligation under section 805(f) of the FD&C Act to provide an FSVP exemption for small quantities of food imported for research and evaluation purposes.

(Comment 75) Some comments request an exemption from the FSVP requirements for food samples imported for trade shows. The comments maintain that trade show food samples provide an important marketing opportunity for small and medium companies at the early stage of expanding their business in the United States, and they contend it would be difficult for such companies to comply with the FSVP regulation.

(Response 75) We do not agree that it is appropriate to exempt from the scope of the FSVP requirements food samples

imported for consumption at trade shows. Section 805(f) of the FD&C Act directs FDA to establish an exemption for food imported in small quantities for research and evaluation purposes, “provided that such foods are not intended for retail sale and are not sold or distributed to the public.” Because food imported for consumption at trade shows would be sold or distributed to the public generally (*i.e.*, anyone could attend the trade show), we conclude that exempting such food from the FSVP regulation would be inconsistent with the limitation in section 805(f). We also believe such an exemption would be inconsistent with the broader intent of section 805, which is to help ensure the safety of imported food.

(Comment 76) One comment requests that pet food imported for use in in-home studies conducted under contracts with pet owners be exempt from the FSVP requirements.

(Response 76) Provided that food imported for use in such in-home studies is imported in small quantities and meets the additional requirements of § 1.501(c), we agree that such food would be exempt from the FSVP requirements. Because the food would be used as part of a defined study with a discrete set of test subjects for research and evaluation purposes, it does not appear that such food would be sold or distributed to the general public.

(Comment 77) One comment asks that we clarify that if materials produced in a research and development facility will be used in products that are consumed by the public, such as in market research activities like home-use tests, consumer panels, and sales samples, the facility will be subject to the FSVP regulation.

(Response 77) Imported food that is sold or distributed to the public is not eligible for the exemption for food for research and evaluation purposes in § 1.501(c). Therefore, if the comment is referring to a foreign supplier that is a research and development facility but is producing food to be distributed or made available to the public generally (rather than provided under defined research conditions with a discrete set of test subjects), that food imported from that foreign supplier would not be exempt from FSVP. If the comment is referring to an importer that is a research and development facility using imported food to produce food products to be distributed to the public, the importer will be subject to FSVP for that food. If the importer is also a “facility” under section 415 of the FD&C Act and therefore subject to the preventive controls regulations, and if the facility has established and implemented

supply-chain program requirements for an imported raw material or other ingredient in compliance with subpart G of part 117 or subpart E of part 507 with respect to the food, the facility would be deemed to be in compliance with the FSVP requirements, except for the requirements in § 1.509 (see § 1.502(c) of the final rule).

(Comment 78) One comment suggests that if a facility conducts research and development activities on the same site at which food is manufactured or processed, the exemption should apply only to the food intended for research or evaluation purposes instead of all food from the facility.

(Response 78) We agree. The exemption for food imported for research or evaluation applies only to food that meets the requirements for the exemption set forth in § 1.501(c) of the final rule. Importation of other food from a foreign supplier that also provides food for research or evaluation would not be exempt from the FSVP requirements.

(Comment 79) Some comments request that first shipments of a food imported into the United States be exempt from the FSVP requirements. According to the comments, the FSVP regulation might prohibit emerging products from entering the United States and hinder innovation by foreign suppliers.

(Response 79) We do not agree. In enacting section 805(f) of the FD&C Act, Congress specified that the exemption for research and evaluation apply only for “food . . . for research and evaluation purposes.” Congress further specified that the exemption applies “provided that such foods are not intended for retail sale and are not sold or distributed to the public.” Extending the exemption to all “first shipments” of a particular food would not be consistent with that limited exemption.

3. Exemption for Food Imported for Personal Consumption

Consistent with section 805(f) of the FD&C Act, we proposed to exempt from the FSVP regulation food that is imported for personal consumption, provided such food is not intended for retail sale and is not sold or distributed to the public (proposed § 1.501(d)). We proposed to specify that food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(Comment 80) One comment asserts that the term “small quantity” is subjective and asks whether we will

clarify the term. However, one comment asks that we not define “small quantity” because doing so might conflict with other FDA food regulations (*e.g.*, 21 CFR 1.277(b)(1) and 1.327(m)) that refer to food for “personal consumption” or “personal use” without further elaboration. This comment suggests that if we do define “small quantity” for personal consumption, we should allow importation of a supply of a given food that would permit at least a number of years’ worth of personal consumption (assuming the food item is shelf stable).

(Response 80) We conclude it is not appropriate to define “small quantity” for purposes of the exemption for food imported for personal consumption. The determination of what quantity of food is “consistent with a non-commercial purpose” must be made on a case-by-case basis and might vary depending on the type of food and other factors. In some cases, a supply that exceeds what one person might consume in a relatively short period of time might suggest a commercial purpose (and thus fall outside of the personal consumption exemption for FSVP). In other cases, a small supply that one person might consume over a period of years might be consistent with a personal consumption purpose and therefore might fall within the scope of the personal consumption exemption in § 1.501(d). However, in all cases the quantity of imported food would have to be consistent with a non-commercial purpose and the food could not be sold or distributed to the public in order to be subject to the exemption.

(Comment 81) One comment expresses concern that the exemption for personal consumption might be abused. The comment asserts that foods are often shipped or smuggled into the United States purportedly for personal use but are instead sold at ethnic food stores. The comment recommends that FDA and State and local agencies share information about such food to better control such violations.

(Response 81) We agree it is important that agencies involved in ensuring the safety of food imported into the United States share relevant information when possible and permitted by law. We routinely work with our State and local regulatory partners to address activities affecting the safety of imported food, and we intend to include implementation of the FSVP regulation among these activities. To the extent we become aware of any abuses of the personal consumption exemption in § 1.501(d), we intend to take appropriate action in response.

4. Exemption for Alcoholic Beverages

Under proposed § 1.501(e), we proposed to exempt from the FSVP regulation alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

- Under the Federal Alcohol Administration Act (FAAA) (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and
- Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

We also proposed that the FSVP regulation would not apply to food other than alcoholic beverages that is imported from a foreign supplier described in § 1.501(e)(1) provided that such food:

- (1) Is in prepackaged form that prevents any direct human contact with such food; and
- (2) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

We tentatively concluded that these provisions were consistent with the provisions on alcohol-related facilities in section 116 of FSMA (21 U.S.C. 2206(a)) and the proposed regulation on preventive controls for human food.

(Comment 82) Some comments request that we exempt from the FSVP requirements importation of raw materials and ingredients (*e.g.*, grapes, grains, hops, flavors) used to produce alcoholic beverages. The comments maintain that such an exemption would be consistent with the regulations on preventive controls for human food and accreditation of third-party auditors. The comments further assert that such an exemption would ensure consistency between domestic and foreign facilities and be consistent with Congressional intent regarding section 116 of FSMA.

(Response 82) For the reasons stated in the following paragraphs, we agree that some importers that import raw materials and other ingredients used to produce alcoholic beverages should be exempt from the FSVP regulation, but only with respect to alcoholic beverages an importer manufactures/processes, packs, or holds at a facility that meets the requirements to be exempt from the

preventive controls regulation under § 117.5(i) and as further described in the following paragraphs.

We believe that the context and purpose of FSMA supports this approach. Section 116(a) of FSMA provides that, except as provided by certain listed sections in FSMA, nothing in that act, or the amendments made by it, shall be construed to apply to a facility that (1) under the FAAA (or chapter 51 of subtitle E of the Internal Revenue Code of 1986) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and (2) under section 415 of the FD&C Act is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages (with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages).

The regulation on preventive controls for human food includes provisions implementing section 116 of FSMA. As reflected in the final rule on preventive controls for human food, FDA has determined that the alcoholic beverage exemption contemplated by section 116 exempts from the preventive controls regulation alcoholic beverages at facilities meeting the two specified conditions in section 116. (The exemption from the preventive controls regulation also applies with respect to food other than alcoholic beverages at facilities described in the exemption, provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility.) Notably, we interpret the exemption to apply not only to domestic facilities that are required to secure a permit, registration, or approval from the Secretary of the Treasury under the relevant statutes, but also to foreign facilities of a type that would require such a permit, registration, or approval if they were domestic facilities.

In the FSVP proposed rule, we discussed two possible approaches to interpreting section 116 of FSMA for purposes of the FSVP regulation. In doing so, we noted that section 116 is premised in part on status as a facility required to register under section 415 of the FD&C Act (section 116(a)(2) of FSMA). We also noted that under the definition of “importer” in the proposed rule, an “importer” under the FSVP regulation might be a registered facility but would not necessarily be one. Given section 116’s emphasis on status as a facility that is required to register under section 415 of the FD&C Act, we noted

that one approach to implementing section 116 would be to base an exemption from the FSVP regulation on whether the importer of an alcoholic beverage was a registered facility. The second approach we identified was to focus on the foreign supplier and to exempt from the FSVP regulation alcoholic beverages from foreign suppliers that would be exempt from the preventive controls regulation. As explained in the proposed rule, we proposed to adopt the second approach.

In reaching this tentative conclusion we noted that, under the first approach, firms might import the same product (*e.g.*, a bottled alcoholic beverage) and one firm would be eligible for the alcoholic beverage exemption from the FSVP regulation because it is required to register (*e.g.*, it packs or holds the alcoholic beverage), while the other would not be eligible for this exemption because it is not required to register (*e.g.*, it is a commodity broker that does not manufacture, process, pack, or hold food for consumption in the United States, or it is a restaurant or retailer). The latter importer would need to conduct supplier verification under section 805 of the FD&C Act while the former would not.

The second approach of focusing on the foreign supplier, however, tentatively seemed to be more consistent with FDA’s approach to alcoholic beverages in the proposed regulations on preventive controls for human food. Under this approach, if an alcoholic beverage is being imported, the foreign supplier would, by definition, be a facility that is required to register with FDA. Our proposed definition of “foreign supplier” meant that the supplier would be engaged in manufacturing/processing the alcoholic beverage and that this beverage would not undergo further manufacturing/processing before being exported to the United States, except for labeling or any similar activity of a de minimis nature (see § 1.226 regarding foreign facility registration). Under this interpretation, whether an imported food is exempt from section 805 of the FD&C Act would not depend on who the importer happens to be, but on the nature of the product being imported—whether the foreign supplier and the food in question (*i.e.*, the alcoholic beverage or food other than alcoholic beverages) meet the requirements for exemption under section 116 of FSMA. We tentatively concluded that this interpretation was consistent with the preventive controls proposed regulation because, in considering the two proposals together, if a foreign supplier is exempt from section 418 of the FD&C

Act by operation of section 116 of FSMA for a particular food, then the importer would not be required to conduct verification of the supplier for the food under section 805.

In proposing this second approach, however, we created an unanticipated inconsistency with the preventive controls regulation. Under the proposed FSVP regulation, a facility that meets the requirements for the alcoholic beverage exemption under § 117.5(i) of the regulation on preventive controls for human food could nevertheless be subject to the FSVP regulation if it imports, for example, raw materials to be used in the manufacture/processing of alcoholic beverages. Because the importer/facility would be exempt from the preventive controls regulation under § 117.5(j), it would not be required to establish and implement a risk-based supplier program under that regulation. That would mean that the importer would not be exempt from most FSVP requirements under the proposal to deem importers in compliance if they are required to establish and implement a risk-based supplier program under the preventive controls regulation, and are in compliance with those requirements. This is because only importers required under the preventive controls regulation to establish and implement such a supplier program could be deemed in compliance under that proposal. Under the proposed FSVP regulation, such an importer would not be exempt from FSVP because the food it imports would not be alcoholic beverages from a foreign supplier that meets the proposed requirements for the FSVP alcoholic beverage exemption. For facilities that meet the requirements for the alcoholic beverage exemption under § 117.5(i) and that also import raw materials for use in the manufacture/processing of alcoholic beverages, the result of this proposed approach would be to simultaneously exempt such facilities from the supplier verification requirements of the preventive controls regulation by operation of § 117.5(i), while requiring such facilities to conduct supplier verification activities under the FSVP regulation because they import food that would not be subject to the FSVP proposed exemption for alcoholic beverages.

We conclude that such a result would not be consistent with the risk-based public health principles underlying section 805 of the FD&C Act and FSMA generally. In enacting section 116 of FSMA, Congress must have considered it a lower public health priority to apply FSMA's core requirements to the manufacture/processing, packing, and holding of alcoholic beverages. Congress

may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB). In this context, we concluded that section 116 of FSMA should be interpreted to indicate that the manufacturing, processing, packing, or holding of alcoholic beverages at most alcohol-related facilities should not be subject to the preventive controls requirements of FSMA. For that reason, we established § 117.5(i). As discussed in the previous paragraphs, we included supplier verification requirements in the preventive control regulation. As a result, requiring alcohol-related facilities that are exempt from the supplier verification requirements in the preventive controls regulation under § 117.5(i) to nevertheless conduct supplier verification for imported ingredients used in the manufacture/processing of alcoholic beverages would effectively undo part of the exemption established by § 117.5(i).

For these reasons, we conclude that it is appropriate to adjust the scope of the alcoholic beverage exemption in the FSVP regulation. The final rule continues to exempt the alcoholic beverages that the proposed rule proposed to exempt, but also adds an exemption for food used in the production of alcoholic beverages that is based on the first approach to interpreting section 116 of FSMA that we discussed in the proposed rule, with additional limitations. Specifically, the final rule adds an exemption that only applies to importers required to be registered under section 415 of the FD&C Act, when such facilities are exempt from the preventive controls regulation under § 117.5(i). This exemption applies to food, such as grapes, hops, grains, and other ingredients, that is used by the importer in the manufacturing/processing, packing, or holding of alcoholic beverages.

Also in this final rule, we are clarifying the exemption for food that is not an alcoholic beverage imported from foreign suppliers described in § 1.501(e)(1) that is in prepackaged form preventing any direct human contact with the food, when such food constitutes not more than 5 percent of the overall sales of the facility. Instead of using the term "food other than alcoholic beverages" to describe the applicability of the exemption, as we proposed, we are now using the term "food that is not an alcoholic beverage."

5. Inapplicability to Food That Is Transshipped or Imported for Further Processing and Export

We proposed that the FSVP regulations would not apply to food that is transshipped through the United States to another country or to food that is imported for future export and that is neither consumed nor distributed in the United States.

(Comment 83) One comment expresses concern that the exemptions for transshipped food and food imported for further processing inappropriately shift the burden for ensuring the safety of imported food to the domestic manufacturer.

(Response 83) As stated in the preamble to the proposed rule, section 805 of the FD&C Act is designed to require importers to take affirmative steps to verify the compliance of the food with U.S. safety requirements. Given that context, we tentatively concluded that section 805 is not intended to apply to food that is neither consumed nor distributed in the United States and that is imported for further processing and export. We have not received any comments in response to the proposed rule that have caused us to change this tentative conclusion. The final rule therefore retains the exemption for transshipped food and for food that is imported for further processing and export. However, we are making several clarifications to these exemptions. First, we are clarifying that the exemption for transshipment only applies to food that is neither consumed nor distributed to the public in the United States. Second, the exemption for food that is imported for export applies when the food is being imported for processing, followed by export. Third, this exemption applies when the food is not consumed or distributed to the public in the United States. (The proposed rule proposed to specify that the exemption would apply when the food is not "consumed or distributed" in the United States, but did not explain that distributed means "distributed to the public.")

To the extent that the comment suggests that the exemptions place an unfair burden on ensuring the safety of imported food on U.S. manufacturers, we do not agree. By definition, U.S. manufacturers are not involved in the manufacturing/processing of transshipped food and thus are not affected by such food. We also believe the exemptions are consistent with the intent of section 805 of the FD&C Act.

(Comment 84) One comment asks whether the exemption for transshipped food applies to all imported food or only

food that is bonded by CBP, which permits merchandise to be moved from one port to another without the merchandise being appraised or duties imposed.

(Response 84) The exemption for transshipped food applies to all food that is transshipped through the United States to another country, provided that the food is not consumed or distributed to the public in the United States. The exemption does not hinge on whether the food is bonded by CBP.

6. U.S. Goods Returned

(Comment 85) Several comments asked that the transshipment exemption apply to food that is produced in and exported from the United States and is returned to the exporter after being rejected by the foreign purchaser or a foreign government (referred to as “U.S. goods returned” or “American goods returned”), sometimes for reasons other than the safety of the food. (Several other comments also asked for such an exemption, independent of the transshipment exemption.) One comment maintains that conducting verification for food that is returned to its U.S. producer in its original packaging would not constitute risk-based verification because there would be no hazards in such food. One comment asserts that because entries of U.S. goods returned are easily identified by their Harmonized Tariff Schedule (HTS) code, FDA should be able to manage any risks with such food through other mechanisms, including the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) electronic import screening system. The comments maintain that the FSVP requirements should not apply to U.S. goods returned because there is no foreign supplier of the food and the “importer” of the food would be conducting verification of its own operations.

(Response 85) We agree in part and disagree in part. Considering the context of section 805 of the FD&C Act, under which the importer must take affirmative steps to verify the compliance of imported food with U.S. safety requirements, we reaffirm our tentative conclusion (stated in the preamble to the proposed rule) that section 805 is not intended to apply to food that is neither consumed nor distributed in the United States. Therefore, we are finalizing § 1.501(f) with a few minor changes.

We think that similar considerations make it reasonable to conclude that the FSVP requirements do not apply to food that is manufactured/processed, raised, or grown in the United States, exported,

and then returned to the United States. Although section 805 of the FD&C Act applies to “each importer” and “the food imported by the importer or agent of an importer,” we think that section 805 of the FD&C Act is not intended to apply to circumstances in which there would not be a true foreign supplier of the food. Applying FSVP requirements in such circumstances would not be consistent with the underlying purpose of the FSVP provisions. Section 805(c)(2)(A) states that FDA’s implementing regulations must require that the FSVP of each importer be adequate to provide assurances that each of the importer’s foreign suppliers produces food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under sections 418 or 419 of the FD&C Act, as appropriate, and in compliance with sections 402 and 403(w) of the FD&C Act. Section 805(c)(2)(B) states that these regulations must include such other requirements as FDA deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States. Food that is originally manufactured/processed, grown, harvested, or raised in the United States is generally already subject to sections 402, 403(w), 418, and 419 of the FD&C Act, as applicable, and is therefore already subject to requirements that the food be as safe as other food produced and sold in the United States. Therefore, there is no reason to subject such food to the FSVP requirements and doing so would not be consistent with the context and purpose of section 805. Consequently, the final rule includes a provision, § 1.501(g), specifying that the FSVP regulation does not apply to such U.S. foods returned to the United States.

7. Raw Agricultural Commodities

(Comment 86) Some comments request that we exempt commingled or consolidated RACs (other than fruits and vegetables) from the FSVP regulations. Some comments request specific exemption for such RACs as dairy products, coffee and cocoa beans, and milled rice, canola meal, and cottonseed used for animal food. The comments maintain that these RACs generally are low-risk foods and are further processed at facilities in the United States that are required to register under section 415 of the FD&C Act, and that the U.S. facilities will address any hazards in the foods. The comments assert that, because of the complexity of RAC supply chains, it

would be prohibitively expensive for importers to conduct supplier verification for all of the farms associated with consolidated shipments of RACs. The comments maintain that RACs may change hands many times between the farm and the foreign port facility and also between the importer and the U.S. facility that manufactures/processes the RAC. The comments also contend that, because distributors may refuse to reveal their suppliers for competitive reasons or may not know the identity of the farms where the RACs are grown, it might not be possible for the importer to identify the growers. Some comments assert that exemption from FSVP is appropriate because FDA has not established standards for growers and traders of RACs that are not subject to the produce safety regulation and has limited standards for others in RAC supply chains.

(Response 86) We decline to exempt importers of RACs that are not subject to the produce safety regulation from the FSVP regulation. Although we have not established specific safety requirements for these RACs under the produce safety regulation, the requirements for FSVP are separate from the requirements for produce safety. We do not believe that an exemption for all RACs other than fruits and vegetables—whether commingled, consolidated, or otherwise—is appropriate. As discussed in response to other comments, section 805 of the FD&C Act applies to “each importer” and “the food imported by the importer or agent of an importer.” Given Congress’ decision to include exemptions for some types of food (*e.g.*, seafood and juice products subject to, and in compliance with, FDA’s HACCP regulations), but not RACs, we believe that Congress intended for FDA to establish FSVP regulations to ensure that imported RACs of the type discussed in the comments are as safe as similar RACs produced in the United States. As such, the RACs discussed in the comments are subject to the FSVP regulation, and importers of such RACs generally must conduct supplier verification activities in accordance with the FSVP requirements. However, if an importer determines under § 1.504(f) of the final rule that there are no hazards requiring a control in a particular RAC, the importer would not be required to determine what foreign supplier verification and related activities would need to be conducted, and the importer would not have to conduct such activities (see section III.E.7 of this document).

In addition, as discussed in more detail in section III.H.2 of this

document, under § 1.507 of the final rule, an importer will not be required to conduct the standard supplier verification activities when the hazards in a food (including a RAC) will be significantly minimized or prevented by the importer's customer. Instead, the importer will be required to (1) disclose in documents accompanying the food that the food is not processed to control identified hazards, and (2) obtain written assurance that its customer or an entity after its customer is processing the food for food safety. Similar procedures also are available when an entity in the distribution chain after the importer's immediate customer is processing the food for food safety. The final rule also would not require compliance with the standard supplier verification requirements for foods that could not be consumed without the application of an appropriate control (as may be the case with some RACs discussed in the comments) or when the importer implements a system that ensures control of the hazards in a food at a later distribution step.

8. Produce Rarely Consumed Raw and Food Intended for Commercial Processing

(Comment 87) One comment asks that we exempt from the FSVP requirements produce that is rarely consumed raw and produce that is intended for commercial processing (presumably, processing that would adequately reduce the presence of pathogens), asserting that such an exemption would be consistent with the exemption for such foods from the produce safety regulation. Another comment opposes the exemption of produce rarely consumed raw from the produce safety regulation and asks that these products not be exempt from the FSVP regulation.

(Response 87) The final rule does not exempt from the FSVP regulation produce rarely consumed raw or produce intended for commercial processing, whether or not the processing would adequately reduce the presence of microorganisms of public health significance. Regarding produce rarely consumed raw, we are allowing importers to rely on the provisions in §§ 1.505, 1.506, and 1.507 instead of providing an exemption. For some produce in this category, an importer might determine it is appropriate to conduct supplier verification activities to ensure that hazards in the food have been significantly minimized or prevented before importation. For other produce in this category, we are establishing requirements in § 1.507 that we believe are generally more suitable

to ensuring the safety of many of these foods than the standard FSVP requirements and that would not require the importer to conduct standard supplier verification activities. As described in section III.H.2 of this document, the final rule provides flexibility for situations in which an entity in the United States that is not the importer will control the hazards in a food.

Regarding imported produce intended for commercial processing, under § 1.502(c) of the final rule, when the importer itself is a receiving facility as defined in the preventive controls regulations and either (1) implements preventive controls for the hazards in the food, (2) is not required to implement a preventive control under § 117.135 or § 507.34, or (3) has implemented a supply-chain program for the food in compliance with the preventive controls regulations, the importer would be deemed in compliance with most of the FSVP requirements (except for the requirements in § 1.509). When such processing is performed by the importer's customer or a subsequent entity, the flexibility provided in § 1.507 would allow the importer to forego supplier verification activities provided it meets certain other requirements to help ensure that the processing is adequately performed before the food is consumed.

9. Products Not for Use as Food

(Comment 88) One comment suggests that for a food that may be used for either a food or non-food use, FDA should regard each shipment of the product offered for import to be food that is subject to the FSVP regulation unless the statement "Not for food use" is included in the commercial documentation accompanying the shipment.

(Response 88) Under FDA's regulation implementing the prior notice requirements of the Bioterrorism Act, prior notice must be submitted for each article of food that is imported or offered for import into the United States (21 CFR 1.281(a)). In our interim final rule on prior notice, we explained that we will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use (68 FR 58974 at 58987, October 10, 2003). In the prior notice final rule, we clarified that we consider a dual use

substance to be "food" for the purpose of prior notice if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301, November 7, 2008). Thus, an article of food is subject to the prior notice requirements if it is capable of multiple uses, provided that it is reasonably likely to be directed to a food use. We believe that a similar approach is appropriate with respect to FSVP. Therefore, we conclude that a substance that is capable of multiple uses is subject to the FSVP regulation if it is reasonably likely to be directed to a food use. We believe this standard is appropriate because it will subject substances that are reasonably likely to be directed to a food use to the FSVP regulation, more so than basing the application of the FSVP regulation on the existence of a "Not for food use" statement that might not necessarily reflect industry practice or the likely use of the substance.

10. Food From Foreign Suppliers That Are Part of Same Corporate Structure

In the preamble to the proposed rule, we stated that some importers might obtain food from foreign suppliers who are part of the same corporate structure as the importer and who might, along with the importer, be subject to a single, integrated, company-wide approach to food safety in which hazards are controlled and verified by a common supply chain management system. We sought comment on whether such importers should be required to conduct foreign supplier verification or should be subject to different FSVP requirements.

(Comment 89) Several comments request that we exempt from the FSVP regulations food that is imported from a foreign supplier who is part of the same corporate structure as the importer. The comments assert that when the importer and the foreign supplier follow the same food safety standards and practices, supplier verification is unnecessary. Some comments request that we exempt from the FSVP regulation food that is imported from a foreign supplier that is an affiliate of the importer; some comments request that the exemption apply when the foreign supplier of a food is under the same corporate structure as the importer and/or is subject to the same integrated, company-wide approach to food safety as the importer. However, some comments express concern that such an exemption might lead to fraudulent schemes to make it appear as if the importer and the foreign supplier are integrated companies.

(Response 89) We decline to exempt from the FSVP regulation food an

importer obtains from a foreign supplier that is part of the same corporate structure as the importer. We also decline to establish an exemption from the FSVP requirements when the foreign supplier and importer may otherwise be affiliated, and when the foreign supplier and importer are part of the same company-wide “approach” to food safety. We conclude that the fact that an importer and its foreign supplier are affiliated and may be operating within a unified corporate structure or food safety system does not necessarily ensure that the foreign supplier is operating in compliance with sections 402 and 403(w) of the FD&C Act (where applicable). Nor does such a relationship necessarily ensure the foreign supplier is operating in compliance with processes and procedures that provide the same level of public health protection as the requirements under the preventive controls or produce safety regulations, where applicable. Consequently, importers should be required to conduct supplier verification in these circumstances. However, we agree that an importer’s corporate affiliation with its foreign supplier might provide the importer with greater assurance regarding the supplier’s compliance with applicable requirements under the FD&C Act. Therefore, an importer of a food from a foreign supplier that is part of the same corporate structure as the importer and/or is subject to the same integrated, corporate approach to food safety may take this into account in evaluating the foreign supplier’s performance under § 1.505 of the final rule and determining appropriate supplier verification activities for the supplier under § 1.506.

(Comment 90) One comment asserts that requiring supplier verification for imports from suppliers with the same corporate parent may increase trade burdens in violation of WTO agreements. The comment provided the example of Company A in San Diego that imports finished packaged cereal from Company A in Tijuana, Mexico. The comment states that under the proposed rule, the company would be required to conduct supplier verification of itself, but the company would not be required to conduct supplier verification if it had manufactured the cereal in California. The comment maintains that without exempting the Tijuana-produced food from FSVP, U.S.-produced goods would receive favorable treatment because FSVP would impose a paperwork burden for intra-company imports.

(Response 90) We do not agree. FSVP would not impose a trade or paperwork

burden for the intra-company imports described in the comment. If the company in the example manufactured the cereal product in California, the company would be subject to the supply-chain program requirements in the preventive controls for human food regulation, and therefore would be required to verify its ingredient suppliers. It also would be required to review its supply-chain program records to determine whether the program is effective. Therefore, it is not correct that if the company manufactured the cereal product in California, it would not need to conduct verification activities with respect to the product. In addition, FSVP-related verification activities for the cereal product manufactured in Tijuana need only be commensurate with the risk posed by the cereal, and the importer of the cereal can take the intra-company relationship into account in evaluating the foreign supplier and determining appropriate verification activities. Therefore, we do not believe the FSVP regulation increases trade burdens on importers of suppliers with the same corporate parent.

We also note that the California facility would be part of a domestic U.S. Integrated Food Safety System (IFSS) that includes multiple Federal, State, territorial, tribal, and local regulatory and public health agencies (see the discussion of the IFSS in Response 105). Inspections of domestic food facilities (including farms, manufacturing facilities, and retail facilities) are overseen by a mix of Federal, State, local, tribal, and territorial agencies. When compared to this comprehensive system of domestic oversight for food production and distribution from farm to retail (discussed in more detail in section III.C.1.g of this document), we believe that the supplier verification requirements for imported foods under the FSVP regulation are no more burdensome than the oversight and control measures applied to domestic foods. Consequently, the California facility would be subject to oversight that is no less burdensome than the verification that the Tijuana facility would face under FSVP.

11. Other Requests for Exemption

(Comment 91) One comment requests an exemption from FSVP based on an agreement with the foreign government of the country in which the foreign supplier is located. One comment suggests a product-specific exemption for a foreign supplier who was in compliance with the foreign government’s applicable regulations.

(Response 91) As discussed more fully in section III.N of this document

and in the preamble to the proposed rule, we are excluding from many of the standard FSVP requirements food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the importer documents that certain conditions are met. These modified FSVP requirements are set forth in § 1.513 of the final rule. Depending on the scope of the official recognition or equivalence determination regarding a foreign food safety authority, these modified FSVP requirements might apply to all foods from suppliers in the relevant country or only certain products or commodities.

(Comment 92) One comment suggests that exemptions from the FSVP regulation be based on factors such as the size of the company, the type of food, and the risk posed by the food.

(Response 92) As discussed previously, the final rule contains exemptions or partial exemptions for several types of foods consistent with exemptions provided under section 805(e) of the FD&C Act. These include exemptions for juice and seafood products and thermally processed low-acid foods packaged in hermetically sealed containers (“low-acid canned foods” or LACF) (discussed in section III.C.2 of this document), subject to certain conditions. Although the final rule does not exempt very small importers from the FSVP requirements, it contains modified provisions for these importers that will significantly reduce the number of FSVP requirements they must meet (see § 1.512 of the final rule and section III.M of this document). In addition, the FSVP regulation takes into account the risk posed by foods in several ways (e.g., no verification activities required when there are no hazards in a food, certain supplier verification activity provisions for foods with hazards that can result in serious adverse health consequences or death to humans or animals (SAHCODHA)). These provisions of the rule adequately address the different risks posed by different foods and businesses of different sizes.

(Comment 93) One comment states that cattle, poultry meat, and egg products should be exempt from the FSVP regulations because they are subject to regulation by the USDA’s Food Safety and Inspection Service (FSIS). One comment asks whether the FSVP regulation applies to live animals intended for consumption, specifically cattle. The comment asserts that for live cattle imported from Canada, the Canadian government and USDA’s

Animal and Plant Health Inspection Service (APHIS) and FSIS share responsibility for verifying safety (with respect to bovine spongiform encephalopathy (BSE)), and it would be duplicative to require the importer to comply with the FSVP regulation with respect to such cattle.

(Response 93) We agree that an exemption is appropriate with respect to cattle, poultry, and egg products, but not live animals. The final rule adds § 1.501(h), which states that the FSVP regulation does not apply to meat, poultry, and egg products that at the time of importation are subject to the requirements of the USDA under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). We conclude that this provision is consistent with the context and purpose of FSMA generally, and with section 805 of the FD&C Act in particular. In enacting section 805, Congress intended to ensure that food imported into the United States is produced in a manner consistent with U.S. standards. At the same time Congress enacted section 805, it also enacted section 403 of FSMA (21 U.S.C. 2251), entitled “Rule of Construction,” which states that nothing in FSMA must be construed to alter or limit the jurisdiction of the Secretary of the Department of Agriculture. For many decades, USDA has exercised authority and responsibility over the import of such meat, poultry, and egg products, and has adopted detailed regulations and procedures implementing this authority. In light of USDA’s role with respect to the importation of these products, and also in light of section 403 of FSMA, we conclude that Congress did not intend the FSVP regulation to apply to meat, poultry, and egg products that at the time of importation are subject to USDA requirements under the MPIA, PPIA, and EPIA, respectively. We therefore conclude that § 1.501(h) is consistent with Congress’ intent in promulgating section 403 of FSMA and section 805 of the FD&C Act.

However, we do not agree that the FSVP regulation should not apply to live animals, including cattle, intended for consumption. Live animals raised for food, even though not in their final, edible form, are considered to be food under the FD&C Act (see *United States v. Tomahara Enterprises Ltd.*, Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food); *United States v. Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio 1995) (live hogs are food)). Further, live

animals, such as poultry and cattle, are not subject to the USDA requirements under the FMIA or PPIA at the time of importation. Indeed, FDA has exercised authority and responsibility over the importation of live food animals. For example, FDA’s final rule on prior notice requirements specifically includes live animals that are imported for food use (see 73 FR 66294 at 66306). Only food that is subject to the requirements of the USDA under the FMIA, the PPIA, or the EPIA at the time of importation are excluded from the scope of the FSVP regulation under § 1.501(h).

However, with respect to live animals that are eventually processed at FSIS-inspected slaughter and production plants or inspected by States under cooperative agreements with FSIS, we expect that importers likely will determine, in accordance with § 1.507 of the final rule, that the live animals could not be consumed without application of an appropriate control in the supply or distribution chain, so that the importers will not be required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506. The principal hazards for such live animals are chemical hazards such as unlawful drug residues and BSE. FSIS and APHIS have comprehensive regulatory requirements that control these hazards, including HACCP requirements. FSIS-regulated meat and poultry establishments are required to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from, for example, drug residues, and are also required to develop systems to guard against these hazards. In addition, FSIS oversees the requirements related to the identification and control of hazards, and collects samples of meat, poultry, and egg products and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, among other contaminants. Thus, when USDA-regulated establishments are in compliance with the USDA-administered HACCP and other requirements, the hazards associated with the live animals processed at such establishments ordinarily would be controlled and the live animals could not be consumed without such controls.

However, importers of live animals of species such as bison and elk that are not processed at USDA-regulated slaughter and production plants under HACCP requirements might determine that there are drug residues or other hazards requiring control. Importers of such live animals might therefore be required to conduct supplier

verification for the foreign supplier that raised the animals.

C. Purpose and Scope of FSVPs (§ 1.502)

In § 1.502 of the proposed rule, we proposed that importers be required to have an FSVP for each food they import that would provide adequate assurances that the standard of food safety set forth in section 805 of the FD&C Act would be met. We included a modification of that proposed requirement with respect to microbiological hazards in thermally processed low-acid foods packaged in hermetically sealed containers (low-acid canned foods or LACF). In the Supplemental Notice, we revised proposed § 1.502 to include provisions under which importers who were in compliance with the supplier program provisions of the preventive controls regulations (or whose customers were in compliance with those provisions) would be deemed in compliance with most of the FSVP requirements. As discussed in the following paragraphs, the final rule includes several changes to proposed § 1.502 in response to comments and on our own initiative.

1. Requirement To Develop and Follow an FSVP

We proposed to require importers to develop, maintain, and follow an FSVP for each food imported that provides adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either was applicable, and was producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act.

On our own initiative, to clarify the relevant requirements, we have revised § 1.502(a) to refer not only to sections 418 and 419 of the FD&C Act but also to “the implementing regulations” for those sections, *i.e.*, the preventive controls and produce safety regulations, respectively. In addition, because we are interpreting section 403(w) of the FD&C Act regarding misbranding with respect to allergen labeling to be inapplicable to animal food, we have revised § 1.502(a) to specify that an importer’s FSVP must provide assurance that a foreign supplier is producing a food in compliance with section 403(w) “if applicable.” We have made corresponding changes to other

provisions in the FSVP regulation citing this FSMA standard for FSVPs.

a. Meaning of “For Each Food”

(Comment 94) Several comments ask that we clarify the meaning of proposed § 1.502(a) with respect to having an FSVP “for each food.” For example, the comments ask whether importers would be required to have a different FSVP for each of similar foods (e.g., red and green grapes) or even different package sizes (e.g., 9-count and 12-count) of the same food product. The comments maintain that having to develop an FSVP for each individual food product would be burdensome without contributing to food safety. Some comments ask that importers be allowed to have an FSVP for foods that are of the same “type.” Some comments suggest that importers be permitted to include foods in similar commodity groups (e.g., different types of squash and zucchini) in the same FSVP. Some comments suggest that importers be allowed to have one FSVP for produce grown, harvested, and packed under the same conditions.

(Response 94) We decline to make the suggested changes. Section 805(c)(2)(A) of the FD&C Act requires that the FSVP of each importer be adequate to provide assurances that each foreign supplier to the importer produces “the imported food” in compliance with the standard set forth in that provision; it does not state that an importer’s FSVP would be for a “type of food” from a foreign supplier. However, we agree with the comments that an importer should not be required to establish separate FSVPs for different versions of the same food when the differences in the products will not impact the safety of the food. For example, it might be appropriate for an importer to develop a single FSVP covering several different packaging sizes or formats for a particular food, provided that these packaging differences do not pose different hazards that need to be controlled by the foreign supplier and addressed in supplier verification activities. We intend to provide additional examples of what constitutes the same food for purposes of establishing an FSVP for the importation of the food in the FSVP draft guidance.

Although an importer must have an FSVP for each food it imports from each foreign supplier, we conclude (as discussed more fully in section III.E.2 of this document) that it might be appropriate to conduct a hazard analysis for a “type” of food, such as different varieties of the same fruit or vegetable, provided all aspects of the hazard analysis are applicable to all foods that the importer regards as being of the

same type. However, it would not be appropriate to use the same hazard analysis for foods that, though very similar, have different hazards requiring control. For example, even if two foods were grown, harvested, and packed under the same conditions, it would not be appropriate to use the same hazard analysis for both foods if one food was susceptible to certain microbiological hazards but the other food was not.

It is also important to note that importers must establish an FSVP for each foreign supplier of a food. Thus, if an importer obtains a particular food from multiple foreign suppliers, the importer must have a separate FSVP for each supplier. This is appropriate because the FSVP regulation requires importers to consider not just hazards inherent in the foods they import, but also the performance history and characteristics of the foreign suppliers of the food, and to conduct supplier verification activities that are tailored to the particular food and foreign supplier. However, as discussed elsewhere in this document, importers may be able to rely on foreign supplier evaluations and verification activities conducted by other entities in meeting these requirements.

(Comment 95) Some comments request that we provide guidance on appropriate processes for safely producing products that fall into similar categories.

(Response 95) The FSVP regulation does not establish requirements for the safe production of food; those requirements are set forth in other FDA regulations, including those on produce safety and preventive controls for human and animal food. However, as stated previously, the FSVP draft guidance will provide additional examples regarding what importers may regard as the same food that can be addressed in a particular FSVP.

b. Role of Importer’s Corporate Headquarters

(Comment 96) Several comments state that § 1.502(a) should acknowledge that an importer’s corporate headquarters might establish or develop the importer’s FSVP for a food and might do the same for a contract manufacturer. The comments add that FDA should conduct its inspections of importers accordingly.

(Response 96) The requirements to develop FSVPs and keep records apply to importers as defined in § 1.500 of the final rule, and § 1.502(a) accordingly does not refer to a particular “facility” but to the importer. For purposes of FDA inspection of importers, the importer’s location is where the

importer conducts business. This might be, but is not required to be, the place where the importer retains its FSVP records. For some importers that import food into the United States through multiple ports, the importers’ FSVPs for the foods they import might be developed and maintained at a single location, such as a corporate headquarters. However, while entities other than the importer may conduct activities to satisfy various FSVP requirements (provided that the importer reviews and assesses results of those activities, among other things), an importer of a food is responsible for maintaining and administering its FSVP. Therefore, if a contract manufacturer for a U.S. food facility is the importer of a food under § 1.500, the contract manufacturer would be required to maintain and administer the FSVP for the food.

c. Entity Controlling the Hazards

(Comment 97) One comment states that the requirement to have an FSVP for an imported food should be limited to a food that a hazard analysis indicates may contain a significant hazard that is addressed by a foreign supplier, because sometimes the importer, not the foreign supplier, will control the hazards in the food.

(Response 97) We agree that it will not be necessary for an importer that is also a food facility under section 415 of the FD&C Act and is controlling hazards under the preventive controls regulations to comply with the majority of the provisions of this rule. As discussed in section III.C.3 of this document, under § 1.502(c) of the final rule, if an importer is a receiving facility that implements preventive controls for the hazards in a food in accordance with § 117.135 or § 507.34 for a food it imports, the receiving facility is deemed to be in compliance with the requirements of the FSVP regulation, except for the requirements in § 1.509. For these reasons, it is not necessary to change § 1.502(a) as suggested.

d. Adequate Assurances of Foreign Supplier’s Adherence to Food Safety Standards

(Comment 98) Some comments suggest that we explain what constitutes “adequate assurances” that foreign suppliers are producing food in accordance with the standard specified in § 1.502(a). One comment suggests that when considering whether adequate assurances exist, the importer should consider issues such as whether the foreign supplier has an adequate food safety plan that accounts for all hazards in a food. One comment asks

that we specify what kind of assurance of compliance importers need from their suppliers (e.g., certification with the International Standards Organization (ISO), HACCP compliance, reports of FDA inspections), adding that the requirements should be the same for both domestic and foreign establishments. One comment states that the need to provide adequate assurance of compliance with the relevant standards elevates the importance of clear definitions of those standards.

(Response 98) Importers must obtain adequate assurances of foreign supplier compliance with the applicable standards stated in § 1.502(a) primarily through foreign supplier verification activities conducted under § 1.506 of the final rule, which must reflect the evaluation of the food and foreign supplier conducted under § 1.505. Section 1.506(c) states that foreign supplier verification activities must provide the adequate assurance that the hazards requiring a control in imported foods have been significantly minimized or prevented (because such control of hazards provides assurance that the standard specified in § 1.502(a) is met). Section 1.506 specifies the foreign supplier verification activities that are appropriate under different circumstances for providing adequate assurances of compliance.

For foreign suppliers subject to the preventive controls or produce safety regulations, the adequate assurances that importers must obtain through their FSVPs primarily will be that the supplier is producing the food in a manner that provides the same level of public health protection as the applicable regulations. For foreign suppliers subject to the preventive controls regulations, adequate assurance of compliance would include, as the comments suggest, a consideration of the adequacy of the supplier's food safety plan as well as other elements of the preventive controls regulations and whether the supplier's processes and procedures provide the same level of public health protection as the processes and procedures required under those regulations. As such, the processes and procedures used by foreign farms and facilities covered by the produce safety and preventive controls regulations are expected to provide no more—and no less—public health protection than those used by domestic farms and facilities. Section III.G.4 of this document addresses the specific information that importers must review under § 1.506 of the final rule when conducting supplier verification activities to assess whether the supplier

is producing food in accordance with U.S. standards.

e. Same Level of Public Health Protection

(Comment 99) Several comments request that we provide clarity regarding the nature of processes and procedures that will provide the same level of public health protection as those required under the preventive controls or produce safety regulations. Some comments express concern that permitting use of the “same level of public health protection” standard raises questions about whether there will be a level playing field for domestic and foreign producers. Some comments state that we must apply the same food safety standards (in particular the produce safety regulation) to domestic and foreign producers. Some comments assert that we should also require verification of foreign supplier compliance with USDA requirements concerning fertilizers, herbicides, pesticides, and fumigants.

One comment states that the “same level of public health protection” language appears to allow foreign suppliers to establish alternative standards to preventive controls and produce safety requirements within the FSVP regulations, even though there is no process for adopting alternative procedures under the preventive controls regulations and the ability to adopt alternative procedures under the produce safety regulation is limited. Some comments ask that we specify how importers should determine whether use of an alternative procedure results in the same level of public health protection and which entity is permitted to make a determination regarding the same level of public health protection. One comment recommends that we allow a flexible approach for meeting the same level of public health protection standard because of issues raised by the application of preventive controls requirements to foreign facilities. One comment requests that the regulation specify the standards that verification activities must meet to demonstrate an equivalent level of public health protection, but adds that if these standards are instead to be set forth in guidance, it should be a level 1 guidance and the Agency should hold public meetings and advisory committee meetings. One comment suggests that we include a requirement for importers to identify when a foreign supplier is using an alternative procedure if use of alternative procedures is not an option for domestic firms under the applicable food safety regulations.

(Response 99) As the comments note, FSMA itself (section 805(c)(2)(A) of the FD&C Act) directs FDA to establish regulations that require importers to obtain assurances that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations, as appropriate. Importers must determine whether particular processes and procedures used by foreign suppliers that differ from those required under the preventive controls or produce safety regulations nevertheless provide the same level of public health protection, although FDA will be able to review such determinations as part of records reviews of importers for compliance with the FSVP requirements.

The produce safety regulation includes provisions (§ 112.12) permitting the use of alternatives to certain requirements in the regulation provided the producer of the food (the farm) has adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable provision and would not increase the likelihood that the produce was adulterated. The produce safety regulation also includes provisions (subpart P of part 112) under which States, tribes, and foreign countries may request a variance from the produce safety requirements when the State, tribe, or foreign country determines that the variance is necessary in light of local growing conditions and the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated and to provide the same level of public health protection. Although the preventive controls regulations do not include similar alternative or variance procedures, those regulations are designed to allow facilities the flexibility to tailor their processes and procedures in a manner that is appropriate to the food and the facility, with management components that are appropriate to the food, the facility, and the nature of the preventive controls and their role in the facility's food safety system.

To the extent that the comment is suggesting that § 1.502 include a requirement that importers document each procedure used by a foreign supplier that differs from the preventive controls or produce safety regulations, we conclude it is not necessary to do so. However, where such use of such alternative procedures is relevant to an importer's evaluation of a foreign supplier's performance under § 1.505 or

the results of foreign supplier verification activities under § 1.506, information about the alternative procedures must be included in the documentation for these FSVP requirements. With respect to the variance provisions under the produce safety regulations for States, tribes, and foreign countries, there may be circumstances in which approved variances are relevant to determining whether a particular foreign supplier's processes and procedures provide the same level of public health protection as the requirements under section 419 of the FD&C Act. Audits of suppliers following procedures, processes, or practices specified in an approved variance from the produce safety regulation conducted for the purpose of FSVP compliance may consider that FDA, in granting the variance, determined that those procedures, processes, or practices are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements under section 419.

We conclude it is not necessary to state in the regulation specific actions that importers must take in evaluating whether alternative procedures used by foreign suppliers provide the same level of public health protection as procedures required in the regulations implementing sections 418 and 419 of the FD&C Act.

(Comment 100) One comment maintains that food safety regulations in the EU, and particularly in France, provide the same level of public health protection as the FSMA standards and urges that we recognize these standards.

(Response 100) We do not have sufficient information at this time to determine whether the food safety regulations in particular countries or regions provide the same level of public health protection as U.S. standards. However, importers may find that compliance with the laws of France and other EU countries is relevant to determining whether foods are being produced using processes and procedures that provide the same level of public health protection as those required under FDA's regulations. In addition, as discussed in section III.N of this document, FDA has established a systems recognition initiative, under which we are conducting comprehensive assessments of foreign food safety systems to determine whether they provide similar protections to those offered under the U.S. system and a similar level of oversight and monitoring. As discussed in more detail in section III.N, the

systems recognition program is based on the principle that foreign food producers can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country whose food safety system we have found to be comparable. Under § 1.513 of the final rule, once we have made a determination that a foreign food safety system is comparable to ours, certain foods within the scope of such a determination may be imported under modified FSVP requirements (provided that certain conditions are met). These provisions will allow the importation of such food without being subject to most of the standard FSVP requirements.

(Comment 101) Some comments state that, to ensure that the concept of "same level of public health protection" is applied consistently, FDA must conduct risk assessments of foods to formulate an appropriate risk matrix that can be applied domestically and internationally. The comments request that, before we issue the final rules on produce safety and FSVPs, we issue for public comment the risk model that we intend to use for evaluating requests for variances under the produce safety proposed regulation.

(Response 101) We do not agree. This rule establishes a flexible, risk-based approach to foreign supplier verification based in significant part on a requirement that importers understand the hazards in the foods they import so they can take appropriate steps to verify that their suppliers have adequately controlled these hazards. We believe that a system of hazard analysis, control, and verification is well accepted and understood throughout the international food safety community and provides the most effective way to implement a risk-based framework for foreign supplier verification. We have confidence that importers will be able to implement FSVPs based on their own hazard analyses or their review of analyses conducted by others, without our having to conduct risk assessments for all foods to generate a risk matrix that all food producers would use. As stated previously, we intend to issue guidance to assist importers and foreign and domestic producers in complying with the new regulations that we are adopting under FSMA, including guidance on the analysis of hazards in food. With respect to variances under the produce safety regulation, we note that the final rule adopting that regulation published elsewhere in this issue of the **Federal Register** addresses how FDA will evaluate requests for variances submitted in accordance with subpart P of part 112.

f. Relevant Statutory Requirements

(Comment 102) One comment states that FSVPs should be limited to verifying foreign supplier compliance with the preventive controls or produce safety regulations. One comment states that the FSVP regulation should not impose any additional obligations on foreign suppliers beyond those required under other FDA regulations, and should be based on relevant international standards and conform to U.S. international obligations.

(Response 102) The purpose and scope of importers' FSVPs, as set forth in § 1.502(a) of the final rule, implements the standard mandated in FSMA for FSVPs. Consequently, it requires importers to take steps to ensure that their foreign suppliers are producing food in a manner consistent with the preventive controls or produce safety regulations, to the extent that those regulations apply to the foreign supplier's production of a food, and to ensure that the food from the supplier is not adulterated and is not misbranded with respect to allergen labeling, if applicable. The FSVP regulation does not impose on foreign suppliers any requirements that they are not already subject to under the FD&C Act and implementing regulations, including the regulations on preventive controls and produce safety. In addition, the FSVP regulation is drafted to be consistent with U.S. obligations under international agreements.

(Comment 103) One comment suggests that the phrase "if either is applicable" when referring to the preventive controls and produce safety provisions be interpreted to mean that if a type of produce is covered by section 419 (and the produce safety regulation), it must be in compliance with section 419, rather than meaning that any imported "produce" would be subject to section 419.

(Response 103) We agree. If an imported item of produce is not subject to the produce safety regulation, the importer would not be required to verify that the produce was grown in accordance with that regulation.

(Comment 104) One comment suggests that the requirement to have an FSVP be limited to problems that "cause a risk to the public health," which the comment maintains would be consistent with the statement in the preamble to the proposed rule that the regulation should focus on foreseeable food safety risks identified through hazard assessment rather than all risks covered by the adulteration provisions. The comment contends that not all adulterants cause a food safety risk and

many forms of adulteration are not amenable to discovery by the importer.

(Response 104) We do not believe that the proposed change is necessary. The importance of the existence of a risk to public health is incorporated in the definition of "hazard," meaning any biological, chemical, or physical agent that is reasonably likely to cause illness or injury. Except as specified otherwise, each importer would need to have an FSVP for each food that it imports from each foreign supplier and to conduct a hazard analysis for each type of food in accordance with § 1.504 of the final rule. However, under § 1.504(f), if an importer determines there are no hazards requiring a control in a food, the importer would not be required to conduct an evaluation of the risk posed by the food and the foreign supplier's performance and would not be required to conduct supplier verification activities.

g. U.S. International Obligations

(Comment 105) One comment notes that domestic farms supplying foods directly to retailers are not subject to supplier verification requirements because the supplying entity (*i.e.*, the farm) and receiving entity (*i.e.*, the retailer) are not subject to the regulations on preventive controls, which contain supplier program provisions. The comment asks that we revise the FSVP provisions regarding produce to ensure that there are no differences in treatment between domestic and foreign suppliers with respect to the obligations of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (Ref. 4).

(Response 105) The FSVP regulation aligns with the supply-chain program provisions of the preventive controls regulations by requiring importers to verify that their suppliers have systems in place to significantly minimize or prevent the hazards associated with the foods they are supplying and that their suppliers meet or provide the same level of public health protection as required under applicable FDA safety standards. In addition, an importer conducting supplier verification under the preventive controls regulations for imported raw materials or other ingredients would be deemed in compliance with most of the FSVP requirements.

Nevertheless, the supply-chain program provisions of the preventive controls regulations do not apply to certain domestic entities, including restaurants or retail food establishments. However, this does not mean that farms that supply produce to such entities are

subject to different or lesser safety standards than foreign farms that supply produce to U.S. importers subject to the FSVP regulation. To the contrary, the requirements in the produce safety regulation apply with equal force to domestic and foreign farms.

Under the food safety system envisioned by FSMA, supplier verification of imported produce to be sold by U.S. retailers is needed to ensure a consistent level of oversight and protection for domestic and imported food. Consistent with other provisions of FSMA, FDA is taking several steps to establish a more comprehensive, effective, risk-based approach to domestic food safety oversight and enforcement. We are working through the Partnership for Food Protection (PFP), a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health, to develop and implement a national Integrated Food Safety System (IFSS) for domestic compliance oversight (Ref. 5). We are also adopting a new domestic inspection paradigm, stemming from our authority to inspect under section 704 of the FD&C Act (21 U.S.C. 374), focused on whether firms are implementing systems that effectively prevent or significantly minimize food contamination in compliance with the new FSMA regulations, including those on preventive controls and produce safety. This new paradigm involves a major reorientation and retraining of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors.

In addition, section 201 of FSMA (section 421 of the FD&C Act (21 U.S.C. 350j)) mandates that we inspect domestic high-risk facilities not less than once every 3 years. We are currently meeting this mandate and we intend to significantly exceed it as part of our strategy to implement the new food safety standards. We intend there to be an FDA or State inspection of every domestic high-risk human food facility annually to verify compliance with the new regulations.

Our implementation of the final rule on produce safety (published elsewhere in this issue of the **Federal Register**) will entail a broad, collaborative effort to foster awareness and compliance domestically. Our strategy includes guidance, education, technical assistance, and verification. Verification will be achieved through the actions of multiple public and private entities, including inspections by FDA and

partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers. In keeping with this broad vision, we intend to focus our domestic efforts on several important activities, including the following:

- Supporting and collaborating with public and private parties involved in audits and other accountability and verification activities;
- Conducting targeted domestic on-farm surveys and risk-based inspections to understand current practices and identify gaps in compliance; and
- Taking administrative compliance and enforcement action when needed to correct problems that put consumers at risk.

We have the authority to inspect farms subject to the produce safety regulation under section 704 of the FD&C Act. We will target our inspections on the basis of risk. We intend to rely heavily on the States to conduct a large proportion of the routine inspections of farms, and we are committed to working closely with the States to verify compliance with the new FSMA requirements. In addition to FDA and State inspections, we will leverage third-party audits conducted by USDA and others with a goal of annual verification of all domestic farms subject to the produce safety rule.

In contrast, we expect to have a far less robust system of direct public oversight of foreign food facilities and farms that are subject to the new FSMA regulations. We have less ability to physically inspect and take enforcement actions against those who produce food abroad for export to the United States due to legal and practical limitations. For example, diplomatic and practical logistics associated with conducting foreign inspections in most countries complicate, and in some cases make impossible, the kind of routine unannounced inspections of establishments that we conduct in the United States. As a result, neither we nor our IFSS partners can rely on unannounced inspections abroad in the same way as we can domestically.

We also face challenges in conducting "for cause" inspections of foreign facilities when we have evidence of a compliance problem. Domestically, we can respond to a refusal to permit inspection or a refusal to permit access to or copying of records by obtaining inspection warrants in the federal courts. For foreign inspections, however, we do not have the same access to the courts, and it can be challenging to compel inspections and access to records when needed. We also face diplomatic and logistical challenges

in conducting foreign civil and criminal investigations and prosecutions when violations occur that do not hinder our domestic enforcement efforts. In addition to legal issues related to extraterritoriality, practical and operational challenges to our foreign enforcement activities include obtaining visas and official travel documents, finding qualified translators, procuring foreign travel authorizations, difficulties in coordinating with foreign authorities, and extradition.

Because of these challenges, we largely rely on the cooperation of foreign governments when conducting inspections in foreign countries and bringing enforcement actions against foreign businesses and individuals. Today, our main approach to oversight of imported food is reactive, involving sampling and testing food at ports of entry. However, with the increased volume of imported foods coming across U.S. borders and limited resources, we are able to physically examine less than 2 percent of food offered for import each year.

Given the difficulties in conducting direct FDA regulatory oversight of foreign producers, FSMA requires importers to share responsibility for verifying the safety of imported food. The FSVP regulation requires that U.S. importers, who are domestic entities under direct legal jurisdiction, take action to ensure the safety of the food they import by performing risk-based supplier verification activities. Combined with FDA's foreign inspections and enforcement efforts, the FSVP requirements will help ensure that imported food is subject to the same level of risk-based oversight and accountability that applies to domestic food under our comprehensive, integrated domestic food safety system.

In establishing these requirements for supplier verification by importers, we are integrating practices that industry has adopted in the last two decades to ensure that imported food is produced under modern food safety standards. Global industry best practices include not only risk-based, prevention-oriented standards for producing safe food but also verification measures to ensure that those standards are being met, including supplier verification and other supply-chain management activities. These oversight and verification approaches also are recognized by the Codex Alimentarius Commission (Codex) and are consistent with the approach of export oversight agencies in governments of countries with which the United States trades (see the discussion of Codex and relevant Codex standards and guidelines in Response

106). Therefore, in relying on the FSVP regulation to help ensure that oversight of imported food matches the level of domestic oversight made possible under FSMA, we are relying on mechanisms that are consistent with internationally recognized standards.

Our goal is for our domestic implementation strategy, including outreach, inspection frequencies, and other mechanisms to achieve compliance, to be operational on a schedule that corresponds with the dates by which domestic food producers are required to comply with the new FSMA standards. We have designed the compliance dates for importers under this final rule in a parallel fashion. As described in section IV.B of this guidance, an FSVP importer whose foreign supplier is subject to new FSMA requirements will not have to comply with the FSVP regulation until after its supplier is required to comply with its new requirements.

(Comment 106) Some comments assert that assigning responsibility for ensuring food safety to importers could result in events that might breach WTO agreements, such as importer-specific supplier verification lists, different importers imposing different verification criteria on the same foreign supplier, and additional and more frequent onsite auditing. Some comments maintain that oversight of foreign suppliers is best left to the private sector, and imposing requirements on importers might be inconsistent with WTO obligations.

(Response 106) We do not agree. Supplier verification of imported food is needed to ensure a consistent level of oversight and protection for domestic and imported food. Requiring importers to share responsibility for ensuring that imported food is safe is consistent with industry practice, principles of Codex, and the approaches of export oversight agencies of many U.S. trading partners.

As a member of the WTO trade agreements, the United States has assumed international obligations including those set out in the SPS Agreement. The SPS Agreement requires that measures adopted by WTO members to protect human or animal health be risk-based and that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

Codex was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts

such as codes of practice, and is recognized under the SPS Agreement as the international standards organization for food safety. In describing the general characteristics of food import control systems, the Guidelines for Food Import Control Systems (CAC/GL 47–2003) (Food Import Guidelines) issued by the Codex Committee on Food Import and Export Inspection and Certification Systems (Ref. 6) note the importance of clearly defined legislation on import control systems and recognize the value of importer verification systems. The Food Import Guidelines recognize the need for importing countries to perform inspections and audits where appropriate in exporting countries, and also acknowledge the utility of additional activities in ensuring that imported foods are safe. The Guidelines recommend that standards should be based on risk and, as far as possible, applied equally to imported and domestic food.

The FSVP regulation contains requirements to ensure that imported foods are produced in compliance with processes and procedures that provide the same level of public health protection as those required under the preventive controls and produce safety regulations, and in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. These underlying preventive controls regulations are based on and conform to scientific evidence and international food safety standards, including the HACCP Annex to the Codex General Principles of Food Hygiene (Annex to CAC/RCP 1–1969 (Rev. 4–2003)) (HACCP Annex) (Ref. 7). In developing these regulations, we also considered the recommendations of the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53–2003) (the Codex Code) (Ref. 8). Similarly, components of the FSVP regulation, including the hazard analysis requirements, are consistent with principles in the HACCP Annex that require private sector food producers to play a role in implementing HACCP by conducting hazard identification, evaluation, and subsequent control operations. In addition, certain FSVP requirements correlate with Codex codes and principles on food safety relating to the basic definition of food safety standards and to the Codex standards for labeling of allergens in prepackaged foods (Refs. 7, 9).

Many countries have adopted similar food safety regulations mandating that certain principles and conditions be applied to food manufacturing and food

importation. These include mandatory HACCP programs for seafood and other foods.

In addition to aligning with Codex standards and guidance, the FSVP regulation incorporates a risk-based approach to food safety that allows importers the flexibility to tailor the supplier verification activities they conduct so that they provide adequate assurance that hazards in the food they import have been significantly minimized or prevented. The regulations are also designed to require verification that imported food meets the same standards that apply to domestic food (including the preventive controls and produce safety regulations) and align with the supplier verification provisions that apply to food from domestic suppliers under the preventive controls regulations.

Regarding the comments' assertion that the FSVP regulation will result in more onsite auditing of foreign suppliers, we note that the FSVP regulation does not require importers to conduct onsite audits of foreign suppliers. Instead, applying risk-based principles, importers are required to determine appropriate supplier verification activities based on the risks associated with the food being imported and the capabilities of the foreign supplier of the food. Because the FSVP requirements are flexible and not prescriptive, we do not agree that the FSVP regulations will significantly increase costs or impede trade.

With respect to the possibility that different importers might subject the same foreign supplier to different verification activities, we believe it is unlikely that different importers would identify significantly different hazards requiring control for the same food from the same foreign supplier. We do not expect that to happen because all importers likely will be considering similar information on hazards associated with particular foods that is available from food producers, consultants, trade associations, industry-related publications, and regulatory agencies. Therefore, we anticipate that different importers are likely to conduct (or obtain documentation of) similar supplier verification activities for particular types of food. In addition, the final rule allows importers to rely on verification activities conducted by other importers for the same food imported from the same foreign supplier. This flexibility reduces the potential extent to which foreign suppliers might be subject to different verification activities by different importers. We also note that, to the extent private food safety audit

scheme owners and benchmarking organizations continue to develop tools to verify that foreign suppliers produce food consistent with FDA food safety standards, importers could rely on such audit schemes to help meet FSVP requirements. If this were to occur, multiple importers of the same food from the same foreign supplier might choose to rely on the same supplier audit conducted in accordance with such a scheme.

(Comment 107) One comment maintains that, to satisfy WTO obligations, we need to ensure that domestic and foreign supplier verification requirements are aligned, and therefore need to require that domestic food facilities conduct supplier verification with respect to RACs (if RACs are subject to the FSVP regulation as proposed).

(Response 107) The regulations on preventive controls for human and animal foods include supply-chain program requirements that are closely aligned with the FSVP supplier verification requirements, which we believe, for the reasons previously stated, are consistent with our WTO obligations. Raw materials and other ingredients such as RACs that are manufactured/processed at domestic U.S. receiving facilities (as well as at foreign receiving facilities) are within the scope of the supply-chain program requirements in the FSVP and preventive controls regulations.

2. Low-Acid Canned Foods

In accordance with section 805(e)(3) of the FD&C Act, we proposed that, with respect to those microbiological hazards that are controlled by the LACF regulation set forth in part 113 (21 CFR part 113), the importer of an LACF would be required to verify and document that the food was produced in accordance with part 113. For all matters not controlled by part 113 (e.g., hazards other than microbiological hazards addressed under part 113), the importer would be required to have an FSVP as specified in proposed § 1.502(a). In the preamble to the proposed rule, we noted that an LACF importer would not know if it was importing the food from a foreign supplier whose facility was in compliance with part 113 unless it conducted some appropriate form of verification, such as auditing. We therefore suggested that, in addition to providing assurance that non-microbiological hazards in LACF were adequately controlled, following the FSVP provisions would also be an appropriate verification approach for all

hazards, including microbiological hazards.

On our own initiative, we are adopting corresponding FSVP requirements for the importation of raw materials and other ingredients of LACF by LACF manufacturers, for reasons similar to those we stated (in section III.B.1 of this document) for exempting from the FSVP regulation importers of juice or seafood raw materials or other ingredients that are manufacturers or processors of juice or seafood products. As we stated with respect to section 805(e)(1) and (e)(2) of the FD&C Act regarding juice and seafood, we conclude that in enacting section 805(e)(3), Congress intended to exclude from the FSVP provisions food covered by and in compliance with the LACF regulation in part 113 (with respect to microbiological hazards addressed under those regulations), likely reflecting a conclusion that the LACF regulation makes supplier verification under FSVP unnecessary for microbiological hazards because importers who are in compliance with the LACF regulation will be addressing the microbiological hazards in such food. We therefore conclude that a more reasonable interpretation of section 805(e)(3) than what we originally proposed to adopt is that Congress intended to exempt from the FSVP requirements the activities of a facility that are subject to the LACF regulation in part 113 with respect to microbiological hazards.

Based on this interpretation, we are applying section 805(e)(3) not only to the importation of LACF produced by foreign suppliers subject to and in compliance with the LACF regulation, but also to the importation of raw materials and other ingredients by U.S. facilities for use in manufacturing or processing LACF. Therefore, § 1.502(b)(2) of the final rule states that with respect to microbiological hazards that are controlled by part 113, an importer is not required to comply with the FSVP requirements for raw materials or other ingredients that it imports for use in the manufacturing or processing of LACF provided that the importer is in compliance with part 113 with respect to the LACF that it manufactures or processes from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, the importer must have an FSVP for the raw materials and other ingredients that it uses in the manufacture or processing of LACF.

(Comment 108) One comment requests that we advise importers of

LACF to conduct finished product testing for typical pathogens and spoilage organisms because finished canned goods can be contaminated and might be used in producing other products.

(Response 108) We do not agree that periodic sampling and testing of an imported LACF would be an appropriate means of verifying control of all hazards in such food. The primary hazard of concern for LACF is *C. botulinum* toxin, and strict controls as required under part 113 are needed to address this hazard. Sampling and testing cannot provide statistically valid assurance that potential pathogens in LACF products are adequately controlled.

Section 805(e) of the FD&C Act states that the section does not apply to LACF facilities that are required to comply, and are in compliance, with the FDA standards and regulations on LACF, but only with respect to the microbiological hazards regulated under part 113. In accordance with section 805(e), § 1.502(b) of the final rule provides that with respect to those microbiological hazards that are controlled under part 113, an importer of an LACF must verify and document that the food was produced in accordance with part 113. An importer of an LACF would not know if it was importing the food from a foreign supplier whose facility was in compliance with part 113 (and thus eligible for the exemption from section 805 with respect to microbiological hazards) unless it conducted some appropriate form of verification. Although the proposed rule suggested that an audit would be an appropriate form of verification, we conclude that an audit might not be necessary. Although the importer may still choose to do an audit, an appropriate verification activity might also be reviewing the scheduled processes and processing and production records required under part 113 that relate to the specific LACF being offered for import, as well as verifying that cans are not swollen or leaking. With respect to hazards other than microbiological hazards controlled under part 113 that an importer might identify, an importer of an LACF must have an FSVP as specified in § 1.502(a). For such an FSVP, sampling and testing might be appropriate verification activities in addition to an audit (or an audit might be used to verify control of non-microbial as well as microbial hazards).

(Comment 109) One comment, noting that proposed § 1.502(b) does not address acidified foods, states that if we intentionally omitted acidified foods from § 1.502(b), we should provide a

rationale for treating acidified food differently than LACF.

(Response 109) The provisions regarding LACF in § 1.502(b) reflect the statutory exemption (in section 805(e) of the FD&C Act) from the FSVP requirements for microbiological hazards in LACF. There is no analogous statutory exemption for acidified foods.

An importer of acidified foods can consider the processor's current scheduled processes, established in accordance with the regulation on acidified foods in part 114 (21 CFR part 114), when conducting the hazard analysis required in § 1.504 and the evaluation required in § 1.505. An importer of acidified foods could, through its hazard analysis, determine that the microbiological hazards associated with the imported food are addressed by controls in the supplier's scheduled processes established under part 114. In turn, an importer of acidified foods can consider the processor's current procedures when determining what supplier verification activities are appropriate. For example, an importer might determine that reviewing its foreign supplier's validated scheduled process and records and reports is an appropriate supplier verification activity. As another example, it may be appropriate for an importer to review its foreign supplier's procedures for complying with the requirements of part 114, including frequent testing and recording of results, to verify that the finished equilibrium pH values for an acidified food are not higher than 4.6 (see § 114.80(a)(2)) and to confirm the response to any deviations from scheduled processes (see § 114.89).

3. Importers in Compliance With Supply-Chain Program Provisions in the Preventive Controls Regulations

In the Supplemental Notice, we proposed to specify (in § 1.502(c)) that if an importer was required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer was in compliance with the supplier program requirements in those regulations, the importer would be deemed in compliance with the FSVP regulation (except for the requirement to identify the importer at entry of the food into the United States). We proposed this change in response to several comments and consistent with our intent (as stated in the preambles of the proposed rules on FSVP and preventive controls for human food) to avoid imposing redundant supplier verification requirements on importers that also are

food facilities that would be required to comply with any supplier verification provisions in the preventive controls regulations.

(Comment 110) Although the comments agree that there should not be redundant supplier verification requirements under the FSVP and preventive controls regulations, the comments differ in their views on how the regulations should achieve this. Some comments state that, rather than deem importers in compliance with the preventive controls supplier program provisions to be in compliance with the FSVP requirements, the regulations should deem receiving facilities that are in compliance with the FSVP requirements to be in compliance with the preventive controls supplier program provisions. One comment suggests that the preventive controls supplier program requirements be applied only to verification of domestic suppliers unless the imported food was exempt from the FSVP requirements. However, some comments assert that entities subject to the preventive controls regulations are in a better position to determine the safety of imported ingredients in the context of the finished food product. Some comments request that the FSVP and preventive controls final rules allow for recognition of supplier verification performed under either rule, even if the verification was performed by a third party. Some comments request that the preventive controls regulations include a provision exempting from the supplier program requirements any food that had already been subject to verification under the FSVP regulation, even if the verification was conducted by a third party. Some comments suggest that a facility receiving such food for processing should be required to ensure that the importer met its FSVP obligations; one comment suggests that such a facility be required to annually obtain written assurance of FSVP compliance from the importer.

(Response 110) We conclude that it is appropriate, under § 1.502(c)(3) of the final rule, to deem to be in compliance with most of the FSVP requirements those importers that are receiving facilities that have established and implemented a risk-based supply-chain program in compliance with the regulations on preventive controls for human food or animal food (subpart G of part 117 and subpart E of part 507, respectively). Given that we have aligned the supply-chain program provisions of the preventive controls regulations and the FSVP requirements to the extent appropriate and feasible, the preventive controls regulations

allow importers that are receiving facilities to take advantage of that fact so they do not have to conduct duplicative verification activities. Under the preventive controls regulations, receiving facilities that are importers in compliance with the FSVP requirements and have documentation of activities conducted under § 1.506(e) need not conduct verification activities for that raw material or other ingredient (see §§ 117.405(a)(2) and 507.105(a)(2)). The issue of what, if any, additional effect the preventive controls regulations should give to an importer's FSVP is beyond the scope of this rulemaking. However, we note that importers that are receiving facilities might obtain raw materials and other ingredients from both domestic and foreign suppliers. Given that receiving facilities should already be complying with other provisions in the preventive controls regulations, we believe that the preventive controls regulations avoid unnecessary duplication while ensuring that raw materials and other ingredients from both domestic and foreign suppliers are subject to appropriate verification activities.

In addition, we have broadened § 1.502(c) to include not just those importers that have implemented a supply-chain program in accordance with the preventive controls regulations, but also two other circumstances in which the importer is also a food facility. These circumstances are:

- When the importer/facility is not required to have a supply-chain program under the preventive controls regulations because it implements preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34; and

- When the importer/facility is not required to implement a preventive control under § 117.136 or § 507.36 (e.g., because the food is a type of food that cannot be consumed without application of an appropriate control, or because the facility's customer or a subsequent entity in the distribution chain is controlling the hazards and certain other conditions are met).

In the Supplemental Notice, we proposed to specify, in § 1.504(g) of the proposed regulations, that if the preventive controls an importer and/or its customer implemented in accordance with the preventive controls regulations were adequate to significantly minimize or prevent all significant hazards in an imported food, the importer would not be required to determine appropriate foreign supplier verification and related activities or to conduct any such activities. We included § 1.504(g) in the revised proposed rule because proposed

§ 1.502(c) did not encompass certain circumstances in which a receiving facility is not required to have a supply-chain program for a raw material or other ingredient.

Rather than separately specify, in § 1.504(g), the requirements for importers that control all hazards requiring a control, we have broadened the scope of § 1.502(c) to incorporate these circumstances. Thus, § 1.502(c)(1) specifies that if an importer is a receiving facility that implements preventive controls for the hazards in a food in accordance with § 117.135 or § 507.34, then the importer is deemed to be in compliance with the FSVP regulation, except for the requirement to identify the importer at entry in § 1.509.

In addition, § 1.502(c)(2) of the final rule deems in compliance with the FSVP regulation (except the requirements of § 1.509) importers that are food facilities who are not required to implement a preventive control for a hazard in a food they import in accordance with § 117.136 or § 507.35 (in the regulations on preventive controls for human food and animal food, respectively). Under those provisions, a food manufacturer/processor is not required to implement a preventive control when it identifies a hazard requiring a preventive control and one of the following applies:

- The manufacturer/processor determines and documents that the type of food (e.g., a RAC such coffee beans) could not be consumed without application of an appropriate control (see §§ 117.136(a)(1) and 507.36(a)(1));

- The manufacturer/processor relies on its customer who is subject to the preventive controls requirements to ensure that the identified hazard will be significantly minimized or prevented, and the manufacturer/processor meets certain disclosure (i.e., that the food has not been processed to control identified hazards) and written assurance requirements (see §§ 117.136(a)(2) and 507.36(a)(2));

- The manufacturer/processor relies on its customer who is not subject to the preventive controls requirements to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements, and the manufacturer/processor meets certain disclosure and written assurance requirements (see §§ 117.136(a)(3) and 507.36(a)(3));

- The manufacturer/processor relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the

manufacturer/processor meets certain disclosure and written assurance requirements (see §§ 117.136(a)(4) and 507.36(a)(4)); or

- The manufacturer/processor has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food it distributes (see §§ 117.136(a)(5) and 507.36(a)(5)).

We conclude that it is appropriate to exempt from the FSVP requirements importers that are facilities importing a food and acting in accordance with § 117.136 or § 507.36 with respect to that food, because compliance with those requirements will provide adequate assurance of the safety of this food. The FSVP regulation contains similar provisions regarding foods that cannot be consumed without application of a control and foods whose hazards will be controlled by the importer's customer or a subsequent entity in the distribution chain. These provisions, which appear in § 1.507 of the final rule, are discussed in section III.H of this document. Because these FSVP provisions so closely align with the preventive controls regulations, we see no need for importers that are receiving facilities to have to comply with both §§ 1.507 and 117.136 or § 507.36, as applicable. Although the preventive controls regulations do not include a provision comparable to § 1.502(c)(2) that deems receiving facilities that are importers to be in compliance with § 117.136 or § 507.36 if they are in compliance with § 1.507 in the FSVP regulation, we do not believe that such receiving facilities need to comply with these provisions in both the FSVP and preventive controls regulations. Therefore, we intend to consider receiving facilities that are importers to be in compliance with § 117.136 or § 507.36, as applicable, if they are in compliance with § 1.507.

(Comment 111) One comment asks that we state how we will certify that an importer/facility is in compliance with the preventive controls supplier program requirements.

(Response 111) Although we will inspect food facilities for compliance with the preventive controls regulations, including the supply-chain program provisions, we will not "certify" or otherwise designate a facility as being in compliance with the supply-chain program requirements. Rather, an importer that expects to be deemed in compliance with most of the FSVP requirements under § 1.502(c)(3) will be responsible for ensuring that it is in compliance with the supply-chain program provisions of the preventive

controls regulations and will need to be able to demonstrate its compliance during an inspection.

(Comment 112) Some comments suggest that § 1.502(c) should specify § 507.37 rather than § 507.43 to refer to the supplier program provisions in the regulations on preventive controls for animal food.

(Response 112) Because the supply-chain program provisions in the regulations on preventive controls for animal food are in subpart E of part 507, § 1.502(c)(3) of the FSVP final rule cites that subpart.

4. Importer Whose Customer Is in Compliance With the Preventive Controls Supply-Chain Program Requirements

We proposed, in § 1.502(d), that if an importer's customer was required to establish and implement a risk-based supply-chain program under the preventive controls regulations (for either human or animal food), and the importer annually obtained written assurance that its customer was in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulation (except for the requirement to identify the importer at entry of the food into the United States and the requirement to maintain records of the written assurances).

We conclude that it is appropriate to address verification requirements that apply when an importer's customer controls the hazards in an imported food in the same provisions as those that apply to control of hazards by entities after the importer's customer in the U.S. distribution chain. As previously stated, these provisions are set forth in § 1.507 of the final rule. In section III.H.2 of this document we discuss § 1.507 and respond to the comments we received regarding proposed § 1.502(d) concerning importers whose customers are in compliance with the supply-chain program provisions of the preventive controls regulations.

D. Personnel Developing and Performing FSVP Activities (§ 1.503)

We proposed to require, in § 1.503, that importers use a qualified individual to conduct most FSVP activities, and provided several exceptions to this proposed requirement. We then updated this proposal in the Supplemental Notice with a revised reference to one of the exceptions and deleted one of the exceptions because it was no longer applicable under the changes to the proposed rule provided by the Supplemental Notice. As the proposal

was updated in the Supplemental Notice, the exceptions to the requirement to use a qualified individual were the activities required under proposed §§ 1.506(a) (procedures to ensure the importation of food from approved suppliers), 1.509 (identification of the importer at entry), 1.510 (recordkeeping), 1.511(c)(2) (procedures to ensure the importation of dietary supplements from approved suppliers), and 1.512(b)(5) (recordkeeping by very small importers).

In addition, as stated in sections III.A.18 and III.A.19 of this document, we have concluded that it is appropriate to specify the general qualifications that qualified individuals and qualified auditors must have in provisions outside of the definitions of those terms—specifically, in § 1.503 of the final rule. Under § 1.503(a), a qualified individual must have education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity. Under § 1.503(b), a qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A) and must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

In the final rule, for several reasons we are eliminating the proposed exemption of the performance of certain FSVP activities from the requirement to use a qualified individual, as well as the proposed exemption for certain importers from having to use a qualified individual to meet FSVP requirements. First, requiring use of a qualified individual to meet all FSVP requirements is consistent with the goal of aligning the FSVP regulation with the preventive controls regulations. Those preventive controls regulations (§§ 117.4(a)(2) and 507.4(a)(2)) require that every person engaged in the manufacturing, processing, packing, or holding of food subject to the preventive controls regulations, including the supply-chain program provisions, must be a qualified individual. This requirement applies to all tasks related to these activities, including such tasks as ensuring the receipt of food from approved suppliers and recordkeeping.

Second, we note that the FSVP final rule makes the definition and requirements for qualified individuals more flexible and less burdensome than as originally proposed, thus making the requirement applicable to a wider variety of tasks. Instead of a qualified

individual having to possess necessary education, training, *and* experience (as we initially proposed), the final rule states that a qualified individual must have education, training, or experience—or a combination of these elements—necessary to perform an assigned FSVP activity. This allows importers more flexibility in meeting the requirement to have qualified individuals perform required tasks. This also means that the final rule does not require any particular education, training, or experience beyond what is needed to successfully perform the FSVP task to which the qualified individual is assigned, whether the task is a core component of the FSVP requirements (*e.g.*, hazard analysis, supplier verification activities) or something requiring expertise not necessarily directly related to food safety, such as recordkeeping or ensuring that the importer is identified as the FSVP importer for the food at entry. In light of the revised definition of a qualified individual, we conclude that a person who meets the definition should always perform any activity required under the FSVP regulation. Any other individual might not necessarily have the ability to effectively perform the activity.

With respect to the proposed exemption from the use of a qualified individual requirement for the development of procedures to ensure the use of approved foreign suppliers, we note that in the Supplemental Notice we had substituted the requirement to establish and follow such procedures for a proposed requirement (set forth in the proposed rule) to maintain a written list of foreign suppliers. That change effectively transformed this requirement from an administrative one to a substantive one. Requiring use of a qualified individual for developing and implementing procedures to ensure the use of approved suppliers is consistent with the principle stated in the preamble to the proposed rule that education and training are important to ensure the development of FSVPs. Similarly, although recordkeeping and ensuring that the importer is properly identified as the importer of the food at entry may require comparably less food safety training and experience, we conclude that persons responsible for meeting these FSVP requirements should have the education, training, and/or experience needed to effectively perform these tasks.

In the proposed rule, we also proposed to exempt from the requirement to use a qualified individual the following types of importers:

- Importers of certain dietary supplements and dietary supplement components who are in compliance with proposed § 1.511(a) or (b); and
- Importers of food from foreign suppliers in countries whose food safety systems FDA has recognized as comparable or determined to be equivalent to that of the United States in accordance with proposed § 1.513.

Although the modified FSVP requirements applicable to these importers under §§ 1.511(a) and (b) and 1.513 of the final rule are limited (in the case of § 1.511(a) and (b), to recordkeeping and/or identification of the importer at entry), we believe that it is nevertheless appropriate that persons with necessary education, training, and/or experience perform the tasks required under these provisions.

(Comment 113) One comment on proposed § 1.503 states that importers should not be required to have a qualified individual conduct the review of a foreign supplier's food safety records.

(Response 113) We do not agree. We conclude that to adequately review and understand a foreign supplier's food safety records, a person must have adequate education, training, and/or experience regarding the food safety operations addressed in the records, including, where applicable, training in the principles of hazard analysis and risk-based preventive controls and measures to ensure produce safety. Review of food safety records requires an understanding of the applicable food safety principles.

(Comment 114) One comment states that a foreign government employee who is designated as a qualified individual by the foreign government should have the authority to conduct any kind of verification activities under the FSVP regulations without having to be accredited as a third-party auditor.

(Response 114) The importer of a food, not a foreign government or any other entity, is responsible for determining whether a person who is to conduct FSVP activities has the education, training, and/or experience necessary to conduct those activities in accordance § 1.503(a) of the final rule. The FSVP regulations do not require that a qualified auditor or qualified individual be accredited under any accreditation scheme or system, including FDA's regulations on the accreditation of third-party certification bodies implementing section 808 of the FD&C Act, as long as the person otherwise satisfies the requirements to be a qualified auditor or individual under § 1.503.

E. Hazard Analysis (§ 1.504)

In the Supplemental Notice, we made several changes to the proposed requirements concerning importers' analysis of the hazards in the foods they import in response to several comments and to align the FSVP requirements with the proposed supply-chain program provisions in the preventive controls regulations. These revisions primarily involved changing the requirement to analyze hazards that are reasonably likely to occur to a requirement to analyze known or reasonably foreseeable hazards (to determine if these hazards are significant), as well as the addition of a proposed requirement that importers consider hazards intentionally introduced for purposes of economic gain.

As discussed in the following paragraphs, we are making several additional changes to the hazard analysis provisions in response to comments. We also are adding flexibility by broadening the proposed provision allowing an importer to rely on a hazard analysis conducted by its foreign supplier (rather than conducting an entirely separate evaluation of hazards using information that the importer itself has obtained). As described further in the following paragraphs, the final rule permits reliance on a hazard analysis conducted by additional entities in importers' supply chains.

1. General

(Comment 115) Some comments suggest that the hazard analysis provisions in the FSVP regulations should cross-reference the hazard analysis provisions in the regulations on preventive controls for human food.

(Response 115) We conclude that this is not necessary or appropriate. Although the hazard analysis provisions in the two regulations are very similar, there are some differences in the requirements that primarily reflect the difference in scope between the FSVP regulation and the preventive control for human food regulation. The former generally apply to importers who must analyze the hazards in the foods produced by their foreign suppliers, while the latter primarily apply to food facilities that must determine the hazards for the food that they themselves manufacture, process, pack, or hold.

(Comment 116) Some comments request that we not apply the FSVP regulation to any food until we have conducted a risk assessment and made a risk management determination for

each food according to internationally agreed standards and after public comment. The comments assert that requiring importers to identify hazards and conduct verification will cause small businesses to withdraw from the market or choose too carefully which products to import and from which geographic regions, stifling international trade. The comments maintain that this will happen not because there are hazards in particular foods but because the importer or foreign supplier cannot scientifically identify it or because the verification requirements will be unnecessarily stringent or costly for most foods. However, the comments assert that most foods do not present a food safety risk and that there is no scientific proof that specific foods covered by FSMA are unsafe or need to be made safer.

The comments also assert that we must conduct the risk assessments to meet U.S. obligations under the SPS Agreement. The comments object to what they regard as FDA's shifting of its obligation to conduct risk assessments to the private sector by requiring importers to conduct hazard analyses.

The comments also request that the FSVP regulations be applied only to designated high-risk foods for at least 5 years after we have designated such foods.

(Response 116) We do not agree with the suggested approach to the determination of risks in imported foods. There are known hazards in many types of food, and many types of domestic and foreign foods have been identified as the source of foodborne illness outbreaks in the United States. As stated previously, we conclude that it is appropriate to require importers to analyze the hazards in the foods they import and conduct foreign supplier verification activities that take into account the risks posed by these hazards and provide assurances that suppliers are following procedures to ensure food safety consistent with U.S. standards, including the preventive controls and produce safety regulations. Therefore, we do not believe that the comments provide a justification for requiring that we conduct individual risk assessments of specific foods before we require importers to conduct hazard analyses and supplier verification activities. However, we note that to the extent that the comments express particular concern about the ability of smaller entities to comply with the FSVP regulations, § 1.512 of the final rule (discussed in section III.M of this document) specifies modified requirements for very small importers

and importers of food from certain small foreign suppliers.

We also deny the request that the FSVP regulation be applied only to foods that we have designated as high risk for at least 5 years after we make such designations. Under the regulation, importers will be responsible for determining the hazards in the food they import, evaluating the risk posed by that food and the characteristics of the foreign supplier, and determining appropriate foreign supplier verification activities based on that evaluation. Thus, the regulation allows importers the flexibility to tailor the supplier verification they conduct to the nature of the risks posed by the foods they import. In addition, as discussed in section IV.B of this document, we are providing considerable time for importers to adjust their procedures and practices (if necessary) to come into compliance with the regulation. Consequently, we conclude that it is unnecessary and not in the interest of public health to delay implementation of the FSVP regulation until we conduct risk assessments and designate high-risk foods, or to limit the scope of the regulation to high-risk foods for 5 years.

2. Requirement To Conduct a Hazard Analysis

We proposed to require that an importer identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each food it imports to determine whether there are any significant hazards (proposed § 1.504(a)). We further proposed to define a “significant hazard” as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records), as appropriate to the food, the facility, and the control.

We also proposed that the hazard analysis be written (proposed § 1.504(a)).

As discussed in section III.A.11 of this document, the final rule uses the term “hazard requiring a control” instead of “significant hazard.” Following is a discussion of comments on other aspects of the proposed hazard analysis requirements in § 1.504(a).

(Comment 117) One comment requests that we replace “illness data” with “FDA foodborne illness data” to

ensure that a review of illness data is based on a well-known and relatively easy-to-access source of information.

(Response 117) We decline to make the change because illness data from any reliable source, not just FDA, would be relevant in evaluating known or reasonably foreseeable hazards. For example, importers might consider data on foodborne illnesses published by the Centers for Disease Control in determining whether hazards that cause such illnesses are hazards that require a control.

(Comment 118) Some comments ask that we change proposed § 1.504(a) to refer to “experience, illness data, scientific reports, or other information” instead of “and other information” because they believe that there might not be any such data or reports regarding animal food.

(Response 118) We decline this request. We agree that in some cases some of the specified types of information might not be available. For example, there would be no illness data for a food that has never been associated with a foodborne illness. However, changing the provision as requested would allow importers to choose which information to evaluate, irrespective of whether the information is available. We conclude that importers must consider each of these types of information—to the extent that each type exists for a food—in conducting a hazard analysis.

(Comment 119) One comment suggests that importers should be required to evaluate known or reasonably foreseeable hazards for each “type of food” rather than each “food.” The comment maintains that it would be unnecessarily burdensome to require a separate hazard analysis for each individual food imported; instead, the comment requests that importers be permitted to group foods appropriately by type for purposes of hazard analysis.

(Response 119) We agree and have changed § 1.504(a) accordingly. We conclude that it might be appropriate to analyze the hazards for a particular type of food, rather than an individual food product, if the resulting determination of hazards requiring a control will apply for all foods of this type. For example, it might be appropriate to conduct a hazard analysis for multiple product sizes of a particular food, or to conduct one hazard analysis applicable to two or more related foods that are manufactured, processed, grown, or harvested under very similar conditions if all such food involves the same hazards. However, if foods that might be said to be of the same “type” have different hazards that require a control,

it generally would not be appropriate to use the same hazard analysis for each of those foods.

3. Hazard Identification

a. General Types of Hazards

We proposed to require, in § 1.504(b)(1), that an importer’s analysis of the known or reasonably foreseeable hazards in each food include the following types of hazards:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
- Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
- Physical hazards.

(Comment 120) Some comments ask that we delete “decomposition” from the listing of chemical hazards. The comments assert that many products used in the animal food industry have begun decomposition but are processed in a controlled system to halt decomposition before harmful toxins are formed. The comments maintain that the inclusion of “natural toxins” among chemical hazards addresses the Agency’s concerns about hazards associated with uncontrolled decomposition or spoiled foods resulting from chemical changes induced by the microbial breakdown that releases potentially hazardous toxins, and that including “decomposition” would be redundant and unnecessary because some levels of decomposition do not pose an animal food safety risk.

(Response 120) We decline to make this change. Decomposition of animal food consists of microbial breakdown of normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, tastes, textures, colors, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, potentially resulting in illness or death. Thus, decomposition can be a hazard requiring a control in animal food.

(Comment 121) Some comments ask that we add the term “nutrient deficiencies or toxicities” to the list of chemical hazards because animal safety is related to established nutrient deficiencies and toxicities.

(Response 121) We agree that nutrient deficiencies or toxicities may be hazards in animal food (for reasons discussed in the preventive controls for animal food rulemaking) and have revised the list of chemical hazards accordingly.

b. Reasons for Presence of a Hazard

We proposed to require, in § 1.504(b)(2), that an importer's analysis of hazards include hazards that may be present in a food for any of the following reasons:

- The hazard occurs naturally;
- The hazard may be unintentionally introduced; or
- The hazard may be intentionally introduced for purposes of economic gain.

(Comment 122) Several comments object to the proposed requirement to consider hazards that might be intentionally introduced for purposes of economic gain. Some comments assert that because economically motivated adulteration (EMA) is nearly always an issue of product quality and integrity rather than food safety, requiring importers to consider EMA hazards would provide little benefit to food safety. Some comments suggest that it would not be appropriate to require consideration of EMA hazards because such hazards often are addressed by a corporate parent company rather than at the facility level. Some comments maintain that addressing EMA requires a completely different approach than that used for unintentional adulteration and that it would be better to address EMA in an importer's food defense plan. Some comments therefore request that we consider proposing regulations on EMA in a future rulemaking rather than in the FSVP regulation.

(Response 122) We decline to delete this requirement. EMA can and has resulted in safety concerns, including, as in the case of melamine in infant formula and pet food, the deaths of humans and animals. The fact that a plan for addressing EMA might be developed at the corporate level is irrelevant to whether an importer can determine whether EMA in a particular food is known or reasonably foreseeable. Further, we disagree that economically motivated adulteration requires a completely different approach than unintentional adulteration. Although we acknowledge that many firms currently might not include EMA in their analyses of safety hazards in food, as we stated in the Supplemental Notice, some of the measures that industry uses in supplier verification programs, such as audits and sample testing, are used to guard against EMA. Moreover, we believe that the burden posed by having to analyze potential EMA hazards is limited because, as with hazards that occur naturally or that may be unintentionally introduced, we define hazards to include only those agents that have the potential to cause illness or injury. In

the EMA context, we anticipate that importers will identify such hazards in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration of a food. Therefore, we conclude it is appropriate that importers consider EMA hazards under the FSVP regulation.

(Comment 123) Some comments assert that it would be more appropriate to address EMA hazards separately from the hazard analysis because they are not considered as part of the hazard analysis when designing a food safety plan; rather, the comments maintain that EMA should be considered as part of supplier verification.

(Response 123) We do not agree. Importers are required to conduct a hazard analysis under § 1.504 of the final rule precisely to understand what manner of supplier verification under § 1.506 is needed and appropriate. Therefore, importers need to evaluate EMA as part of the hazard analysis for a food so that, if EMA is determined to be a hazard requiring a control for that food, importers can conduct appropriate supplier verification activities to obtain assurance that the food has not been intentionally adulterated for economic gain.

(Comment 124) One comment asserts that looking retrospectively at instances of economic adulteration might not be effective because it would be less likely that others would engage in such activity in the future.

(Response 124) We are not aware of evidence supporting the comment's assertion. However, given that it would not be feasible or appropriate to require importers to speculate about, and guard against, any conceivable form of EMA of a food, we conclude that it is reasonable to require importers to consider, among other things, whether a food has been previously linked to EMA that might cause harm to consumers.

(Comment 125) Some comments assert that the analysis of hazards intentionally introduced for economic gain should be limited to whether there is a history of any particular EMA. Some comments request that we limit the requirement to consider hazards that might be intentionally introduced for economic gain to such hazards that are "already known" or for which there is a "historical precedent."

(Response 125) As with other hazards, importers need only consider EMA hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. We expect that EMA hazards will be identified in rare circumstances, usually in cases where

there has been a pattern of EMA in the past. The revisions suggested by the comments are unnecessary and could be interpreted to narrow the requirement that importers consider hazards that are known or reasonably foreseeable. We continue to believe that this requirement is appropriate, even for EMA, and we reiterate that we would not expect importers to consider merely hypothetical EMA scenarios for their food products. This is consistent with our position on EMA in the preventive controls regulations.

(Comment 126) One comment requests that if the requirement to consider EMA is included in the final rule, it should be limited to "food safety" hazards that might be intentionally introduced for economic gain.

(Response 126) We conclude that this change is unnecessary. Because "hazards" are defined as certain agents that are reasonably likely to cause illness or injury, the requirement to consider hazards that might be introduced for purposes of economic gain is already limited to EMA that relates to food safety. EMA that relates to the quality of food (for example) but not food safety is beyond the scope of this rulemaking.

(Comment 127) Some comments request that importers be given flexibility to determine appropriate verification activities for EMA hazards. Some comments assert that testing should not be the only suitable control or verification measure for EMA because for many facilities it would be impractical to test every imported lot of ingredients.

(Response 127) Section 1.506 of the final rule provides importers flexibility in determining appropriate supplier verification activities for all hazards—including EMA—consistent with the evaluation of the risk posed by a food and the foreign supplier's performance, among other factors, conducted in accordance with § 1.505.

(Comment 128) Some comments suggest that we publish a list of previous instances of EMA that importers should use in considering possible EMA hazards.

(Response 128) Although we agree that it would be useful to have a centralized list involving all previous instances of EMA, creating such a list would likely be unduly resource-intensive for FDA and therefore would not be consistent with the efficient enforcement of section 805 of the FD&C Act. We therefore decline this request. We note, however, that information about incidents of EMA is widely

available from public sources (Refs. 10–12).

(Comment 129) One comment asks that we require importers to identify harmless economically motivated adulterants during the review process.

(Response 129) Although we encourage importers to identify—and verify control of—all EMA, we think it is appropriate to treat EMA consistently with our general approach to hazard analysis and only require identification of those agents that have the potential to cause illness or injury. We therefore decline this request.

4. Hazard Evaluation

a. Probability and Severity of Hazards

We proposed in § 1.504(c)(1) to require that the importer's hazard analysis include an assessment of the probability that hazards will occur in the absence of controls and the severity of the illness or injury if the hazards were to occur.

(Comment 130) Some comments suggest that the provision should require importers to consider any relevant geographic, temporal, agricultural, or other factors that might affect the severity or probability of a hazard.

(Response 130) We do not believe it is appropriate to address these factors within the basic requirement to assess the probability that hazards will occur in the absence of controls and the severity of illness or injury if the hazards were to occur. Rather, we think that this requirement, stated in § 1.504(c)(1), establishes the general scope of the hazard analysis. However, we agree that such factors might be relevant in a hazard evaluation for a food, such as year-to-year fluctuation of aflatoxin levels in some RACs due to weather conditions. We therefore believe it is appropriate to include these factors in the list of factors that must be considered in the hazard evaluation required under § 1.504(c)(3) of the final rule. Thus, we have revised the list of factors that a hazard evaluation must address under § 1.504(c)(3) to include, among “other relevant factors,” the temporal (*e.g.*, weather-related) nature of some hazards, such as levels of natural toxins.

b. Environmental Pathogens in Certain Ready-To-Eat Foods

We proposed that a hazard evaluation would have to include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment that would significantly

minimize the pathogen (proposed § 1.504(c)(2)).

In the final rule, we have revised this requirement to specify that instead of receiving a treatment to significantly minimize the pathogen, the ready-to-eat food might include a control measure (such as a formulation that is lethal to the pathogen) that would significantly minimize the pathogen, because controls such as formulation can function as a “kill step,” and the provision should make clear that such controls can be used in lieu of “treatment.” This change is consistent with corresponding provisions in the preventive controls regulations.

(Comment 131) Some comments ask that we expand the requirement to evaluate environmental pathogens to include all foods, not just certain ready-to-eat foods.

(Response 131) We conclude that this change is not needed because importers will be required, under § 1.504(b)(1)(i), to consider whether there are any known or reasonably foreseeable environmental pathogens in a food. The requirement in § 1.504(c)(2) is designed to address the specific safety concern known to be associated with ready-to-eat foods that are exposed to the environment before packaging and would not undergo treatment (or otherwise include a control measure) to significantly minimize environmental pathogens.

(Comment 132) One comment requests that we limit the requirement concerning ready-to-eat foods that are exposed to the environment to such foods that are “capable of supporting pathogen growth to, or survival at, infectious levels.”

(Response 132) We decline to make this change because this suggestion prejudices the outcome of the hazard analysis for a wide variety of food products. An importer may consider factors such as whether the formulation of a food would not support the growth of a pathogen to increased numbers, or would cause pathogens to die off over time, in determining whether an environmental pathogen is a hazard requiring a control. If an importer determines that any environmental pathogens in a ready-to-eat food would not pose a hazard that requires a control, the importer would need to document the basis for that determination in its written hazard analysis.

(Comment 133) Some comments request that we delete this proposed requirement or define what is meant by a ready-to-eat food that is “exposed to the environment.”

(Response 133) We decline this request. The Appendix to the 2013 proposed rule on preventive controls for human food provides examples of food products that are, or are not, exposed to the environment (78 FR 3646 at 3819).

(Comment 134) One comment asks that the requirement specify that a qualified individual must determine that exposure of the ready-to-eat food to the environment before packaging would constitute a risk of introduction of a significant hazard. The comment asserts that a qualified individual is best suited to make a determination of whether the exposure poses an actual risk.

(Response 134) We decline to make this change. As with all activities required under the FSVP regulation, a qualified individual must conduct the hazard analysis for each food that the importer imports. Therefore, it is unnecessary to specify in § 1.504(c)(2) that a qualified individual must make the determination of whether exposure to the environment of a ready-to-eat food might result in the development of an environmental pathogen that requires a control.

c. Hazard Evaluation Factors

We proposed, under § 1.504(c)(3), that an importer's hazard evaluation of a food would have to consider the effect of the following factors on the safety of the finished food for the intended consumer:

1. The formulation of the food;
2. The condition, function, and design of the foreign supplier's establishment and equipment;
3. Raw materials and ingredients;
4. Transportation practices;
5. Harvesting, raising, manufacturing, processing, and packing procedures;
6. Packaging and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors.

(Comment 135) Some comments request that importers be required to consider the hazard evaluation factors only “as appropriate” because not all factors will be relevant in every case. The comments maintain that because an importer is not always procuring a finished food, a hazard analysis of a foreign supplier conducted for FSVP purposes has a narrower scope than a hazard analysis conducted as part of a food safety plan. The comments also assert that importers might not always know all foreseeable uses of an ingredient when initially sourcing it from a foreign supplier. Therefore, the

comments maintain that importers should have the flexibility to apply the listed factors as they deem appropriate.

(Response 135) We decline to require that importers only consider the hazard evaluation factors “as appropriate.” We understand that importers might import raw materials or other ingredients and that this might affect how some of the factors are evaluated, such as the intended use of a raw material that is used in many foods. But importers must at least consider the potential effect of each of the factors on the safety of the finished food. If a factor is not relevant with respect to a particular food, the consideration might be brief. With regard to the importation of raw materials or other ingredients, we note that the final rule includes provisions applicable to when an imported raw material or other ingredient will be processed further in the United States.

(Comment 136) Some comments express concern that the proposed requirement to consider the condition, function, and design of the foreign supplier’s establishment and equipment would necessitate an onsite audit of the foreign supplier. Some comments request that if onsite audits are required, we should provide guidance regarding such audits.

(Response 136) Importers will not be required to conduct onsite audits of potential foreign suppliers as part of the hazard analysis of a food under § 1.504(c)(3)(ii) of the final rule. We have revised this hazard evaluation factor from the “condition, function, and design of the foreign supplier’s establishment and equipment” to the “condition, function, and design of the establishment and equipment of a typical entity that manufactures/ processes, grows, harvests, or raises this type of food.” This change is designed to make clear that importers must consider how a typical establishment and equipment used to manufacture/ process, grow, harvest, or raise a food affect the hazards in the food, rather than the potential effect of a particular foreign supplier’s operations. (The requirement to consider a particular foreign supplier’s performance is located in § 1.505 of the final rule, which sets forth the requirements for evaluation for foreign supplier approval and verification.) Importers can obtain information about the nature of establishments that produce a particular food and the equipment they use by consulting a number of sources of information other than audits. These may include, for example, trade journals and other publications, academic literature, and materials obtained

directly from potential foreign suppliers.

(Comment 137) Some comments suggest that we substitute “expected use” for “intended or reasonably foreseeable use” because they believe that the former is too vague to provide clear direction to importers and the Agency regarding compliance obligations.

(Response 137) We decline this request. Although we agree that the term “expected use” has the potential to communicate both intended and reasonably foreseeable use, we are concerned that the term might not be universally interpreted that way. For example, an importer might interpret “expected use” to mean “probable use” and consequently not consider reasonably foreseeable uses as part of the hazard evaluation. Therefore, we are retaining the term “intended or reasonably foreseeable use” to make it clear that an importer must consider use that is reasonably foreseeable in addition to intended use.

5. Review of Another Entity’s Hazard Analysis

We proposed to provide that if the importer’s foreign supplier had analyzed the known or reasonably foreseeable hazards for the food to determine whether there were any significant hazards, the importer could meet its requirement to determine whether there were any significant hazards by reviewing and assessing the hazard analysis conducted by the foreign supplier (proposed § 1.504(d)).

As described in sections III.E.5, III.F.4, and III.G.4 of this document, we conclude that it is appropriate to allow importers to obtain certain information needed to meet their FSVP responsibilities from other entities, in some cases in their supply chains, for the foods they import. Therefore, we have revised § 1.504(d) to provide that if another entity (including the foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for a food to determine whether there are any hazards requiring a control, the importer may meet its requirement to determine whether there are any hazards requiring a control for the food by reviewing and assessing the hazard analysis conducted by that entity. The importer is also required to document its review and assessment of the other entity’s hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(Comment 138) Some comments assert that importers’ opportunities to rely on a hazard analysis conducted by

the foreign supplier might be limited because many suppliers would not want to share their hazard analyses.

(Response 138) We recognize that, due to commercial confidentiality concerns or other reasons, there might be circumstances in which some foreign suppliers might be reluctant to share their hazard analyses of foods that importers seek to obtain from them. However, we also believe that some foreign suppliers will desire to share their hazard analyses as a means of attracting customers for their products. In those cases, we want to provide importers with the flexibility to eliminate redundancy that would have occurred by not requiring the importer to conduct an independent hazard analysis when the foreign supplier has already conducted one.

(Comment 139) One comment suggests that we substitute “food safety hazard” for “hazard” so importers do not conclude that they must address all types of hazards.

(Response 139) We conclude that this change is unnecessary because this provision refers to another entity’s analysis of known or reasonably foreseeable hazards for a food, and a hazard is specifically defined in the FSVP regulation as an agent that is reasonably likely to cause illness or injury if not controlled, *i.e.*, it affects the safety of the food.

6. Biological Hazards in RACs That Are Fruits or Vegetables

We proposed to provide that an importer of a RAC that is a fruit or vegetable would not be required to determine whether there were any significant microbiological hazards in such food (proposed § 1.504(e) in the Supplemental Notice). We stated in the preamble to the proposed rule that the hazard analysis requirements were not needed for RACs that are fruits or vegetables and that are subject to the regulation on produce safety in part 112 because FDA has already identified the biological hazards associated with fruits and vegetables and has proposed requirements for measures intended to prevent the introduction of these hazards into produce.

(Comment 140) Several comments ask that we clarify proposed § 1.504(e). Some comments ask that we specify that imported food is subject to the produce safety regulation when applicable, which would directly address the microbial hazards in the food. The comments assert that biological hazards are very significant in some fruits and vegetables and importers should consider them. The comments ask whether the provision is intended to

apply to RACs that are fruits or vegetables that are not covered under the produce safety regulation. Some comments ask that we clarify how the FSVP and produce safety regulations work together. Some comments assert that all fresh produce must be subject to supplier verification, including evaluation of hazards, whether covered under the FSVP regulation or the produce safety regulation.

(Response 140) We proposed to “exempt” importers of RACs that are fruits or vegetables that are “covered produce” (as that term is defined in the produce safety regulation) from having to analyze the microbiological hazards in such food. Although proposed § 1.504(e) did not specifically state that the “exemption” from hazard analysis only applies when the imported RACs are “covered produce” as defined in proposed § 112.3, the preamble to the proposed rule essentially stated that the exemption only applies in these circumstances and explained the reason for the exemption. Specifically, the preamble explained that the exemption is appropriate because FDA has designed the produce safety regulation so that compliance with the regulation would ensure that microbiological hazards are adequately addressed. (Although proposed § 1.504(e) refers to “microbiological” hazards, it should have referred to “biological” hazards because “hazard” is defined in both the proposed and final rules on produce safety as any “biological agent” that is reasonably likely to cause illness or injury in the absence of its control.) Indeed, the produce safety regulation is intended to minimize the risk of serious adverse health consequences or death from the introduction of known or reasonably foreseeable biological hazards in produce, and to provide assurance that fruits and vegetables are not adulterated because of such hazards. To make this clear, we have revised § 1.504(e) to state that an importer of a RAC that is a fruit or vegetable is not required to determine whether there are any biological hazards requiring a control in such food only if the RACs are “covered produce” as defined in § 112.3 (*i.e.*, produce that is subject to the produce safety regulation in accordance with §§ 112.1 and 112.2).

In addition, we are clarifying that this partial exemption from the hazard analysis requirements is appropriate because the biological hazards in such fruits or vegetables require a control and compliance with the regulation in part 112 significantly minimizes or prevents the biological hazards. Although importers of such RACs need not conduct a hazard analysis with respect

to the biological hazards in this food, they must conduct supplier verification for the food in accordance with § 1.506 of the final rule to ensure that all hazards in the RACs, including biological hazards, are significantly minimized or prevented.

(Comment 141) Some comments request that importers of RACs that are fruits or vegetables not be required to analyze non-biological hazards in the food. The comments assert that there have been no outbreaks linked to chemical or physical hazards in imported produce, no examples of EMA in fresh produce, and no chemical contamination of fresh produce at levels reasonably likely to cause illness. The comments maintain that analyzing non-biological hazards would be very burdensome because it would likely require a visit to the location in which the food is grown, and would be complicated by the seasonal nature of fruit and vegetable production and harvesting.

(Response 141) We decline to make this change. In the preamble to the proposed rule on produce safety (78 FR 3504 at 3524), we acknowledged that there can be non-biological hazards in produce, and a reference memorandum to that proposed rule provided an overview of the chemical, physical, and radiological agents that are reasonably likely to occur in produce at the farm and are capable of causing adverse health effects (Ref. 13). Our analysis of those hazards led us to conclude that they rarely pose a risk of serious adverse health consequences or death for consumers of produce, making it unnecessary to establish a new regulatory regime for their control under section 105 of FSMA. We stated that existing programs, such as the registration of pesticides with the Environmental Protection Agency (EPA) and State and industry efforts to control the presence of pesticides and mycotoxins in produce, are sufficient to keep these hazards under control. We also noted that FDA monitors natural toxins, pesticides, industrial chemicals, other chemical contaminants, and radionuclides in food. For these reasons, we tentatively concluded that it was appropriate to limit the scope of the produce safety regulations to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (78 FR 3504 at 3524). We have reaffirmed this conclusion in the final rule on produce safety published elsewhere in this issue of the **Federal Register**.

Thus, although the produce safety regulation does not address non-biological hazards in fruits or vegetables, such hazards are sometimes associated with this food. We conclude that it is appropriate to require importers to determine whether there are any such hazards requiring a control in a fruit or vegetable they are importing because section 805 of the FD&C Act requires importers to verify that produce is produced not only in compliance with the produce safety regulation issued in accordance with section 419 of the FD&C Act but also in accordance with section 402, *i.e.*, that it is not adulterated. As we stated in the preamble to the FSVP proposed rule, we do not believe that the analysis of non-biological hazards will create a significant burden for importers of fruits and vegetables; importers will need to be aware of how a crop is produced and whether there have been non-biological hazards, such as pesticide residues, associated with it. We believe that in many cases importers can obtain the information they need to assess non-biological hazards from public sources, such as any regulations applicable to the control of such hazards, scientific literature, and information on FDA’s Web site (including guidance documents, import alerts, recall notices, warning letters, and untitled letters), as well as information from the foreign suppliers themselves. The consideration of chemical and physical hazards for RACs that are fruits and vegetables is consistent with the requirements for these products under the regulation on preventive controls for human food.

(Comment 142) One comment notes that importers of produce must include chemical and physical contamination hazards when they analyze hazards in imported produce while domestic purchasers of produce need only confirm that the produce was produced in compliance with the produce safety regulation, which requires the control of biological hazards but not chemical or physical hazards. The comment asserts that this constitutes inconsistent treatment of domestic and imported products and may invite a challenge before the WTO.

(Response 142) We do not agree. The FSVP regulation does not result in different treatment of foreign and domestic produce producers with respect to chemical and physical hazards in produce. Although the produce safety regulation does not address such hazards, the presence of such hazards may cause produce—whether produced domestically or overseas—to be adulterated under section 402 of the FD&C Act. Therefore,

both domestic and foreign producers of produce are prohibited from distributing produce contaminated with certain chemical and physical hazards, and domestic and foreign-produced produce is held to the same standard.

(Comment 143) One comment suggests that instead of “fruits or vegetables,” the provision should refer to RACs that are “fresh, intact fruits, nuts, culinary herbs, or vegetables.” The comment maintains that this change is needed because many importers will not be aware of FDA’s scheme to distinguish RACs from processed foods and may not understand that the Agency considers fruits and vegetables to include nuts and culinary herbs. The comment suggests a corresponding change to proposed § 1.504(f).

(Response 143) We decline to make this change because the produce safety regulation refers to fruits, nuts, culinary herbs, and vegetables collectively as “fruits and vegetables.” We believe it would be confusing, and could imply a different meaning, if we were to adopt a different term to capture the same set of food in the FSVP regulation.

(Comment 144) Some comments suggest that this provision state whether importers of RACs that are fruits or vegetables must analyze hazards other than biological hazards.

(Response 144) We agree and have revised § 1.504(e) to specify that importers of RACs that are fruits or vegetables must analyze hazards other than biological hazards in such food.

7. No Hazards Requiring a Control

We proposed to provide, in § 1.504(f), that if an importer evaluates the known and reasonably foreseeable hazards in a food and determines that there are no significant hazards, the importer would not be required to determine what foreign supplier verification and related activities to conduct under § 1.505 and would not be required to conduct such activities under § 1.506. We proposed that this provision would not apply if the food is a RAC that is a fruit or vegetable and that is subject to the produce safety regulation.

Consistent with the change to § 1.504(e) discussed in Response 140, we have revised § 1.504(f) to state that it does not apply if the food is a RAC that is a fruit or vegetable that is “covered produce” as defined in § 112.3 in the produce safety regulation.

(Comment 145) Some comments assert that we should declare certain foods, such as chocolates, confectionery, jams, preserves, baked goods, and non-alcoholic beverages, to be safe, as the Agency has done with several products

under the proposed rule on produce safety.

(Response 145) We are finalizing proposed § 1.504(f) because we agree that there are many foods that have no hazards requiring a control. In the preamble to the proposed rule, we suggested salt and certain food-grade chemicals as examples of food for which, depending on the circumstances, there might not be any hazards that would be reasonably likely to occur. Other examples of food for which there might be no hazards requiring a control include, but are not limited to, many crackers, most bread, dried pasta, many types of cookies, many types of candy (e.g., hard candy, fudge, maple candy, taffy, toffee), honey, molasses, sugar, syrup, soft drinks, and jams, jellies, and preserves from acid fruits.

However, because many of these foods can be made using a variety of ingredients under different processes by different manufacturers, we decline to completely exempt these foods from the FSVP regulation by declaring them to be “safe.” Rather, we conclude that it is appropriate to require importers to determine whether there are any hazards requiring a control in a particular food. However, as previously stated, importers will be able to rely on hazard analyses conducted by other entities, including analyses that find no hazards requiring a control in foods.

(Comment 146) Some comments request that importers be required to reevaluate food and foreign supplier risks annually even when an importer determines that there are no significant hazards in a food.

(Response 146) We do not agree. Under § 1.505(c) of the final rule, importers will be required to reevaluate the risk posed by a food as well as a foreign supplier’s performance when the importer becomes aware of new information about these matters (including new information about potential hazards), or at least every 3 years (see section III.F.3 of this document). We conclude that it is unnecessary to require more frequent reevaluation of the risks in a food and a foreign supplier’s performance for those foods for which an importer determines that there are no hazards requiring a control.

(Comment 147) Some comments maintain that proposed § 1.504(f) conflicts with proposed § 1.504(e), which exempts importers of RACs that are fruits or vegetables from having to analyze the biological hazards in such produce. Some comments suggest that § 1.504(f) creates an assumption that there are always significant hazards in

fruits and vegetables subject to the produce safety regulations.

(Response 147) We do not believe that § 1.504(f) conflicts with § 1.504(e). As we stated in the preamble to the proposed rule, this exception is appropriate because for such food the importer is not conducting a hazard analysis to identify the biological hazards that need to be significantly minimized or prevented. If we did not specify that § 1.504(f) did not apply to RACs that are fruits or vegetables that are covered produce, an importer of such food might mistakenly conclude that because it had determined that there were no non-biological hazards requiring a control in the food, the importer need not conduct supplier verification. However, because there are presumed to be biological hazards associated with all fruits and vegetables that are covered produce under the produce safety regulation, even if there are no non-biological hazards in a fruit or vegetable, the importer must conduct supplier verification to obtain assurances that the food was grown and harvested consistent with the produce safety regulation and is not adulterated.

8. Hazards Controlled by the Importer or Its Customer

In the Supplemental Notice, we proposed to provide (in § 1.504(g)) that if the preventive controls that the importer and/or its customer implement in accordance with the proposed preventive controls requirements in subpart C of part 117 are adequate to significantly minimize or prevent all significant hazards in a food, the importer would not be required to determine or conduct appropriate foreign supplier verification. Proposed § 1.504(g) further stated that if the importer’s customer controlled one or more such hazards, the importer would be required to annually obtain from the customer written assurance that it had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard.

As set forth in § 1.507 of the final rule and discussed in section III.H of this document, we have broadened the circumstances under which certain importers are not required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506 when the hazard requiring a control in a food will be adequately controlled by another entity and certain other requirements are met. We discuss those provisions and respond to the comments on proposed § 1.504(g) in section III.H.

F. Evaluation for Foreign Supplier Approval and Verification (§ 1.505)

In the Supplemental Notice, we replaced a proposed requirement that importers conduct a compliance status review of the food and foreign supplier with a requirement to evaluate the risks associated with a food to be imported (as determined in the hazard analysis for the food) and the potential foreign supplier of that food. Although the comments generally support this more comprehensive, “holistic” approach to selecting suppliers, several comments suggest changes regarding the proposed risk factors or the proposal to require reevaluation of risk. As discussed in the following paragraphs, we have made some relatively minor changes with respect to the proposed food and foreign supplier factors, and the final rule permits importers to rely on evaluations of these factors conducted by other entities (except for the foreign supplier), provided that the importer reviews and assesses the evaluation and documents the review and assessment. In addition, we have revised the provisions concerning reevaluation of these factors so that they take the place of the proposed requirements on FSVP reassessment.

1. Evaluation for Approving Suppliers and Determining Verification Activities

We proposed (in § 1.505(a)(1)(i) through (vi)) to require importers, in determining the appropriate supplier verification and related activities to conduct, to consider the following:

- The hazard analysis for the food conducted under proposed § 1.504, including the nature of the hazard.
- The entity that will be applying controls for the hazards, such as the foreign supplier or the foreign supplier’s raw material or ingredient supplier.
- The foreign supplier’s procedures, processes, and practices related to the safety of the food.
- Applicable FDA food safety regulations and information regarding the foreign supplier’s compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.
- The foreign supplier’s food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier’s record of correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

We also proposed to require importers to document their risk evaluations.

a. General

(Comment 148) Some comments request that we define “risk” because some people might not understand the difference between “risk” and “hazard” as the terms are frequently interchanged in common usage. One comment suggests that the regulations define “risk” as “the chance or probability that harm will occur, taking into account both the likelihood that a hazard will occur in the absence of controls to prevent it and the severity of the illness or injury that the hazard might cause.”

(Response 148) Although we conclude that it is not necessary to include a definition of risk in the codified provisions, we agree that, in the context of food safety science, a risk is different from a hazard. Although the regulations on preventive controls for human food and for animal food do not include a definition of “risk,” in those regulations we regard risk in the way that it is described in the Codex Alimentarius, which defines “risk” as “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in a food.” Therefore, a risk posed by a food is the potential effect on health related to the hazards in the food.

Because Codex defines risk in relation to inherent food hazards only, rather than also considering the effect of actions by a producer or supplier of a food, we conclude that, to apply the term “risk” consistently throughout the FSMA regulations, § 1.505 of the FSVP regulation should not refer to the “risks” posed by a foreign supplier. Therefore, we have revised § 1.505(a) so that it refers, in § 1.505(a)(1)(iii)(A) through (C) of the final rule, to factors related to the foreign supplier’s “performance” rather than the “risks” associated with the foreign supplier. These factors, which we have not substantially changed in the final rule, are the supplier’s food safety-related processes and procedures, its compliance with FDA food safety regulations, and its food safety history with the importer and others.

(Comment 149) Several comments ask that we revise § 1.505(a)(1) to state that importers must consider the food and foreign supplier factors in deciding whether to approve a supplier, rather than in selecting appropriate supplier verification activities.

(Response 149) We do not agree that the use of the factors should be limited in this way. Many comments assert that factors such as a foreign supplier’s compliance status and contractual performance history can play an important role in determining

appropriate verification activities, such as in concluding that onsite auditing on an annual basis of a highly-compliant foreign supplier is not necessary even when the supplier is providing foods with SAHCODHA hazards. Therefore, we conclude that it is appropriate that importers evaluate certain safety factors related to a food and the foreign supplier in deciding what supplier verification activities (and the frequency of such activities) are needed to provide adequate assurance of the safety of the food.

Although proposed § 1.506(a) stated that importers must have procedures to ensure that they import food only from foreign suppliers approved based on the evaluation conducted under proposed § 1.505, we have revised § 1.505(a)(1) to make clear that an importer must conduct an evaluation of the foreign supplier’s performance and the risks posed by a food to both approve foreign suppliers and determine appropriate foreign supplier verification activities.

(Comment 150) Some comments ask that we revise § 1.505(a) to give importers the flexibility to consider only those factors that they conclude are appropriate for a particular food and foreign supplier. As an example, one comment states that an importer typically would not review a supplier’s FDA compliance history to determine a verification activity but might consider it later as part of the actual verification and qualification of the supplier.

(Response 150) We decline to make this change. We conclude that generally each of the factors set forth in § 1.505(a) will be relevant to approving a foreign supplier for a particular food and to determining appropriate verification activities for the supplier. If a particular factor is of little or no relevance with respect to a particular food and foreign supplier, the importer might only need to briefly consider that factor. For example, an importer that has never obtained food from a potential foreign supplier would not have any direct “history” with that supplier; for a foreign supplier that has just begun exporting food and, therefore, would not have been inspected by FDA, there might not be any associated warning letters or other compliance-related documents. However, with respect to a foreign supplier’s compliance with FDA food safety regulations, we believe that there would be very few circumstances in which this factor would not be relevant to deciding whether to approve a foreign supplier as a source of a food and selecting appropriate supplier verification activities.

b. Hazard Analysis

On our own initiative, we have revised § 1.505(a)(1)(i) to include the hazard analysis “of the food conducted under § 1.504” because, as discussed in section III.E.5 of this document, under § 1.504(d) of the final rule an importer may review and assess a hazard analysis conducted by another entity.

(Comment 151) One comment states that, when considering the hazard analysis, the requirement to include the nature of the hazard should refer to the nature of the “hazard requiring control” because importers should evaluate supplier risks primarily as they relate to those hazards.

(Response 151) We agree that referring to the nature of the hazard requiring a control is appropriate and have revised § 1.505(a)(1)(i) accordingly.

c. Entity Applying Controls

(Comment 152) Several comments express concern regarding the proposed requirement to consider the entity that will be applying hazard controls because it refers not only to the foreign supplier but to the foreign supplier's raw material or ingredient supplier (proposed § 1.505(a)(1)(ii)). Several comments state that the importer's responsibility to conduct supplier verification should be limited to its direct supplier's compliance with applicable regulations, maintaining that this would be consistent with the Bioterrorism Act requirements, which provide for the identification of the immediate non-transporter previous source and subsequent recipient. Some comments state that requiring importers to document the actions of their suppliers' suppliers would require a major change to the produce supply chain because the identity of a broker's or aggregator's suppliers often is proprietary information.

(Response 152) We do not agree that it is inappropriate to require importers to consider which entities control hazards, regardless of whether the entity is the foreign supplier, the foreign supplier's supplier, or some other entity in the supply chain. The records requirements of the Bioterrorism Act serve a different function and are not directly applicable to the scope of evaluations conducted in accordance with the FSVP provisions of FSMA. Moreover, knowing the entity or entities that will be significantly minimizing or preventing the hazards in a food is directly relevant to the type of foreign supplier or other verification activity that the importer will need to conduct under § 1.506 or § 1.507 of the final rule. For example, when a foreign supplier's

raw material supplier is controlling a hazard in a food that the importer obtains from the foreign supplier, the importer might conclude that reviewing the foreign supplier's records of verification that its supplier produced the raw material in accordance with the preventive controls or produce safety regulations is more appropriate than auditing the foreign supplier with respect to this hazard.

In the final rule, we are revising § 1.505(a)(1)(ii) to require consideration of the entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in the importer's supply chain. (The provision refers to significant minimization or prevention of hazards in accordance with the change we are making to proposed § 1.506(c), discussed in section III.G.3 of this document.) We conclude that this clarification is needed to address circumstances such as when a foreign supplier grows produce but another entity performs certain activities, such as harvesting the produce. Entities that fit the definition of “farm,” such as harvesters, might be required to significantly minimize or prevent hazards under the produce safety regulation. To ensure that the importer will meet its obligation under section 805(a)(1) of the FD&C to perform supplier verification activities to verify that the imported food is produced in compliance with sections 418 and 419, as applicable, and not adulterated under section 402 or misbranded under section 403(w), the importer must evaluate which entities in the supply chain have either significantly minimized or prevented the hazards or verified that the hazards were significantly minimized or prevented. The results of this evaluation might be a factor in determining (1) whether to approve the foreign supplier (the grower of the produce) or (2) the type and frequency of verification activities. Consequently, we conclude that importers must consider the entities that will be significantly minimizing or preventing the hazards or verifying significant minimization or prevention of the hazards in the foods they import as part of the evaluation conducted for supplier approval and determination of supplier verification activities.

d. Foreign Supplier's Safety Procedures, Processes, and Practices

(Comment 153) Some comments express concern about how the confidentiality of a foreign supplier's food safety procedures, processes, and practices will be ensured, considering that some information regarding these matters might include data of a commercially sensitive nature. The comments suggest that we revise these provisions to respect the right of foreign companies not to disclose confidential information to third parties (the comments raise this same concern with respect to information regarding a foreign supplier's food safety performance history under proposed § 1.505(a)(1)(v)).

(Response 153) We decline to make this change. As discussed in section III.K.6 of this document, under § 1.510(f) of the final rule, records obtained by FDA in accordance with the FSVP regulation will be subject to the public disclosure provisions in part 20 (21 CFR part 20), including the protections against disclosure of trade secrets and commercial or financial information that is privileged or confidential. How foreign suppliers and importers choose to handle the issues surrounding the sharing of any confidential information with each other is between those parties. While we recognize that there might be some suppliers who are reluctant to provide information relevant to the kind of verification activities required by this rule, we believe that many suppliers will agree to such activities in order to facilitate the exportation of their products to the United States and access new customers.

e. Supplier's Compliance With Applicable FDA Food Safety Regulations

On our own initiative, we have modified the proposed requirement to consider applicable FDA food safety regulations and the foreign supplier's compliance with those regulations to address circumstances in which a potential foreign supplier is in a country whose food safety system we have officially recognized as comparable or determined to be equivalent to the U.S. system. Section 1.505(a)(1)(iii)(B) of the final rule requires importers, when applicable, to consider the relevant laws and regulations of a country whose food safety system we have officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations. This means that if an

importer's potential foreign supplier is located in a country whose food safety system we have officially recognized as comparable or determined to be equivalent (as discussed in section III.N of this document), the importer would consider, as part of its evaluation of the supplier, the supplier's compliance with the laws and regulations of that country rather than its compliance with U.S. food safety law. As discussed in section III.N, this reflects the nature of FDA recognition of the comparability of a foreign food safety authority in a systems recognition arrangement.

(Comment 154) Some comments express concern about the availability to importers of information about foreign suppliers' compliance with FDA food safety regulations. Some comments state that information about warning letters and import alerts often is not available on the FDA Web site in a timely manner and it can be difficult to navigate the Web site. Some comments assert that any requirement to consider foreign supplier compliance information should be limited to information that is available on our Web site or to information that is publicly available. One comment states that we should not require a prescriptive review of regulatory information unless we develop a system that allows importers to efficiently monitor new regulatory enforcement actions. One comment asks that we consider developing online databases that importers could use to obtain information on foreign suppliers.

(Response 154) We agree with the comments that the requirement to consider information on a foreign supplier's compliance with applicable FDA food safety regulations—as well as information on the other factors in § 1.505(a)(1)—should be limited to information that is publicly available or that the importer has otherwise been able to obtain (e.g., from a foreign supplier). We currently have searchable online databases for warning letters and import alerts; both of these databases are available to the public from our Web homepage at <http://www.fda.gov>. Other relevant compliance-related information available on FDA's Web site includes recall notices and notices of suspensions of facility registrations. We are considering ways to make this information more accessible to importers who will now be required to check the compliance history of their suppliers. To make clear that an importer must consider such publicly available information, § 1.505(a)(1)(iii)(B) of the final rule specifies that the applicable information includes whether the foreign supplier is the subject of any “other FDA

compliance action related to food safety.” We also note that, although the requirement to consider information on supplier compliance with applicable FDA food safety regulations is limited to publicly available information or information that the importer has otherwise obtained, if we became aware that an importer did not consider information that it had obtained relating to a supplier's FDA compliance, that would be a violation of the requirement.

(Comment 155) Some comments assert that this provision should be deleted because an importer's evaluation of the food and the foreign supplier should focus on information pertaining to risks identified in the imported food rather than the supplier. The comments note that if a foreign supplier were subject to an FDA warning letter or import alert for a food other than the food the importer was importing, that information would not be relevant to the importer's risk evaluation.

(Response 155) We do not agree. We conclude that evidence that a foreign supplier had received a warning letter or been placed on import alert with respect to a particular food, even a food different than the food an importer is considering obtaining from the foreign supplier, could be relevant to deciding whether to source a food from the supplier. In particular, a pattern of non-compliance, even if it did not involve the particular food that the importer sought to obtain, should affect an importer's decision on whether to approve a foreign supplier and, if so, what supplier verification activities would be appropriate with respect to this supplier.

(Comment 156) Some comments suggest that the scope of data sources reviewed be expanded to include Food Facility Registration Module (FFRM) status, Reportable Food Registry (RFR) entries, and outcomes from recent FDA CGMP inspections.

(Response 156) In accordance with section 415(a)(5) of the FD&C Act regarding disclosure of certain food facility registration information, information regarding whether a particular food facility is registered is generally not publicly available; however, as stated previously, FDA may publicize actions to suspend a facility's registration, which would be relevant information under § 1.505(a)(1)(iii)(B). In addition, importers may obtain information about a foreign facility's registration status from the foreign facility. Information from the RFR that we make available in our RFR annual reports is generally not provided on a company-specific basis. Under section

417(h) of the FD&C Act (21 U.S.C. 350f(h)), a record in the RFR is subject to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552), except that FDA registration numbers and information derived from such registrations are protected from disclosure to the extent that they would disclose the identity or location of a specific registered person in accordance with section 415(a)(5) of the FD&C Act. In addition, confidential commercial information in such records is also protected from disclosure, and in many cases the name of the original producer of the food may constitute confidential commercial information. We also generally do not proactively make available information related to FDA inspections of foreign suppliers, including Form FDA 483s and Establishment Inspection Reports (EIRs), although it is possible that an importer could obtain such information from a foreign supplier or from FDA through a FOIA request. Any confidential commercial information, trade secret information, or other protected information in Form FDA 483s and EIRs that we provide through a FOIA request would be redacted (i.e., deleted) in accordance with the disclosure exemptions set forth in the FOIA and FDA's public information provisions in part 20.

f. Foreign Supplier's Food Safety History

(Comment 157) One comment suggests that, to be consistent with the preventive controls regulations and to avoid an implied requirement to perform testing and auditing, we should revise proposed § 1.505(a)(1)(v) to state that a foreign supplier's food safety performance history “includ[es] available information” about results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems. One comment states that § 1.505(a)(1)(v) should not obligate an importer (or a foreign supplier through its importer) to provide FDA with details of an audit because this would have a chilling effect on the number of audits to which a supplier submits. The comment asks that we revise § 1.505(a)(1)(v) to refer to supplier performance history that is “relevant to the intended use” of raw materials or ingredients and to make the provision consistent with the corresponding provision in the proposed regulation on preventive controls for animal food.

(Response 157) We have revised this provision (§ 1.505(a)(1)(iii)(C) in the final rule) to make it consistent with the corresponding provisions in the

preventive controls regulations by specifying that the foreign supplier's food safety history includes available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems. We agree that § 1.505(a)(1)(iii)(C) does not require importers to conduct additional testing or auditing, but rather requires them to consider the results of any such activities that the importer has conducted in assessing the performance of its supplier in evaluating or reevaluating the concerns associated with use of a particular supplier, including when considering obtaining an additional food from an approved supplier. We have not limited the requirement to consider only the supplier's history with the importer that is "relevant to the intended use" of a food because some actions of a supplier, such as how quickly it has acted to address safety problems that have emerged in food it has provided to an importer, do not necessarily relate to the intended use of a food but are nevertheless important in assessing a supplier.

g. Other Factors as Appropriate and Necessary

(Comment 158) One comment encourages us to make it clear to FDA investigators that additional considerations, including transportation and storage practices, are not required in all cases and might not be reflected in importers' records. As an example, the comment notes that some food additive and GRAS substances do not require refrigeration and are stored and transported in sealed containers; the comment asserts that changes in those storage and transportation conditions would not create a significant hazard.

(Response 158) We agree that it is possible that an importer might consider the nature of a food as well as a potential foreign supplier and appropriately conclude that there are no "other" factors that will have a significant effect on (1) whether the importer should approve the use of the supplier or (2) what supplier verification activities might be appropriate with respect to assessing the safety of the food obtained from that supplier. Regarding the example provided in the comment, we agree that storage and transportation may not be relevant factors for foods that do not require refrigeration and that are stored and transported in sealed containers. To the extent the comment is requesting a change to the codified to that effect, we do not believe that is necessary.

h. Guidance on Evaluating Food Risk and Foreign Supplier Performance

(Comment 159) Several comments request that we develop guidance on the specific information that importers should consider under each factor in § 1.505(a)(1).

(Response 159) We anticipate that the FSVP guidance, once finalized, will provide recommendations on the information that importers should consider for each factor in § 1.505(a)(1).

2. Approval of Foreign Suppliers

Under proposed § 1.506(a), importers would be required to establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on the risk evaluation they conducted under proposed § 1.505 (or when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods they subject to adequate verification activities before using or distributing). Thus, there was an implicit requirement that importers "approve" their foreign suppliers on the basis of the risk evaluation they conducted. Section 1.505(b) of the final rule makes this requirement clear by specifying that an importer must approve its foreign suppliers (and document the approval) on the basis of the evaluation the importer conducts under § 1.505(a) or the importer's review and assessment of an evaluation conducted by another entity under § 1.505(d) (discussed in section III.F.4 of this document).

3. Reevaluation of Food Risks and Foreign Supplier Performance

We proposed (in § 1.505(b)) to require importers to promptly reevaluate the risk posed by a food and other factors associated with a food or foreign supplier when the importer becomes aware of new information about these factors. We further proposed that if an importer determined that it was appropriate to continue to import the food from the foreign supplier, the importer would have to document the reevaluation and its determination.

(Comment 160) Some comments suggest that we delete the proposed requirement to reevaluate risks in § 1.505(b) because importers would be required to reevaluate the factors affecting food and supplier risks when they become aware of new information about these risks under the FSVP reassessment requirements in § 1.508 of the proposed rule.

(Response 160) We agree that we should eliminate potentially redundant requirements to reevaluate food risks

and foreign supplier performance. However, we conclude that we should do so by deleting the FSVP reassessment requirements in proposed § 1.508 and essentially placing those requirements in § 1.505 of the final rule. We are taking this approach because changes in the risk posed by a food or the performance of the foreign supplier are the principal reasons why it might be necessary to reassess the appropriateness of an importer's FSVP for a food and supplier. Consistent with this approach, the final rule specifies, in § 1.505(c)(1), that if an importer becomes aware of new information about the food and supplier-related factors in § 1.505(a)(1), the importer must promptly reevaluate the concerns associated with those factors and document this reevaluation. Section 1.505(c)(1) further requires that if the importer determines that any of the matters addressed in the evaluation have changed (such as the emergence of a new hazard or a significant supplier compliance problem), the importer must promptly determine (and document) whether to continue to import the food from the foreign supplier and whether the verification activities it conducts need to be changed. Under § 1.505(c)(2), if in any 3-year period an importer has not reevaluated the food and supplier concerns on the basis of new information, the importer must conduct a reevaluation and take other appropriate actions, if necessary, in accordance with § 1.505(c)(1). The importer is required to document such a reevaluation and any subsequent actions it takes under § 1.505(c)(1).

(Comment 161) One comment suggests that, in addition, to being required to document a determination (following a reevaluation of risks) that it is appropriate to continue to import a food from a foreign supplier, importers should be required to document a determination to discontinue importing a food from a foreign supplier.

(Response 161) We agree. Because § 1.505(c)(1) of the final rule requires importers to document their determination as to whether to continue to import food from a foreign supplier, this would include a decision to discontinue use of a supplier.

(Comment 162) Some comments suggest that importers should be required to conduct a reevaluation of food and supplier risks annually regardless of whether the importer becomes aware of new information about risks. The comments maintain that an annual reevaluation would not be overly burdensome, adding that if no changes were required, the importer could simply note that determination. Regarding the proposed FSVP

reevaluation provisions, several comments maintain that, when an importer finds that there are no hazards in a food, the importer should be required to reassess the FSVP annually because importers sometimes incorrectly determine that no hazards are present. On the other hand, several comments assert that importers should not be required to reassess their FSVP at least every 3 years because this is not required by FSMA (unlike the requirement to reanalyze a food safety plan under FSMA's preventive controls provisions) and would not be risk-based because importers do not need to respond to changed conditions within a manufacturing facility, as is the case with facilities' management of food safety plans.

(Response 162) We conclude that it is not necessary to require importers to conduct a reevaluation of the factors in § 1.505(a)(1) annually even when importers do not acquire new information about these factors. We see no reason to establish a different requirement for when an importer has determined that there are no hazards in a food. Instead, § 1.505(c)(2) of the final rule requires importers to reevaluate the factors at least every 3 years. Because importers also are required to conduct a reevaluation when they become aware of new information about the factors, we believe that the 3-year minimum requirement to reevaluate the factors strikes an appropriate balance by providing adequate assurance that importers' FSVPs will remain effectively risk-based without imposing an unnecessary burden on importers. We believe that a requirement to reevaluate within a defined period is necessary because some importers might fail to actively seek information about potential food risks or supplier performance or fail to actually reevaluate these concerns when they become aware of relevant new information. Because changes to food risks and supplier performance are not uncommon, we believe that the 3-year minimum reevaluation requirement likely will have little effect on those importers who are in compliance with the requirement to reevaluate the food and supplier when they become aware of new information.

(Comment 163) Regarding the proposed FSVP reassessment provisions, one comment expresses concern about the suggestion in the preamble to the proposed rule that new information about potential hazards might include changes to the source of raw materials (78 FR 45730 at 45761). The comment states that produce packing operations routinely source

RACs from numerous farms and it would be impractical for importers to reassess their FSVPs every time a new farm is used as a source of a RAC. The comment asserts that the importer should only be expected to ensure that the foreign supplier has controls to qualify suppliers providing ingredients to the foreign supplier.

(Response 163) We do not agree. Obtaining a RAC from a new farm would necessitate conducting an evaluation under § 1.505(a) to determine whether it would be appropriate to source the RAC from the farm and, if so, what the appropriate foreign supplier verification activities for the farm should be. However, as discussed in the following subsection of this document, the importer could rely on another entity (such as a distributor or consolidator in the supply chain for the RAC) to conduct the evaluation of the risk of the food, the entity controlling the hazard, and the foreign supplier's performance.

4. Review of Evaluation or Reevaluation by Another Entity

Consistent with the discussion in sections III.A.7 and III.E.5 of this document, we conclude that it is appropriate to give importers the flexibility to either conduct their own evaluation of the risk posed by a food, the entity that significantly minimizes or prevents hazards in a food or verifies that the hazards have been significantly minimized or prevented, and the foreign supplier's performance under § 1.505(a), or to rely instead on an evaluation conducted by another entity (other than the foreign supplier). For example, an importer of oranges might rely on such an evaluation conducted by a firm that obtains oranges from many farms and exports them to the United States. In this case, the aggregator of the oranges would evaluate the risk posed by the food and the performance of the individual farms in deciding whether to accept oranges from particular farms and in determining what supplier verification activities should be conducted for each farm. Therefore, § 1.505(d) of the final rule provides that if an entity other than the importer (and other than the foreign supplier) has, using a qualified individual, performed the evaluation described in § 1.505(a) or the reevaluation described in § 1.505(c), the importer may meet its requirement under the applicable provision by reviewing and assessing the evaluation or reevaluation conducted by the other entity. If the importer relies on another entity's evaluation or reevaluation, the importer must document its review and assessment of that evaluation or

reevaluation, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

G. Foreign Supplier Verification Activities (§ 1.506)

We proposed to require importers to conduct certain activities to verify that their foreign suppliers are producing food in a manner consistent with FDA requirements. In response to comments we received, in the Supplemental Notice we issued changes to the proposed requirements, including requiring importers to establish procedures to ensure the use of approved suppliers (rather than requiring importers to maintain a list of their suppliers) and changes regarding the manner and documentation of verification activities that importers must conduct. As discussed in the following paragraphs, the final rule incorporates additional changes to the proposed verification activity provisions in response to comments.

In the final rule, we have added significant flexibility in performing supplier verification to reflect modern supply chains. As with other FSVP requirements, we are allowing entities other than the importer to conduct supplier verification activities. In general, entities other than the importer (and other than the foreign supplier) may conduct verification activities as long as the importer reviews and assesses the results of those activities. This additional flexibility is consistent with the flexibility we are allowing with respect to hazard analysis and determination of verification activities and is consistent with the flexibility afforded to receiving facilities implementing supply-chain programs under the preventive controls regulations. To incorporate this flexibility and specify the importer's ultimate responsibility, we have made small revisions, like changing some of the verbs to passive voice (*e.g.*, changing "evaluation you conduct" to "evaluation conducted" in § 1.506(a)) and adding short, clarifying phrases (*e.g.*, changing "you must establish and follow written procedures for conducting appropriate foreign supplier verification activities" to "you must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted" in § 1.506(b)). We also have made small changes to make clear that the verification activities to which the importer subjects unapproved suppliers must take place before "importing the food" rather than before "using or distributing the food."

We also have made more significant changes, such as adding provisions that explicitly allow an importer to rely on the following:

- A determination of appropriate foreign supplier verification activities made by an entity other than the importer (and other than the foreign supplier) if the importer reviews and assesses whether the determination is appropriate (§ 1.506(d)(3)); and
- The performance of activities by an entity other than the importer (and other than the foreign supplier) provided that the importer reviews and assesses the results of these activities (§ 1.506(e)(2)).

The supply-chain program requirements of the preventive controls regulations include corresponding versions of these provisions.

In addition, we have made changes to the terminology used in this section to reflect the change in § 1.505 from “risk evaluation” to “evaluation for foreign supplier approval and verification” and from “evaluation of food and supplier risks” to “evaluation of the foreign supplier’s performance and the risk posed by a food.” Finally, as in other sections of the final rule, we have made additional changes to the codified for consistency with the supply-chain program provisions of the preventive controls regulations.

These and other changes are described more fully in the paragraphs that follow.

1. Procedures To Ensure Use of Approved Suppliers

In the original proposed rule, we proposed to require importers to maintain a written list of foreign suppliers from which the importers obtain food. In response to comments that maintaining such a list would pose logistical or administrative burdens, in the Supplemental Notice we deleted this proposed requirement. Instead, in accordance with several comments, we proposed (in revised § 1.506(a)) that importers be required to establish and follow written procedures to ensure they import foods only from foreign suppliers they have approved based on the risk evaluation they conduct. In addition, we proposed to allow importers, when necessary and appropriate, to obtain food from unapproved suppliers on a temporary basis if the importer subjects the food to adequate verification activities before using or distributing it. We also proposed that importers be required to document their use of these procedures.

In the final rule, we have revised § 1.506(a) to reflect that an entity other than the importer might conduct the evaluation described in § 1.505. In

addition, we have deleted the word “risk” in the phrase “risk evaluation” when describing the evaluation conducted under § 1.505 to reflect the terminology change in that section. Finally, we have added § 1.506(a)(2) to explicitly allow an importer to rely on another entity (other than the foreign supplier) to establish the procedures and perform and document the activities required in proposed § 1.506(a) (finalized as § 1.506(a)(1)) to ensure that importers import foods only from foreign suppliers they have approved (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities before importing the food), provided that the importer reviews and assesses that entity’s documentation of the procedures and activities. Section 1.506(a)(1) also requires importers to document their review and assessment.

a. Use of Approved Suppliers

(Comment 164) Several comments express support for replacing the proposed requirement to maintain a list of foreign suppliers with a requirement to use procedures to ensure the use of approved suppliers. One comment questions how an importer would know whether a food is from an approved supplier if it did not have a list of such suppliers, and states that there is a need to ensure that an importer is using a complete, accurate, and updated approval process.

(Response 164) We agree that, whether through use of a single list, multiple lists, or some other mechanism, importers will need to adopt and follow procedures to enable them to confirm that the food they import is from suppliers they have approved in accordance with the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods importers subject to adequate verification activities before using or distributing). The procedures importers use will need to ensure that the importer can accurately identify approved suppliers and to reflect changes in such suppliers (e.g., addition of new approved suppliers, deletion of suppliers no longer deemed approved).

b. Temporary Use of Unapproved Suppliers

(Comment 165) Two comments suggest that, instead of referring to “unapproved” suppliers, the regulation should refer to foreign suppliers that are

used on a “contingency” or “provisional” basis.

(Response 165) We decline to make this change. The key feature of these suppliers is that they are not approved, thereby necessitating that the importer conduct or review and assess documentation of adequate verification of the food obtained from the supplier before importing the food.

(Comment 166) Some comments request that importers be given considerable flexibility to import from unapproved suppliers on a temporary basis. One comment states that use of an unapproved supplier should be deemed “necessary and appropriate” as long as the importer can provide a necessary and adequate reason to use the unapproved supplier.

Some comments recommend that use of unapproved suppliers be restricted to a designated time period during which the importer must approve the supplier. One comment requests that we provide guidance on what constitutes “temporary” use of an unapproved supplier and on the circumstances under which use of an unapproved supplier might be appropriate.

(Response 166) We agree that importers should have some flexibility to import food from unapproved suppliers, particularly when unexpected circumstances arise that make it impossible for an importer to obtain a food from an approved supplier. We continue to believe that these circumstances will be limited. Examples of circumstances in which the use of an unapproved supplier on a temporary basis would be “necessary and appropriate” include a problem with a long-standing supplier due to an equipment breakdown or an environmental or weather-related crisis (e.g., severe drought or flooding). Because the importer would be unable to immediately fully evaluate the potential supplier, the importer would need to take other steps to verify that the food obtained from the unapproved supplier is safe. We also agree that the use of unapproved suppliers is only appropriate on a temporary basis, though we decline to specify a particular time limitation on such use, given that the appropriate time period might vary depending on the circumstances. We intend to provide additional guidance on these issues.

(Comment 167) Some comments state that the importer should be required to follow guidelines on their “conditional” approval procedures and conduct a reassessment of their hazard analysis for the food.

(Response 167) It is unclear what the comments mean by “guidelines,” but

we do intend to provide guidance on the temporary use of unapproved suppliers. An importer does not necessarily need to reanalyze hazards when using an unapproved supplier unless the nature of the food or the hazards associated with the food have changed. The hazard analysis relates to the type of food being imported and is not necessarily related to the particular supplier providing the food.

(Comment 168) One comment states that it should not be necessary to require verification of food from an unapproved foreign supplier if other importers have imported the same food from that supplier.

(Response 168) An importer must subject food from an unapproved foreign supplier to adequate verification activities before importing the food, but the importer does not need to perform the verification activities itself. As previously described, while the importer is ultimately responsible for compliance with the requirements in § 1.506, other entities may perform certain key activities as long as the importer reviews and assesses documentation of those activities. Consistent with this approach, if one importer has already conducted appropriate verification activities (*e.g.*, sampling and testing) for a food from a foreign supplier, another importer could, depending on the specific circumstances, review and assess that documentation in lieu of conducting the activities itself. In accordance with § 1.503, the individual performing the verification activities must be a qualified individual.

(Comment 169) Some comments suggest activities that importers should be permitted to conduct to verify food from unapproved foreign suppliers before using or distributing the food. These activities include the following: Obtaining certification that a food is produced in accordance with good agricultural practices or good manufacturing practices; testing the imported food; obtaining a certificate of analysis; and obtaining an official verification “result” from the exporting country, the foreign supplier, or FDA. One comment maintains that it is likely that verification procedures for an unapproved supplier would be similar to the procedures used to verify an approved supplier and should be based on the importer’s hazard analysis.

(Response 169) We agree that food verification activities under § 1.506(a)(1) should be based, at least in part, on the hazard analysis conducted under § 1.504. The adequacy of the verification activities will vary depending on the food, the hazard, and the nature of the

control, as well as information that the importer may have about the supplier. Depending on the circumstances, it may be appropriate for an importer to review and assess a certificate, test the imported food, obtain a certificate of analysis, obtain information from the exporting country or other relevant government authority, or conduct some other verification activity.

(Comment 170) One comment asks that we issue guidelines to direct importers to first consider domestic suppliers before seeking to obtain a food from an unapproved foreign supplier.

(Response 170) We do not agree. Such a directive would be beyond the scope of section 805 of the FD&C Act, which requires importers to take appropriate steps to ensure that the food they import is safe.

c. Documentation of Use of Procedures To Ensure Use of Approved Suppliers

(Comment 171) One comment suggests that, instead of having to document use of procedures to ensure importation of food from approved suppliers, an importer should be required to provide evidence to FDA upon request that the importer is using these procedures.

(Response 171) We do not agree with this suggested change. If an importer did not document its use of these receipt-from-approved-supplier procedures, it is unclear how it would be able to demonstrate to FDA investigators that it had actually followed such procedures.

2. Written Procedures for Foreign Supplier Verification

We proposed to require importers to establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods imported. The comments generally support this requirement, which we are finalizing in § 1.506(b) of the final rule.

(Comment 172) One comment asks that we consider providing model verification activity procedures that importers could use.

(Response 172) We intend to provide general guidance on complying with this requirement. However, it is unlikely that we will be able to provide model verification activity procedures for all foods, hazards, and suppliers. In addition to guidance, we will conduct outreach to assist importers in complying with the final rule.

3. Purpose of Supplier Verification

We initially proposed to require that importers’ foreign supplier verification activities provide adequate assurance that identified hazards are adequately

controlled (proposed § 1.506(c)). In response to comments that the proposal was inconsistent with the statute and was improperly limited to hazard control, in the Supplemental Notice we revised the proposed requirement to specify, consistent with section 805(a)(1) of the FD&C Act, that foreign supplier verification activities must provide adequate assurances that the foreign supplier produces the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and produces the food in compliance with sections 402 and 403(w) of the FD&C Act.

As discussed in response to the following comment, in the final rule we are returning to an approach to supplier verification activities similar to what we had originally proposed, in part to align the FSVP regulation with the supply-chain provisions of the preventive controls regulations. We also are changing the first word in § 1.506(c) to refer to “The” foreign supplier verification activities rather than “Your” activities to reflect the flexibility we are providing with respect to the entity who must conduct supplier verification activities.

(Comment 173) Several comments express support for the revised proposed purpose of supplier verification activities. However, one comment states that the purpose of verification activities should be as originally proposed, while one comment states that FSVPs should be designed to ensure that the foreign supplier is producing food in compliance with sections 402 and 403(w), which the comment contends would more closely align the FSVP requirements with domestic requirements.

(Response 173) Upon consideration of the comments on this revised provision as well as the need to align the FSVP regulation with the supply-chain provisions of the preventive controls regulations, the final rule requires that foreign supplier verification activities provide assurance that the hazards requiring a control in imported food have been significantly minimized or prevented. This requirement is consistent with the corresponding requirement in the preventive controls regulations, *i.e.*, that the “supply-chain program must provide adequate assurance that a hazard requiring a supply-chain applied control has been significantly minimized or prevented” (see §§ 117.410(c) and 507.110(c)). As stated in the FSVP proposed rule and the Supplemental Notice, alignment

with the preventive controls regulations is appropriate to avoid imposing redundant requirements (because entities may be both registered food facilities subject to the preventive controls regulations and food importers subject to the FSVP regulation). In addition, we conclude that this modification is consistent with the hazard identification framework of the final rule. Under the final rule, importers are required to comprehensively analyze and evaluate hazards requiring a control (see §§ 1.504 and 1.505). Requiring such analysis and evaluation makes the most sense if the supplier verification activities performed in accordance with § 1.506 are designed to specifically address the hazards that importers have identified and evaluated.

However, we emphasize that this change regarding the requirement of supplier verification activities in § 1.506(c) does not alter the fundamental purpose of importers' FSVPs. Consistent with section 805(c)(2)(A) of the FD&C Act, § 1.502(a) of the final rule directs importers to develop, maintain, and follow FSVPs that provide adequate assurances that their foreign suppliers produce the imported food in compliance with processes and procedures that provide the same level of public health protection as those required under sections 418 and 419 of the FD&C Act (if applicable) and the implementing regulations, as well as assurances that their suppliers are producing food that is not adulterated or misbranded with respect to allergen labeling. The requirement of supplier verification in § 1.506(c) does not change the requirement in § 1.502(a) but instead specifies what we conclude is an appropriate and functional measure for gauging whether foreign supplier verification activities can provide the statutory assurances of food safety. In short, we conclude that conducting activities to verify that hazards requiring a control have been significantly minimized or prevented will serve as an effective mechanism for providing assurance that a foreign supplier is producing food in compliance with the preventive controls or produce safety regulations (when applicable) and that the imported food is not adulterated or misbranded with respect to allergen labeling.

The requirement of supplier verification in § 1.506(c) encompasses situations in which hazards are significantly minimized or prevented directly by a foreign supplier as well as when hazards are addressed by entities in an importer's supply chain other than

the foreign supplier. When an entity other than the foreign supplier is significantly minimizing or preventing the hazards in a food, an importer would need to conduct supplier verification activities to ensure that its foreign supplier is verifying that the hazard is being significantly minimized or prevented or otherwise verify that the other entity is significantly minimizing or preventing the hazard.

As previously discussed, one situation in which an entity other than the foreign supplier significantly minimizes or prevents the hazards in a food is when produce growing and harvesting operations are performed by different business entities. When the foreign supplier of produce is the grower and another entity that is subject to the produce safety regulation performs certain activities such as harvesting, an importer might review applicable records maintained by the harvester, such as records of training for harvest workers and records related to agricultural water quality used in harvest operations. The importer would review such records for hazards not being significantly minimized or prevented by the grower of the produce. As discussed elsewhere, we are allowing various entities to determine, conduct, and document verification activities that apply to foreign suppliers, provided that the importer reviews and assesses applicable documentation provided by that entity and documents the review and assessment. To satisfy the requirements of § 1.506(c), an importer could obtain documentation of review by another entity of applicable records maintained by the harvester or packer and also review and assess the entity's documentation (and document that review and assessment).

(Comment 174) One comment asks whether verification activities also should provide assurance of supplier compliance with sections 416 (concerning sanitary transportation) and 420 (concerning intentional adulteration) of the FD&C Act (21 U.S.C. 350e and 350i, respectively).

(Response 174) We address specifics about the responsibilities of shipping facilities and receiving facilities under section 416 of the FD&C Act in the 2014 proposed rule on sanitary transportation (79 FR 7006, February 5, 2014). We will address comments regarding the responsibilities of shippers and receivers in the final rule on sanitary transportation. However, because the sanitary transport procedures that we proposed in accordance with section 416 are focused on shipment by rail and motor vehicle within or into the United States, that regulation, if finalized as

proposed, would generally not be applicable to transport in foreign countries. For the purpose of supplier verification under the FSVP regulation, whether evaluating transportation practices is necessary will depend on the particular supplier and the particular food being imported. If certain transportation practices could lead to hazards, an importer would need to verify that such hazards are significantly minimized or prevented.

With respect to intentional adulteration, hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed rule on intentional adulteration (78 FR 78014, December 24, 2013) that we issued to implement section 420 of the FD&C Act. Under the FSVP regulation, importers need only consider hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. However, there may be circumstances in which intentional adulteration may present a known or reasonably foreseeable hazard, so part of providing assurance that the hazards in a food have been significantly minimized or prevented might, depending on the circumstances, include ensuring that the food is not intentionally adulterated. In those circumstances, importers may include intentional adulteration in their hazard evaluation and conduct appropriate verification activities for that hazard. One way an importer could do that would be to review a foreign supplier's vulnerability assessment and, if applicable, their plan under the intentional adulteration regulation (once finalized), documenting the measures the supplier would take to mitigate vulnerability to intentional adulteration.

(Comment 175) Two comments contend that asking importers to conduct verification activities to provide assurances that the foreign supplier is producing food in compliance with processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations is unrealistic because there are no established standards for determining "same level of public health protection." One comment requests more clarity on the meaning of "same level of public health protection."

(Response 175) As stated in Response 173, § 1.506(c) of the final rule does not specify that importers must conduct supplier verification activities to provide assurances that the foreign supplier is producing food in compliance with processes and

procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations. In addition, we responded to comments requesting clarity regarding the nature of processes and procedures that will provide the same level of public health protection in Response 99. As previously noted, our draft guidance on FSVPs will include recommendations on how importers should assess foreign suppliers' processes and procedures to determine whether they provide the same level of public health protection as those required under the preventive controls or produce safety regulations.

(Comment 176) One comment suggests that the requirement to conduct activities to provide certain assurances be revised to refer only to food that will not be subject to further processing (including a pathogen mitigation or kill step) because when a food will be subject to further processing, the FSVP regulation should not apply.

(Response 176) We do not believe that this change is necessary. When a food will be subject to further processing by the importer under the preventive controls regulations, the importer will be deemed to be in compliance with most, but not all, of the FSVP requirements if the importer is required to establish and implement a risk-based supply-chain program under the preventive controls regulations for the imported food and is in compliance with those requirements. In other circumstances involving further processing of a food in the United States, the importer might import the food in accordance with § 1.507, as discussed in section III.H of this document.

(Comment 177) Several comments maintain that the revised proposed rule continues to suggest that the primary purpose of supplier verification is control of hazards. The comments maintain that FDA should recognize that importers' records might not show a listing of each hazard and corresponding verification activity.

(Response 177) We agree that importers will not be required to separately document the verification of each individual hazard in an imported food. The FSVP requirements generally do not require documentation of individual hazards and their controls, but rather require documentation with respect to the food and the foreign supplier of the food (*e.g.*, a hazard analysis for a type of food, a food and supplier evaluation, verification activities appropriate for a food and the supplier). On the other hand, some circumstances might necessitate

documentation related to a single particular hazard, such as when the importer determines that there is only one hazard in a food and the importer documents this determination and its determination regarding appropriate supplier verification activities for the food. In addition, when a SAHCOHHA hazard in a food will be controlled by the foreign supplier, the importer must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer makes an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities conducted under § 1.506(e)(1) and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with § 1.506(c).

4. Foreign Supplier Verification Activities

In the Supplemental Notice, we revised our proposed approach to requirements for foreign supplier verification activities in several ways. We discuss the comments on these changes and other aspects of the proposed supplier verification activity requirements in the following paragraphs.

For clarity, § 1.506(d)(1)(i) of the final rule states that an importer must determine and document which verification activities, as well as the frequency with which the activity or activities must be conducted, to provide adequate assurances that the food the importer obtains from the foreign supplier is produced in accordance with § 1.506(c). To reflect changes we are making to § 1.506(c), we have revised § 1.506(d)(1)(i) to specify that verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that hazards have been significantly minimized or prevented (*e.g.*, when an entity other than the grower of produce subject to part 112 harvests or packs the produce, or when the foreign supplier's raw material supplier prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505. Section 1.506(d)(1)(ii) specifies appropriate supplier verification activities: Onsite audits, sampling and testing, review of the foreign supplier's relevant food safety records, and other supplier verification activities determined to be appropriate. The

addition of this list of appropriate supplier verification activities is to aid understanding of the requirements and is not a substantive change from the proposed rule.

We also have added § 1.506(d)(3) to explicitly allow an importer to rely on a determination of appropriate foreign supplier verification activities (including the frequency with which such activities must be conducted) by another entity in an importer's supply chain. To take advantage of this provision, an importer must review and assess whether the entity's determination is appropriate based on the evaluation conducted in accordance with § 1.505. In addition, the importer must document the review and assessment, including documenting that it was made by a qualified individual.

Section 1.506(e) of the final rule, regarding the performance of foreign supplier verification activities, is generally the same as proposed § 1.506(d)(1), with certain changes to provide more flexibility to importers. Section 1.506(e)(1) requires the importer to conduct and document (or obtain documentation of) supplier verification activities in accordance with the determination made under § 1.506(d) and sets forth documentation requirements for these activities. Section 1.506(e)(2) explicitly allows an importer to rely on the performance of verification activities by other entities as long as the importer reviews and assesses the results of the verification activities in accordance with § 1.506(e)(3), and documents the review and assessment.

Section 1.506(e)(3) makes clear that importers must promptly review and assess the results of supplier verification activities and document the review and assessment. This provision also requires that if the results of the verification activity do not provide adequate assurances that the hazards in the food from the foreign supplier have not been significantly minimized or prevented, the importer must take appropriate action in accordance with § 1.508(a) of the final rule (concerning corrective actions). Finally, because we do not believe that it is necessary for public health for the importer itself to retain documentation of supplier verification activities conducted by other entities, § 1.506(e)(3) does not require the importer to retain this documentation, provided that it can obtain the underlying documentation and make it available to FDA upon request, in accordance with the recordkeeping provisions in § 1.510(b).

We have reflected importers' greater flexibility in meeting supplier

verification requirements by adding various phrases throughout § 1.506. For example, we are changing “you must conduct and document one or more . . . supplier verification activities” in § 1.506(e)(1) to “you must conduct (and document) or obtain documentation of one or more . . . supplier verification activities.” Similarly, in § 1.506(e)(1)(ii), documentation of sampling and testing must include documentation that the testing was conducted by a qualified individual. We added this to ensure that even if the importer itself is not conducting sampling and testing, the sampling and testing must be performed by a qualified individual.

In addition, as a general matter, the final rule does not allow foreign suppliers to perform verification activities of themselves because of the potential for a conflict of interest (codified in § 1.506(e)(2)(ii)). However, we recognize that many suppliers have onsite sampling and testing regimes that are reliable, and we see no need to require an importer to duplicate those efforts. Therefore, § 1.506(e)(2)(ii) allows an importer to rely on sampling and testing of food conducted by a foreign supplier as long as the other criteria for the verification activity are met. We emphasize that it is still the importer’s responsibility to ensure that the verification activities conducted for a particular food and foreign supplier are appropriate.

We also have added flexibility to the verification activity of reviewing a foreign supplier’s relevant food safety records. Section 1.506(e)(1)(iii) provides that when reviewing a foreign supplier’s relevant food safety records is the appropriate verification activity, documentation must include the conclusions of the review. This change helps to ensure that an importer has all the information it needs to review and assess the documentation if the importer is relying on another entity to conduct the records review, and is consistent with the documentation requirements for other verification activities.

We have made additional changes to the verification activity provisions as described in the following paragraphs.

a. Verification Activity Requirements

In the proposed rule, we requested comment on two alternatives for supplier verification activity requirements. “Option 1” would have established certain requirements for SAHCODHA hazards to be controlled by the foreign supplier, and different requirements for non-SAHCODHA hazards and SAHCODHA hazards that the foreign supplier verified had been controlled by its raw material or

ingredient supplier. “Option 2” would have required the importer to determine the supplier verification activity it would use for all hazards that the foreign supplier controlled or for which it verified control.

Under Option 1, for a SAHCODHA hazard that was to be controlled at the foreign supplier’s establishment, the importer would have been required to conduct and document initial and subsequent periodic (at least annual) onsite audits of the foreign supplier. For non-SAHCODHA hazards to be controlled by the foreign supplier and all hazards for which the supplier verified control by its raw material or ingredient supplier, Option 1 would have required that the importer conduct one or more of the following activities: Onsite auditing of the foreign supplier, periodic or lot-by-lot sampling and testing of the food, review of the foreign supplier’s food safety records, or some other procedure established as being appropriate based on the risk associated with the hazard.

On the other hand, Option 2 of the original proposal would have allowed the importer to determine, for all hazards either controlled by the foreign supplier or for which the foreign supplier verified control by its supplier, which of the previously listed verification activities would be appropriate to verify that the hazard was adequately controlled.

We received many comments that supported Option 1 for supplier verification activities and many that supported Option 2. In the Supplemental Notice, we proposed an approach to supplier verification activity requirements that is a hybrid of the original proposal’s Option 1 and Option 2. We proposed to establish a general rule under which an importer would be required to conduct and document one or more of the previously listed supplier verification activities for each foreign supplier before using or distributing the food and periodically thereafter. Importers would be required to use the risk evaluation they conduct to determine which verification activity or activities are appropriate and the frequency with which those activities must be conducted. However, with respect to foods with a SAHCODHA hazard that would be controlled by the foreign supplier, the importer would be required to conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer documented a determination, based on the risk evaluation, that instead of initial and annual onsite supplier

auditing, some other supplier verification activities and/or less frequent onsite auditing would be appropriate to provide adequate assurances of safety. We are finalizing the requirement as proposed in the Supplemental Notice.

(Comment 178) Several comments support the revised approach to supplier verification activity requirements because they believe that it will provide flexibility to importers to determine appropriate supplier verification steps based on the importer’s assessment of the risks posed by the food and supplier. However, several comments oppose the lack of a mandatory onsite auditing requirement for SAHCODHA hazards. One comment states that granting flexibility to importers might lead to confusion and place additional responsibility on FDA staff for validating an importer’s verification methods.

(Response 178) We believe that giving importers the flexibility to tailor their supplier verification activities to unique food risks and supplier characteristics more closely aligns with the statutory requirement that importers perform risk-based verification activities. We continue to believe that annual audits would be appropriate for many foods and suppliers, particularly when there is a SAHCODHA hazard in a food. However, we think that even when there is a SAHCODHA hazard in a food, it is possible that an importer might reasonably conclude that because of its supplier’s excellent compliance and performance history, annual audits are not needed to ensure the safety of the food. An importer who chose to conduct an alternative activity in these circumstances would need to maintain documentation that the activity provides adequate assurances of safety, and this documentation would be available for FDA review during any inspection of the importer or review of the importer’s records.

(Comment 179) One comment suggests that the FSVP supplier verification provisions cross-reference the supplier program provisions in the preventive controls regulations as a way of aligning the rules.

(Response 179) We have strived to make the FSVP supplier verification requirements as consistent with the preventive controls regulations’ supply-chain program provisions as is feasible and appropriate. For ease of reading and to facilitate a comprehensive understanding of the FSVP requirements, we set forth those requirements in one place—subpart L of part 1—rather than require the reader to switch back and forth between subpart

L of part 1 and part 117 or part 507 (the preventive controls regulations) through the use of cross-references.

However, as previously stated, § 1.502(c) of the final rule applies to importers that are receiving facilities who are in compliance with certain provisions in part 117 or part 507. Thus, this provision does refer to the supply-chain program provisions in the preventive controls regulations.

(Comment 180) Some comments ask that we provide guidance on how to determine whether a hazard is a SAHCODHA hazard and differentiate such hazards from significant hazards. Some comments request that we provide guidance on circumstances under which verification activities other than annual onsite auditing would provide adequate assurance of safety when there is a SAHCODHA hazard in a food.

(Response 180) As discussed in section III.A.11 of this document, we have replaced the term “significant hazard” with the term “hazard requiring a control.” A hazard requiring a control is a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish one or more controls or measures to significantly minimize or prevent the hazard and components to manage those controls or measures (see the definition of “hazard requiring a control” in § 1.500). All SAHCODHA hazards require a control, but not every hazard requiring a control has the potential to result in serious adverse health consequences or death. For additional information on how we interpret the SAHCODHA standard, see our guidance on the RFR (Ref. 14), which addresses statutory requirements for “reportable foods.” As explained in that guidance, a “reportable food” is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause SAHCODHA. The guidance includes examples of circumstances under which food might be reportable.

(Comment 181) One comment asks that we provide guidance on how importers should verify that their foreign suppliers are verifying the safety practices of their raw material or other ingredient suppliers.

(Response 181) As stated in the preamble to the proposed rule, an importer might rely on a review of its foreign supplier’s food safety records to verify that the foreign supplier is verifying that its raw material or other ingredient supplier is controlling a

hazard in the raw material or other ingredient. For example, because a foreign supplier that is subject to the supply-chain program requirements under the preventive controls regulations would be required to have documentation (e.g., audit results) of its program for verification of its raw material supplier as part of its compliance with those regulations, an importer obtaining food from that supplier might review this documentation in conducting verification of the supplier. However, the FSVP regulation gives importers flexibility to choose the most appropriate verification activity for the circumstance.

(Comment 182) One comment maintains that importers should have discretion as to whether to include the results of supplier verification activities as part of official activities.

(Response 182) To the extent that the comment suggests that importers may disregard the results of supplier verification activities, we do not agree. Importers have the flexibility to determine appropriate verification activities based on the food and supplier evaluations they conduct, but they may not disregard the results of those activities. Instead, importers must review such results and document the review and assessment. If the results do not provide adequate assurances that the imported food is produced in accordance with the standards in this rule, the importer must take appropriate corrective action in accordance with § 1.508.

(Comment 183) Some comments suggest that, if there is no mandatory requirement for annual onsite auditing, importers should be required to affirmatively inform FDA if they determine that verification activities other than annual auditing are appropriate, and the Agency should specify the documentation required to justify the use of such activities.

(Response 183) We do not believe that an affirmative reporting requirement is warranted. When we inspect importers and review their records to determine compliance with the FSVP regulations, we will review the importer’s documentation of the determination of appropriate verification activities. We believe that our ability to conduct inspections and review records provides appropriate tools to ensure compliance. The appropriateness of the justification for a given verification activity will depend on the particular food and supplier. We intend to provide general guidance on the requirements in this rule, but given the rule’s flexibility, we will be unable to specify particular

documentation required for every circumstance.

(Comment 184) Some comments ask that we make clear that an importer is allowed to rely on activities performed by others instead of activities that it has itself conducted.

(Response 184) We agree and have changed the codified to specify that an importer may either conduct (and document) foreign supplier verification activities or obtain documentation of verification activities conducted by others (e.g., the results of a third-party audit of a foreign supplier) (§ 1.506(e)(1)). In addition, as discussed previously, § 1.506(e)(2) permits an importer to rely on the results of verification activities performed by other entities (other than the foreign supplier). The importer remains ultimately responsible for the performance of appropriate supplier verification activities.

b. Need for Multiple Supplier Verification Activities

We proposed to specify, in § 1.506(d)(3), that based on an importer’s risk evaluation of a food and foreign supplier, it might be necessary for the importer to conduct more than one supplier verification activity to address an individual hazard or risk factor or multiple hazards or risk factors.

(Comment 185) One comment recommends that we delete this provision because it is confusing and contrary to other provisions.

(Response 185) We have deleted this provision as redundant because § 1.506(d) and (e) of the final rule require the performance of multiple foreign supplier verification activities when it is determined, based on an evaluation of the hazards in a food and foreign supplier performance in accordance with § 1.505, that conducting more than one activity is necessary to provide adequate assurances of safety.

c. Requirements for Food From Certain Farms, Facilities, and Egg Producers

In the Supplemental Notice, we proposed to require that if a foreign supplier of a food is a farm that is not subject to the produce safety regulation in accordance with § 112.4 regarding a food being imported, the importer would not need to comply with the standard supplier verification activity requirements if the importer did the following:

- Documented, at the end of each calendar year, that the food provided by the foreign supplier was not subject to the produce safety regulation; and

- Obtained written assurance, at least every 2 years, that the foreign supplier was producing the food in compliance with the FD&C Act.

We stated that this modified supplier verification activity was appropriate because FDA had determined that this food did not pose a sufficient risk to public health that it needed to be subject to the standard produce safety requirements.

We are finalizing modified requirements applicable to the importation of food from a farm that grows produce and is not a covered farm under the produce safety regulation in accordance with certain provisions. In addition, we are adding provisions that provide for modified requirements applicable to the importation of food from a qualified facility, as defined under the preventive controls regulations, or a shell egg producer with fewer than 3,000 laying hens. These requirements, which are included in the modified FSVP requirements in § 1.512 of the final rule, are discussed in section III.M of this document.

d. Substitution of Results of Certain Inspections for Onsite Auditing

We proposed to permit importers to rely on, instead of an onsite audit of a foreign supplier, the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted (proposed § 1.506(d)(5)). For inspections that were conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, we proposed that the food that was the subject of the onsite audit would have to be within the scope of the official recognition or equivalence determination, and the foreign supplier would have to be in, and under the regulatory oversight of, that country.

(Comment 186) Some comments oppose the proposed provisions allowing for the substitution of the results of certain inspections for onsite audits of foreign suppliers. The comments assert that an FDA inspection might not assess the relevant lines or processes, there might not be timely access to inspection results, and the proposed rule does not establish parameters for the results of such inspections. The comments are concerned that foreign suppliers might not allow their importers to audit their

facilities for FSVP purposes if the supplier had been subject to an FDA inspection in the last year.

(Response 186) We decline to delete this provision. We believe that inspection results likely will be available to importers on a timely basis, and a lack of timely access in some cases would not warrant entirely eliminating the opportunity to rely on inspection results. In addition, we believe it is unlikely that there would be many foreign suppliers willing to risk losing customers by refusing to be audited because they had recently been inspected by FDA. However, we have made certain changes that we believe address some of the concerns of the comments. To clarify the scope of this provision (which we have moved to § 1.506(e)(1)(i)(E) so that it is part of the requirements for onsite audits), we have added language specifying the food safety standards that an inspection must address, when the inspection is not conducted by a food safety authority in a country whose food safety system FDA has officially recognized as comparable or equivalent. In those cases, an importer may rely only on the written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations. If another authority's inspection does not assess compliance with FDA food safety regulations, the other authority's inspection would not, as a general matter, substitute for an onsite audit.

We have also revised who can perform such inspections to include representatives of other Federal agencies (such as the USDA) and representatives of State, local, tribal, or territorial agencies. These entities are all part of FDA's Integrated Food Safety System, and their inclusion in § 1.506(e)(1)(i)(E)(1) adds flexibility to the rule. Although representatives of foreign governments are not included in this provision, they are still able to conduct onsite audits for FSVP purposes as long as they are qualified auditors and they consider applicable FDA food safety regulations. Importers may rely on such audits to satisfy the requirements of this rule if the audits provide a basis for the importer to determine that the foreign supplier used processes and procedures that provide the same level of public health protection provided by the preventive controls or produce safety regulations, as applicable, and produces the food in compliance with requirements concerning adulteration and misbranding with respect to allergen labeling.

However, for inspections conducted by the food safety authority of a country

whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food safety authority need not inspect for compliance with relevant FDA standards. Under § 1.506(e)(1)(i)(E)(2) of the final rule, provided that the food that is the subject of the onsite inspection or audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, the country with the comparable or equivalent food safety system, the inspection or audit may inspect for compliance with the standards that FDA has recognized as comparable or equivalent.

(Comment 187) One comment asks that we provide information on how we will make available to importers the results of inspections of foreign suppliers by FDA and comparable foreign authorities.

(Response 187) As a routine matter, we do not intend to proactively make available the results of all foreign inspections, either to importers or other members of the public. However, under the FOIA and FDA's implementing regulations in part 20, members of the public (including importers) may submit requests for records in FDA's files, including records of foreign food establishment inspections. In accordance with FOIA, FDA generally makes those records available, except to the extent those records are covered by one or more of the nine exemptions enumerated in the statute (5 U.S.C. 552(b)).

Importantly, exemption 4 of FOIA protects from mandatory disclosure trade secrets and confidential commercial information (5 U.S.C. 552(b)(4)). In addition, section 301(j) of the FD&C Act requires withholding of trade secret information from the public, and the Trade Secrets Act also prohibits disclosure of trade secrets and confidential commercial information unless specifically authorized by law (see 18 U.S.C. 1905). Accordingly, when we receive FOIA requests for foreign inspection reports that are intended for public disclosure (as opposed to requests submitted by the foreign establishment itself), ordinarily we will redact trade secret and confidential commercial information before we release the materials to the public. Given the restrictions on our ability to provide unredacted inspection reports for public disclosure, we recommend that an importer directly ask the foreign supplier for a copy of the results of any government inspection of that foreign supplier.

(Comment 188) Some comments recommend that importers be permitted to rely on the results of an inspection of a supplier by FDA or a comparable/ equivalent food safety authority for longer than 1 year after the date that the onsite audit would have been required to be conducted. One comment states that under National Organic Program (NOP) regulations, an organics certificate is valid until withdrawn, usually up to 18 months after the issue date; therefore, the comment recommends that the FSVP regulations allow for reliance on an inspection for at least 15 months post-issue date. The comment adds that if we cannot permit this, we should require auditing firms to change the way they conduct business, such as by issuing a document on the date of the audit acknowledging its completion and (if applicable) the absence of critical findings. Other comments ask that we change the period in which the inspection needs to have been conducted to within 2 or 3 years of the date by which the importer determined that an onsite audit was appropriate.

(Response 188) We disagree with these comments. We are allowing the specified inspection results to be substituted for an onsite audit because we believe that such inspections may provide an importer with information on the foreign supplier's food safety practices that is sufficiently similar to information that can be obtained from an onsite audit. In addition, use of such inspection results may lessen the burden of conducting supplier verification activities by eliminating the need for an onsite audit. At the same time, we believe that requiring the inspection to have been conducted within 1 year of the date that the onsite audit would have been required to be conducted is appropriate to ensure that any inspection provides relevant and meaningful information that is similar to the information that could be obtained from an audit. Allowing the inspection to be conducted more than 1 year from the date an audit would have been required would make it more likely that the inspection would address different processes and procedures from what an audit would have addressed.

As one comment notes, NOP organic certificates are valid until withdrawn (either suspended or revoked for cause by the certifying agent or voluntarily surrendered by the certified operation), although it is incorrect to suggest that certificates are valid up to 18 months after issuance. Regardless, NOP inspections serve a different function from onsite FSVP audits. Unlike onsite FSVP audits, NOP inspections do not

address whether the processes and procedures of foreign food producers provide the same level of public health protection as sections 418 and 419 of the FD&C Act, and that foreign food is produced in accordance with sections 402 and 403(w) of the FD&C Act, as applicable. Regarding the comment suggesting that if we do not allow for more than a 1-year period, we should instead require auditing firms to change the way they conduct business, such as by issuing a document on the date of the audit acknowledging its completion and (if applicable) the absence of critical findings, such a request is beyond the scope of this rulemaking. The FSVP regulation does not impose any requirements on audit firms, and we do not believe it is necessary to do so in order to efficiently enforce Congress' directive in section 805 of the FD&C Act to ensure that imported food is as safe as domestically-produced food. However, nothing in this rulemaking would preclude audit firms from changing the way they conduct business as the comment suggests, though it is unclear how such a change would be helpful to the importer in meeting the requirements of this rule.

(Comment 189) One comment asks that we explain what is regarded as a food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.

(Response 189) In section III.N of this document we discuss our systems recognition initiative, under which are assessing food safety systems in other countries to determine whether they provide a similar system of protections as that provided under the U.S. food safety system and therefore can be officially recognized as comparable to the U.S. system. We also discuss food safety equivalence determinations. In response to the specific comment, a systems recognition agreement would specify the relevant food safety authority for the country under a particular agreement.

(Comment 190) One comment requests that we accept a State inspection of a foreign supplier as an audit, suggesting that the Manufactured Food Regulatory Program Standards and other programs could be used to evaluate State programs as equivalent food safety authorities.

(Response 190) As stated previously, we have changed § 1.506(e)(1)(i)(E)(1) to allow an importer to rely on the results of an inspection of a foreign supplier conducted by officials from State, local, tribal, or territorial food safety authorities. As discussed in section III.N

of this document, systems recognition only applies to foreign countries.

5. Review of Results of Verification Activities

We proposed to require importers to promptly review the results of their foreign supplier verification activities and, if the results of the review showed that the risks for the food or foreign supplier were not adequately controlled, to take appropriate corrective action (proposed § 1.506(d)(6)). This requirement is codified in § 1.506(e)(3) of the final rule, with the following changes to ensure consistency with other supplier verification activity provisions:

- Importers must promptly review and assess the results of verification activities that they conduct (or obtain documentation of) or that other entities conduct.
- Importers must document their review and assessment.
- Importers must take appropriate action under § 1.508(a) if the results of verification activities do not provide adequate assurances that hazards requiring a control have been significantly minimized or prevented.
- Importers are not required to retain documentation of verification activities conducted by other entities provided that they can obtain such documentation and make it available to FDA in accordance with § 1.510(b).

(Comment 191) One comment requests that we delete the requirement to review results promptly. The comment maintains that this requirement is too prescriptive and that importers should have the flexibility and discretion to review results in a timely manner.

(Response 191) We do not agree. We believe that it is reasonable and appropriate to require importers to promptly review the results of their verification activities so that they can determine whether the results suggest that there is a problem with a supplier and, if so, take steps to address the problem on a timely basis. In the absence of any such review, the verification activities would not serve their intended purpose of ensuring the safety of imported food, as contemplated by section 805 of the FD&C Act.

6. Documentation and Other Requirements for Supplier Verification Activities

In response to concerns primarily regarding the documentation of foreign supplier audits that importers would be required to retain and make available to FDA investigators, in the Supplemental

Notice we added provisions specifying the content of documentation of importers' supplier verification activities. We also proposed other requirements regarding how these activities should be conducted.

(Comment 192) One comment recommended that we not establish specific requirements regarding the format of required documentation.

(Response 192) We agree. The regulations we have adopted do not specify a particular format in which documentation of supplier verification activities must be recorded.

(Comment 193) Some comments express concern that importers might have limited access to qualified auditors and appropriately certified laboratories; the comments recommend that we provide training and certification opportunities. One comment states that we should require auditors to be trained and certified to U.S. standards.

(Response 193) We do not have plans to provide training and certification opportunities for qualified auditors. (We note that, under § 1.500 of the final rule, examples of potential qualified auditors include (but are not limited to) an audit agent of a certification body (also known as a third-party auditor) that has been accredited under subpart M of part 1 (FDA's regulations implementing the third-party certification provisions of FSMA).) We believe there are many opportunities for auditing training available in the private sector, particularly for third-party auditors. We do not agree that auditors must be trained and certified "to U.S. standards" if this refers to being trained by FDA. What is important is that audits conducted for FSVP purposes be conducted by qualified auditors, who are qualified individuals who have the technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform onsite auditing to meet FSVP requirements, and that the audits be conducted in accordance with the requirements for such audits in § 1.506(e)(1)(i) of the final rule, discussed in section III.G.4 of this document.

(Comment 194) Several comments state that FDA should specify which verification activities and corrective actions must be recorded and the circumstances under which the records must be made available or submitted to the Agency.

(Response 194) As specified in § 1.506(e)(1), except for when an importer relies on performance of activities by other entities in accordance with § 1.506(e)(2), importers must document the supplier verification

activities they conduct. If an importer relies on verification activities conducted by another entity, the importer is not required to retain documentation of those activities, provided that it can obtain the documentation and make it available to FDA in accordance with § 1.510(b). In addition, any corrective action taken in accordance with § 1.508 must be documented. Under § 1.510(b)(1), importers must make FSVP records available promptly to an authorized FDA representative, upon request, for inspection and copying. In addition, under § 1.510(b)(3), upon our written request, importers must send records to us electronically or through other prompt means. For more information about the circumstances under which records must be made available or submitted to FDA, see the discussion of § 1.510 in section III.K.3 of this document.

a. Onsite Auditing

In the Supplemental Notice we acknowledged the concerns that having to make full reports of onsite audits of foreign suppliers available to FDA would make suppliers reluctant to be audited or result in less robust audits, and we agreed that importers should not be required to retain full audit reports. Instead, we proposed (in § 1.506(d)(1)(i)) that importers be required to retain documentation of audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor. We also proposed to retain the provision in the proposed rule requiring, for food subject to one or more FDA food safety regulations, that an onsite audit consider those regulations and include a review of the supplier's written food safety plan, if any, and its implementation. In addition, we proposed to require that an onsite audit of a supplier be performed by a qualified auditor.

Section 1.506(e)(1)(i)(B) of the final rule includes the requirement that an onsite audit of a foreign supplier of a food subject to one or more FDA food safety regulations consider those regulations and include a review of any food safety plan and its implementation. However, as previously discussed, we recognize that there might be circumstances in which a company imports a food from a supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, but the modified

requirements for certain food from certain suppliers in such countries in § 1.513 of the final rule do not apply. To account for these circumstances, § 1.506(e)(1)(i)(B) of the final rule specifies that, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.

(Comment 195) Some comments request that audits that are conducted to meet FSVP requirements by auditors accredited under the third-party auditing regulations that FDA is developing under section 808 of the FD&C Act should not be required to meet the proposed requirements for audits conducted under that regulation, including the requirements to submit the audit reports to FDA and to report serious findings to the Agency. The comments assert that applying such requirements to audits conducted for FSVP by third-party auditors accredited under the FDA system would create a disincentive to use such auditors to meet FSVP requirements.

(Response 195) As we have stated in public meetings regarding the FSVP proposed rule, we will not require that audits conducted to meet FSVP requirements by third-party auditors accredited under FDA's third-party certification regulation (in subpart M of part 1) meet the requirements for audits conducted under that regulation, which is set forth in a final rule published elsewhere in this issue of the **Federal Register**. The only audits that must meet the requirements of the third-party certification regulation are regulatory audits performed for the purposes of the issuance of (1) certifications required for participation in the Voluntary Qualified Importer Program (VQIP) under section 806 of the FD&C Act (21 U.S.C. 384b) and (2) mandatory import certifications under section 801(q) of the FD&C Act, as well as consultative audits conducted in preparation for a regulatory audit. To make clear that those auditing requirements do not apply to audits conducted solely for FSVP purposes, § 1.506(e)(1)(i)(C) of the FSVP final rule states that if an onsite audit is conducted solely to meet FSVP requirements by an audit agent of a certification body that has been accredited under the third-party certification regulation, the audit is not subject to that regulation.

(Comment 196) Noting that facility certifications issued by accredited third-party auditors are required for participation in VQIP, one comment questions whether there is a difference in the scope of audits conducted to meet

FSVP requirements and audits conducted in accordance with FDA's third-party certification regulation. The comment asserts that while proposed § 1.506(d) would require that audits conducted to meet FSVP requirements consider all FDA food safety regulations, audits conducted in accordance with the proposed third-party certification regulation must determine a facility's compliance with the FD&C Act. The comment asks what accredited third-party audits will entail given that the FD&C Act addresses more than just food safety requirements.

(Response 196) The scope of accredited third-party audits conducted in accordance with the third-party certification regulation is addressed in the final rule on third-party certification published elsewhere in this issue of the **Federal Register** (see Response 7 in the preamble to the final rule).

(Comment 197) Several comments address the standards that we will require onsite audits of foreign suppliers to meet. Some comments recommend that when third-party audits are used, FDA should require that audits be conducted in accordance with nationally or globally accepted standards, such as schemes that are benchmarked in accordance with the Global Food Safety Initiative (GFSI). One comment recommends that we take into consideration audits conducted by recognized auditing firms and certification bodies. One comment suggests that for fruits and vegetables, good agricultural practice (GAP) and good manufacturing practice (GMP) certificates issued by independent third-party certification bodies accredited by competent authorities should be accepted. One comment states that audits conducted to meet FSVP requirements should be held to the same standards as audits performed domestically. One comment maintains that some private food safety auditing standards provide the same level of public health protection as the FSMA standards.

(Response 197) We agree that audits conducted to meet FSVP requirements should be held to the same standards as audits performed domestically for the purpose of supplier verification. To the extent that the results of GFSI, GAP, or any other audit schemes appropriately verify that the foreign supplier produces the food consistent with FDA food safety standards, importers may use audits conducted under those schemes to meet the requirements of the FSVP regulation. We understand that, as of the publication of this document, many of the widely used food safety auditing schemes are considering whether and

how to revise their practices in light of the requirements of FDA regulations, including our new FSMA regulations. We further understand that the updating of schemes is a lengthy process that often involves engagement with experts and other stakeholders. Therefore, we believe it is premature to reach any definitive conclusions as to whether importers can rely on the results of audits conducted under any existing auditing schemes to verify compliance with the safety requirements of this rule. Over time, we expect that scheme owners and benchmarking organizations will develop tools to assess their schemes against FDA requirements to demonstrate the levels of health protection their schemes provide. We believe there is value in such efforts and foresee possible implications for the Agency's work. Until such time, if an importer chooses to use a GFSI, GAP, or other similar audit, the importer might need to supplement that audit to meet the requirements of § 1.506 or otherwise determine that the audit meets the requirements of this section. Even after scheme owners and benchmarking organizations update their tools to reflect the new FDA food safety requirements, it will remain the importer's responsibility to determine whether the results of any particular audit are adequate to conclude that a foreign supplier produces a food in accordance with the standards required by this rule.

(Comment 198) One comment states that the WTO Agreement on Technical Barriers to Trade (TBT Agreement) encourages WTO members to reduce multiple certification and testing requirements by entering into mutual recognition agreements to facilitate trade. The comment also suggests that we adopt a regulatory scheme similar to that in the juice and seafood HACCP regulations in parts 120 and 123, including allowing foreign government officials to conduct verification audits of suppliers.

(Response 198) Because the FSVP regulation is a food safety measure and therefore are not subject to the TBT Agreement, the provisions in the TBT Agreement regarding mutual recognition agreements do not apply. We agree that reducing multiple testing and certification requirements for food safety is an important guiding principle, and the FSVP regulation does not impose multiple testing and certification requirements on suppliers. The FSVP regulation provides importers with flexibility to determine appropriate supplier verification activities and allows multiple importers to rely on the same results of auditing, testing, and

other verification measures. We believe that as importers and foreign suppliers become more familiar with the FSVP requirements, more suppliers are likely to arrange to be audited and share the audit results with multiple U.S. importers.

We agree that it is appropriate to allow foreign government officials to conduct audits. Under the final rule, onsite audits must be performed by qualified auditors. As we discussed in section III.A.18 of this document, foreign government employees may be qualified auditors, and the standard for being a qualified auditor does not differ when the audit is performed by a foreign government employee. We see no reason why an importer could not rely on an audit of a foreign supplier conducted by a foreign government employee with appropriate technical expertise obtained through education, training, and/or experience, as long as the foreign official considers applicable FDA food safety standards. The importer could rely on such an audit to meet the requirements of this rule if the audit allows the importer to determine whether the foreign supplier uses processes and procedures that provide the same level of health protection provided by the produce safety or preventive controls regulations, as applicable, and produces the food in compliance with sections 402 and 403(w) of the FD&C Act, as applicable. At this time, we do not envision establishing a program to recognize individuals as meeting the definition of qualified auditor for the purposes of FSVP. However, we intend to conduct outreach, develop training modules, and provide technical assistance to facilitate compliance with the FSVP regulation, including regarding importers' reliance on the results of onsite audits of foreign suppliers.

As for other potential ways to design the FSVP regulation to be similar to the importer requirements in FDA's juice and seafood HACCP regulations, we do not agree that doing so would be appropriate. As stated in the preamble to the proposed rule, section 805 of the FD&C Act contemplates a more comprehensive approach to supplier verification than the juice and seafood HACCP regulations. The juice and seafood importer provisions were adopted more than a decade ago, and the U.S. Government Accountability Office has expressed concerns with the effectiveness of the seafood importer provisions (see 78 FR 45730 at 45745). In light of FSMA's increased emphasis on the safety of imported food and importers' role in ensuring food safety, as well as the adoption of the FSVP

regulation, we will consider whether it would be appropriate in the future to initiate a rulemaking to revise the regulations applicable to importers of juice and seafood.

(Comment 199) One comment suggests that we consult the Good Manufacturing Practice and Quality Assurance Guides for Food Additives and GRAS Substances developed by the International Food Additives Council when evaluating audits of foreign suppliers of food additives and GRAS substances.

(Response 199) When evaluating audits of foreign suppliers, we will consider whether the audits verify compliance with applicable food safety requirements contained in the FD&C Act and any FDA regulations to which the food is subject.

(Comment 200) One comment maintains that the added value of an audit conducted by an importer is limited especially when the supplier is already certified or audited. The comment states that importers should be able to provide “data on paper—in the form of an up-to-date dossier” in place of conducting duplicative supplier verification activities. Another comment recommends that importers rely on third-party audits to avoid unnecessary multiple audits of foreign suppliers and suggests that importers who rely on the report of a third-party audit of a supplier be deemed in compliance with the supplier verification requirements.

(Response 200) As a general matter, we agree that if an importer can obtain documentation of an foreign supplier audit conducted in accordance with the requirements of the FSVP regulation (e.g., performed by a qualified auditor and evaluating compliance with applicable FDA food safety standards), the importer can rely on it provided that the importer reviews and assesses the results of the audit. We have explicitly added this flexibility in § 1.506(e)(2) of the final rule. We anticipate that many importers will, in accordance with the FSVP regulation, rely on audits conducted by third-party auditors or by other entities rather than conducting their own separate audit of the supplier.

(Comment 201) One comment states that the frequency of auditing conducted to meet FSVP requirements should take into consideration risks in the food and the quality control capability of suppliers.

(Response 201) We agree. Section 1.506(d)(1) of the final rule states that an importer must determine and document which verification activity or activities (including, potentially, onsite audits) are needed, as well as the frequency with which those activities must be

conducted, to provide adequate assurances that the hazards in the food obtained from the foreign supplier are significantly minimized or prevented. This determination must be based on the evaluation of the food and the foreign supplier conducted under § 1.505.

(Comment 202) One comment requests that the regulation specify that importers must accept verification results of other importers on the same food from the same foreign supplier to avoid multiple verifications.

(Response 202) We decline to require importers to accept verification results of other importers. However, § 1.506(e)(2) of the final rule does allow an importer to rely on verification activities performed by other entities (other than the foreign supplier), and such other entities may include other importers of the same food from the same foreign supplier. In such cases, the importer must review and assess the results of those activities and document the review and assessment. The importer remains ultimately responsible for the safety of the food it imports and its own compliance with this regulation. In accordance with § 1.503, the individual performing the verification activities must be a qualified individual.

(Comment 203) Some comments object to limiting the Agency’s access to complete audit reports. On the other hand, some comments request that the regulation clearly specify that we will not require review of a full audit report. One comment asks us to clarify that summary data and recognized auditor or foreign government certification are adequate. The comment maintains that it is unrealistic to expect foreign suppliers to provide highly confidential data to importers.

(Response 203) As stated in the Supplemental Notice, we conclude that we do not need to see full audit reports to effectively monitor importer compliance with the supplier verification requirements. Section 1.506(e)(1)(i)(D) only requires that an importer retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor. We conclude that it is unnecessary to state in the regulatory text that importers need not retain full audit reports. We believe that the information required under § 1.506(e)(1)(i)(D) is the information our investigators will need to assess the adequacy of the audit and, thus, the

importer’s compliance with the FSVP requirements. In turn, if an importer is relying on another entity (such as a third-party auditor hired by a foreign supplier) to conduct the audit, the importer would need to obtain the relevant information regarding the audit to fulfill its obligation to review the results of the audit. As for the comment that it is unrealistic to expect foreign suppliers to provide highly confidential data to importers, we recognize that, due to commercial confidentiality concerns or other reasons, there might be circumstances in which some foreign suppliers might be reluctant to share food safety information with importers. However, we also believe that some foreign suppliers will desire to share such information as a means of attracting customers for their products.

(Comment 204) One comment contends that making audit conclusions or corrective actions available to FDA could result in suppliers refusing to allow unannounced audits. Therefore, the comment suggests that FDA only review an importer’s procedures for verifying suppliers, including procedures for audits, rather than the results of the procedures. Alternatively, the comment contends that importers should only be required to provide documentation of corrective actions taken to address significant deficiencies that create a risk to public health.

(Response 204) We do not agree that we should only review an importer’s procedures for verifying suppliers. We also need to be able to confirm that those procedures are followed by reviewing the importer’s records, including documentation of review and assessment of audit results and any necessary corrective actions taken. As to whether this will result in suppliers refusing to allow unannounced audits, we note that nothing in the final rule requires that audits be unannounced. Nevertheless, there may be some advantages to unannounced audits, as discussed in the preamble to the proposed rule on third-party certification (see 78 FR 45782 at 45812, July 29, 2013).

With respect to whether importers should only be required to provide documentation of corrective actions taken to address significant deficiencies that create a risk to public health, we do not agree. Section 805(a)(1) of the FD&C Act requires each importer to perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, among other requirements. If imported food is

adulterated or misbranded with respect to allergen labeling, corrective action is required to satisfy the requirements of section 805(a)(1). Because we can only efficiently enforce section 805(a)(1) if we are able to verify such corrective action, and because we can only verify corrective actions if importers provide appropriate documentation, the final rule requires documentation of all corrective actions. However, the particular corrective action warranted could differ depending on the circumstances, including the level of risk to public health posed by the particular non-compliance. The importer's documentation would reflect whatever corrective action might be warranted.

(Comment 205) One comment states that the regulations should recognize that documentation of audits might be maintained by an importer's corporate parent rather than at an individual facility.

(Response 205) We do not object to documentation of audits being maintained by an importer's corporate parent. In accordance with § 1.510(b)(2) of the final rule, offsite storage of records is permissible, as long as such records can be retrieved and provided onsite within 24 hours of request for official review.

b. Sampling and Testing

We proposed (in § 1.506(d)(1)(ii)) that sampling and testing of a food could be conducted by either the importer or the foreign supplier. We proposed that importers be required to retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing. We are finalizing these requirements in § 1.506(e)(1)(ii). In addition, we are adding the requirement that importers retain documentation of the date of the report of the testing because we believe that the date of the report can be important. As previously stated, we are also adding language stating that importers must retain documentation that the testing was performed by a qualified individual (to clarify that testing must be conducted by a qualified individual).

(Comment 206) One comment requests that we clarify that testing could be conducted on behalf of an importer or foreign supplier.

(Response 206) We agree. An importer or a foreign supplier may hire another entity to conduct the testing on its behalf; the importer or supplier need not conduct the actual testing itself. In addition, under § 1.506(e)(2)(i) of the final rule, sampling and testing may be conducted by other entities provided the importer reviews and assesses the results of the testing.

(Comment 207) One comment maintains that because testing documentation is routinely maintained by the testing entity, importers should be required to either retain "or have access to" such documentation.

(Response 207) Importers must obtain the required testing information so that, in accordance with § 1.506(e)(3), they can review the testing results and, if appropriate, take corrective action to address supplier non-compliance. However, as previously noted, § 1.510(b)(2) does allow offsite storage of records if they can be retrieved and provided onsite within 24 hours of request for official review.

(Comment 208) One comment suggests that proposed § 1.506(d)(1)(ii) be revised to reflect that, when outside laboratories are used, the importer might not have access to information about the dates on which tests were conducted, but only information on the dates on which the tests were reported.

(Response 208) We do not agree. Information on the dates on which testing was conducted is standard information in laboratory testing reports and may be important information. However, we agree that the date on which the test results were reported is also important information, so we are revising § 1.506(d)(1)(ii) by adding a reference to "the date of the report of the testing." This change is consistent with the approach taken in the preventive controls regulations for documentation of sampling and testing.

(Comment 209) Some comments suggest that because testing often is more efficient when it is conducted by the supplier, FDA should develop guidance on when "test and hold" procedures could be used.

(Response 209) We recognize that it could be appropriate for testing to be performed by suppliers in certain circumstances. Section 1.506(e)(2)(ii) of the final rule allows for suppliers to perform testing as a verification activity as long as the importer reviews and assesses the relevant documentation.

(Comment 210) One comment suggests that testing should be the preferred activity when detecting or identifying the presence or absence of pathogenic bacteria, allergens, and spoilage organisms.

(Response 210) To the extent that the comment suggests that testing is the preferred supplier verification activity for pathogenic bacteria or allergens, we do not agree. Although testing plays an important role in ensuring the safety of food, contamination with microbial pathogens and some allergens is likely to be non-homogeneous and the numbers of pathogens are likely to be low. A negative result therefore does not guarantee the absence of contamination. An importer should take this into account when deciding which verification activity (or activities) is appropriate. Because of the limitations of sampling and testing, the processes and procedures a supplier has in place to minimize contamination, and the management of those processes and procedures, are key in determining when sampling and testing is appropriate as a verification activity. We discussed the role of testing in ensuring the safety of food in the proposed rule on preventive controls for human food (see the Appendix to the proposed rule (78 FR 3646 at 3818 through 3820), with reference numbers corrected in the **Federal Register** of March 20, 2013 (78 FR 17142 at 17149 through 17151)). For more information about other food safety issues, many of which helped inform both this rulemaking and the preventive controls rulemakings, see generally the proposed, supplemental, and final rule on preventive controls for human food (78 FR 3646; 79 FR 58524, September 29, 2014; 80 FR 55908).

In many cases, an onsite audit to verify control of hazards may be more appropriate than sampling and testing, or may be appropriate to use in conjunction with sampling and testing. Onsite audits provide the opportunity to review a supplier's food safety plan (if the supplier has one) and written procedures and to observe the implementation of those procedures, as well as to review records. In addition, an auditor can interview a supplier's employees to assess their understanding of the food safety measures for which they are responsible. Therefore, an audit can provide for a more comprehensive assessment of food safety implementation than testing. For these reasons, when a SAHCODHA hazard in a food will be controlled by the foreign supplier, importers must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (unless they make an adequate written determination (based on the evaluation conducted under § 1.505) that, instead of such auditing, other supplier verification activities

and/or less frequent onsite auditing are appropriate to provide adequate assurances that the hazards in the food from the foreign supplier are significantly minimized or prevented).

With respect to spoilage organisms, if there is reason to believe spoilage may have occurred (*e.g.*, the product may have been temperature abused during shipment), testing to enumerate certain types of organisms might be appropriate. However, if the testing for spoilage organisms is to verify production processes and procedures, a supplier audit of such procedures and their implementation might be more informative.

(Comment 211) Several comments request that we establish minimum laboratory standards to ensure that laboratories used to test imported foods follow performance standards that are equivalent to U.S. standards. Several comments ask us to issue a proposed rule regarding the accreditation of laboratories and model standards to be used by accredited laboratories in accordance with section 202 of FSMA (section 422 of the FD&C Act (21 U.S.C. 350k)). One comment asks us to require that the laboratory reports on which importers rely align with international standards.

(Response 211) We stated in the preamble to the proposed rule our tentative conclusion that, although we would expect sampling and testing conducted to meet FSVP requirements to be performed in accordance with any applicable regulations or widely accepted industry standards, it was not appropriate to specify testing standards in the FSVP regulation. Although the final rule does not include specific requirements for laboratory testing, importers may not rely on the results of testing that was not conducted in accordance with methodologies and procedures designed to ensure valid and accurate results. We are currently developing a proposed rule to implement section 202 of FSMA. The proposed rule might include proposed circumstances under which use of accredited laboratories and model testing standards would be required.

(Comment 212) One comment suggests that laboratories should make certificates of current accreditation from recognized laboratory accreditation bodies available to importers to provide assurance that the laboratory is in compliance with recognized standards.

(Response 212) We agree that importers could benefit from using accredited laboratories and that it could be beneficial for laboratories to make certificates of accreditation available.

However, such requirements are beyond the scope of this rulemaking.

c. Review of Foreign Supplier Food Safety Records

We proposed (in § 1.506(d)(1)(iii)) that importers be required to retain documentation of each review of relevant supplier food safety records, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual. We are finalizing this requirement in § 1.506(e)(1)(iii). We are adding a requirement that an importer must retain documentation of the conclusions of the review because they are essential to determining whether and what corrective actions are necessary.

(Comment 213) One comment suggests that this provision refer to “food safety compliance records” rather than “relevant food safety records.”

(Response 213) We do not agree. The suggested revision might be interpreted as limiting the provision to only those records that relate to a compliance action with a relevant authority. However, it might be appropriate for an importer to review a broader set of food safety records, including records documenting that the food safety procedures that the supplier has established to control hazards are being followed and are adequately controlling the hazards. Such records might include records of a foreign supplier’s audit of its supplier’s hazard control activities or records of environmental monitoring or product testing.

(Comment 214) One comment maintains that importers should not be required to have a qualified individual conduct a review of supplier food safety records; the comment states that a qualified individual is not required for review of food safety records of a supplier of a raw material or other ingredient under the proposed regulations on preventive controls for animal food.

(Response 214) We do not agree. We believe that an importer must have a qualified individual conduct all foreign supplier verification activities to ensure that these activities are performed adequately. The final rule on preventive controls for animal food requires use of a preventive controls qualified individual to review supplier food safety records (see §§ 507.49(a)(4) and 507.175(b)).

d. Other Appropriate Verification Activities

We proposed to allow importers to conduct supplier verification activities other than those previously discussed if such activities were appropriate to address the risks associated with the food and the foreign supplier (proposed § 1.506(d)(1)(iv)). Although we did not specify how importers would be required to document the performance of such verification activities, we requested comment on whether the final rule should include such requirements and, if so, what they should be.

We are finalizing this provision in § 1.506(e)(1)(iv)(A). To allow flexibility as to who must conduct the verification activities, consistent with other provisions of the final regulatory text, we have revised the phrase “You may conduct and document other supplier verification activities . . .” to “You may conduct (and document) or obtain documentation of other supplier verification activities . . .” We are also adding § 1.506(e)(1)(iv)(B) in response to comments, as discussed below.

(Comment 215) One comment suggests that importers could use third-party remote video auditing systems as an alternative verification measure under proposed § 1.506(d)(1)(iv).

(Response 215) Depending on the circumstances, including the hazard analysis, the evaluation for foreign supplier approval and verification, and the specific characteristics and capabilities of the third-party remote video auditing system, an importer could determine that it is appropriate to use such a system as an appropriate alternative verification activity under § 1.506(e)(1)(iv) of the final rule.

(Comment 216) Some comments suggest that the regulation should not specify requirements for the documentation of such alternative verification activities. One comment states that although FDA might specify minimum parameters for documentation, it would be better to allow specific industry sectors to develop their own forms. Some comments suggest that for these alternative activities, importers should be required to document the date of the activity, the findings, any corrective actions taken, and justification that the activity provides at least the same level of assurance as the other verification activities in the regulations, particularly when there is a SAHCODHA hazard in a food.

(Response 216) As with the previously discussed verification activities, we conclude that it is

appropriate to include certain requirements for documentation of alternative verification conducted under § 1.506(e)(1)(iv). Requiring such documentation will allow us to review the appropriateness of any particular verification activity to determine an importer's compliance with the FSVP regulation, thereby allowing us to efficiently enforce the requirements in section 805 of the FD&C Act. Therefore, § 1.506(e)(1)(iv)(B) of the final rule requires importers to document their use of such alternative activities by retaining a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by qualified individual. We do not believe it is necessary to specifically require an importer to document a justification that the activity provides at least the same level of assurance as the other verification activities, because § 1.506(d)(1) already requires importers to document their determination of the nature and frequency of appropriate supplier verification activities for a particular food and foreign supplier.

7. Independence of Qualified Individuals

We proposed to specify that a qualified individual who conducted any foreign supplier verification activities could not have a financial interest in the supplier and payment could not be related to the results of the activity (proposed § 1.506(d)(7)). However, this provision would not prohibit an importer or one of its employees from conducting verification activities. In the final rule, we have moved this provision to § 1.506(e)(4) and modified it so that it no longer prohibits the existence of a financial interest, but rather prohibits the existence of financial conflicts of interest that influence the results of verification activities in § 1.506(e)(1). The rule continues to specify that payment must not be related to the results of the activity.

(Comment 217) One comment recommends that the conflict of interest provisions in the FSVP regulation be consistent with those in the preventive controls regulations. One comment suggests that the provisions be revised to specify that a qualified individual must not have a "direct personal" financial interest in the foreign supplier.

(Response 217) The conflict of interest provisions in the final rule are the same as those in the preventive controls regulations. We do not believe it is appropriate to limit the type of financial

interest of concern here to a "direct personal" financial interest, particularly since it is unclear what would count as a "direct personal" financial interest as opposed to any other financial interest. If the qualified individual has a financial conflict of interest that influences the results of verification activities, the qualified individual would be precluded from being able to independently conduct verification activities under the FSVP regulation. We believe that this limitation appropriately ensures that qualified individuals act objectively and are free from any undue commercial pressures that could compromise the performance of verification activities.

(Comment 218) One comment requests that we clarify that an importer or its employee may conduct a verification activity "even if the foreign supplier is an affiliate, subsidiary, or parent company of yours."

(Response 218) We decline to add this language. We recognize the variety of business relationships that can exist between importers and foreign suppliers, including a parent-subsidiary relationship or an affiliate relationship. Regardless of how the two entities relate to each other, the conflict of interest provisions in § 1.506(e)(4) are designed to maintain the integrity of the verification activities performed as part of an importer's FSVP. Section 1.506(e)(4) does not prohibit an importer or its employee from conducting a verification activity even if the foreign supplier is an affiliate, subsidiary, or parent company of the importer, and the language requested by the comment is unnecessary. Nevertheless, any financial conflict of interest that may exist cannot influence the results of the verification activity. We expect that if an importer or its employee conducts a verification activity for a foreign supplier that is an affiliate, subsidiary, or parent company of the importer, there will be protections in place to ensure the integrity of the verification activity, including, for example, ensuring that the individual conducting the verification activity is not penalized for identifying food safety concerns. In addition, any payment for the verification activity cannot influence the results of the activity.

(Comment 219) One comment states that the independence provisions should only extend to employees related to a foreign supplier's business, marketing, and distribution because it would be too burdensome to expect an importer to know about any stockholding relationship, deals, or other potentially unethical practices.

(Response 219) We do not believe that the independence requirement is too burdensome. An importer could, for example, ask the qualified individual to attest to whether it has any financial interest in the foreign supplier and, if the qualified individual has one, take steps to ensure that any such interest does not influence the results of the verification activity. The final rule does not per se prohibit the qualified individual from holding any stock or having ever had any dealings with the entity that is the subject of the verification activities.

(Comment 220) One comment states that it is unreasonable to suggest any qualified auditor would not have an interest in the outcome or success of the activities of the supplier. Another comment states that because the activities of employees are influenced by their employers, there can be no assurance that the results of employee activities will be impartial.

(Response 220) We disagree. The relevant requirement in § 1.506(e)(4) is that payment of the qualified individual conducting a verification activity must not be related to the results of the activity. We believe this requirement is necessary to ensure the integrity of the performance of verification activities under this rule.

(Comment 221) Several comments ask that we make clear that the independence requirements would not exclude the use of first-party (internal) audits. One comment states that the regulations should not preclude a manufacturer from using its own qualified auditors from conducting onsite audits or using its qualified employees to conduct other supplier verification activities.

(Response 221) Under § 1.506(e)(4), the independence of qualified individual requirement does not prohibit an importer or its employees from conducting supplier verification activities. It does, however, prohibit a qualified individual who conducts any verification activities from having a financial conflict of interest that may influence the results of an audit or other verification activity. In addition, due to the potential for a conflict of interest, the final rule (in § 1.506(e)(2)(ii)) provides that importers may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities (except with respect to sampling and testing of food). A foreign supplier's audit of itself would therefore not be an appropriate verification activity under the regulation.

(Comment 222) One comment suggests that we not impose limitations

on use of second-party audits (*i.e.*, audits by an employee of a company conducting the verification activities).

(Response 222) To the extent that the comment is asking whether importers may use their own employees to conduct audits of foreign suppliers, this is permissible under the final rule.

(Comment 223) One comment suggests that we consider the conflict of interest provisions in the NOP regulations (7 CFR 205.501(a)).

(Response 223) The conflict of interest provisions in the NOP regulations are tailored to the concerns addressed in those regulations. We regard some provisions, such as 7 CFR 205.501(a)(11)(i), which mandates that a certifying agent not certify an entity if the certifying agent has held a commercial interest in the provision of consulting services, as similar to the requirement we are finalizing here. Many other provisions would not translate at all, *e.g.*, the requirement that a certifying agent must prevent conflicts of interest by not giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification (7 CFR 205.501(a)(11)(iv)). Having reviewed the conflict of interest provisions in the NOP regulations as the comment suggests, we continue to believe that our conflict of interest provisions are well suited for the FSVP regulation.

8. Food Stored for an Extended Time Before Export

In the preamble to the proposed rule, we requested comment on what foreign supplier verification activities might be appropriate for foods that are exported to the United States long after they are produced in a foreign country.

(Comment 224) Some comments state that no additional foreign supplier verification activities are necessary for specific products such as gelatin, which has a shelf life of about 5 years and as a result can be exported long after production. These comments recommend that FDA rely on safety procedures of foreign countries. Other comments see challenges with conducting certain verification activities, such as onsite audits, in situations when there is an extended delay between the production and export of a food. Some comments recommend that we understand different scenarios in which this may occur, stating that it will be easier to develop a procedure or recommend appropriate supplier verification activities once there is a better understanding of the specific circumstances.

(Response 224) As the compliance date for the FSVP regulation approaches, we expect that there will be discussion of scenarios in which different supplier verification activities will be appropriate. The final rule includes considerable flexibility for an importer to determine and conduct the supplier verification activities that are most appropriate given various factors related to the food and the supplier, in accordance with §§ 1.504, 1.505, and 1.506. Consequently, we conclude that it is not necessary to establish provisions specifically applicable to the importation of food stored for an extended period before export.

H. Foods That Cannot Be Consumed Without Control of Hazards and Foods Whose Hazards Are Controlled After Importation (§ 1.507)

In response to comments, we have included, in § 1.507 of the final rule, new provisions to address certain circumstances in which a hazard requiring a control is identified in a food but foreign supplier verification is unnecessary. These provisions in § 1.507 are consistent with similar provisions in the preventive controls regulations.

In response to the proposed rule, we received comments addressing a variety of circumstances under which the hazards in imported food typically are not controlled until after the food arrives in the United States. As discussed in section III.B.7 of this document, several comments request that we exempt from the FSVP regulation importers of certain RACs, in particular coffee beans and cocoa beans, which purportedly cannot be consumed without undergoing processing involving the application of controls that will address all hazards in the food.

Other comments relate to circumstances under which an importer's customer or a subsequent entity controls the hazards in an imported food. As stated in sections III.C.4 and III.E.8 of this document, we proposed to allow for certain alternatives to supplier verification when an importer's customer controlled a hazard in a food. Under proposed § 1.502(d), if an importer's customer was required to establish and implement a supply-chain program under the preventive controls regulations for a food that the importer imported, the importer would be deemed to be in compliance with most of the FSVP requirements if it annually obtained from the customer written assurance that the customer was in compliance with the supply-chain program provisions.

The proposed rule also included proposed provisions in § 1.504(g) regarding when an importer or its customer was controlling the hazards in a food in accordance with the preventive controls regulations but was not required to have a supply-chain program under those regulations (because the importer's preventive controls were adequate to significantly minimize or prevent each hazard, or because the importer relied on its customer to control a hazard and annually obtained written assurance of such control). Under proposed § 1.504(g), the importer in such circumstances would not be subject to the FSVP requirements for evaluating the food and foreign supplier (proposed § 1.505) or conducting supplier verification activities (§ 1.506). However, if the importer's customer controlled one or more hazards, the importer would be required to annually obtain from the customer written assurance that it was following procedures to significantly minimize or prevent the hazard.

We received several comments regarding the proposals to permit importers to obtain written assurance from a customer controlling a hazard in an imported food. Although there is general support for not requiring the importer to conduct supplier verification under these circumstances, many comments object to the proposed requirement to obtain written assurance from customers. Other comments raise concerns about what FSVP requirements should apply when an entity in the distribution chain beyond the importer's customer controls the hazards in the imported food.

In the following paragraphs, we respond to these comments and discuss the requirements under § 1.507 of the final rule applicable to importers of food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation.

1. Food That Cannot Be Consumed Without Application of Controls

(Comment 225) Some comments note that, in the case of the cocoa bean and coffee bean supply chains, the importer does not have a direct relationship with the thousands of farms (the foreign suppliers) involved in the production of the beans. Some comments ask for an exemption from supplier verification activities for foods such as cocoa and coffee beans because current distribution systems do not rely on the farms to control the hazards; instead, the hazards are controlled at the U.S.

processing facility for the beans, which may or may not be the importer.

(Response 225) We agree that an importer of a food should not need to conduct supplier verification when the importer knows that a subsequent entity in its distribution chain is controlling the hazard in the food. Moreover, the foods specifically mentioned by these comments, cocoa beans and coffee beans, are types of food that could not be eaten without processing that would control the typical hazards requiring a control. We believe there are few other foods in this category. Examples of such foods might include grains (for human consumption) and some RACs that are rarely consumed raw (again, as long as they are imported for human consumption). The FSVP regulatory text does not refer to RACs rarely consumed raw because “rarely consumed raw” is not the same as “could not be consumed without application of an appropriate control.” However, depending on the facility, the RAC, and the food produced by the manufacturer/processor, there may be some circumstances where a manufacturer/processor could determine that a particular RAC that passes through its facility could not be consumed without the RAC being processed to control any hazards. Because some or all of the important food safety risks will be controlled before these foods reach consumers, we do not believe it is necessary for importers to conduct the evaluation under § 1.505 or supplier verification under § 1.506 for hazards in these foods. Therefore, § 1.507(a)(1) of the final rule provides that an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if the importer determines and documents that the type of food (*e.g.*, RACs such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control for the hazard by an entity in the supply or distribution chain other than the importer.

2. Control of Hazards by an Importer’s Customer or Subsequent Entities in the Distribution Chain

(Comment 226) We received many comments objecting to our proposal to require importers to obtain annual written assurance from a customer controlling a hazard under either proposed § 1.502(d) or § 1.504(g). Some comments state that an importer may have so many customers that it would not be practical or reasonable to obtain written assurance annually from all customers. Other comments express concern that a customer may be unwilling to disclose confidential trade

secrets in order to identify in writing the procedures the customer has established and is following to control the hazard. Some comments state that an importer may not know the identity of all its individual customers, particularly if the importer sells its products to a distributor who then sells to other entities. Some comments oppose the written assurance requirement because they maintain that it does not contribute to safety given that it does not guarantee that the customer is actually doing anything to effectively minimize or prevent the hazard. Some comments ask that we delete the written assurance requirement because it raises the question of whether the importer must evaluate the adequacy of the customer’s procedures, and the importer might not have the capability to do this.

Other comments suggest that, if the final rule includes a written assurance requirement, one of the following time intervals that should be required to obtain the assurance:

- Every 2 years;
 - Every 3 years or when new information warrants; or
 - Only at the beginning of the importer-customer relationship.
- Some comments maintain that there should be a mechanism for when an importer’s customer’s customer (or a subsequent entity in the distribution chain) controls all the hazards in a food. Some comments suggest that this be addressed by requiring the importer to specify in contracts for sale that the ultimate purchaser must control all hazards before distributing the food to consumers. Some comments suggest that importers could be required to notify their customers of actual or potential hazards in the food that have not been controlled.

(Response 226) In consideration of these comments, we are establishing, in § 1.507, a series of provisions that relieve an importer from the requirements to conduct an evaluation of the food and foreign supplier under § 1.505 and supplier verification activities under § 1.506 when a subsequent entity in the importer’s distribution chain is controlling the hazard in a food. We conclude that compliance with certain requirements will provide adequate assurance that hazards in such food are being controlled by an entity in the importer’s distribution chain and will adequately inform entities in that distribution chain that the food requires a control. These requirements concern the following:

- Disclosure in documentation provided by the customer of an importer, to accompany the food, that the food is “not processed to control

[identified hazard]”, identifying a specific hazard or hazards (*e.g.*, *Salmonella*, *Listeria monocytogenes*) the importer has identified as requiring a control;

- Written assurances from the importer’s customer regarding appropriate processing of the food for safety; and
- Provisions holding the customer and subsequent entities in the distribution chain accountable for the written assurances.

These requirements vary based on whether the importer’s customer controls the hazard in a food (and, if so, whether the customer is or is not subject to the preventive controls regulations) or whether an entity subsequent to the customer in the distribution chain controls the hazard (and, if so, whether the subsequent entity is subject to the preventive controls regulations).

The first of these provisions, § 1.507(a)(2), addresses the situation in which an importer’s customer who is subject to the preventive controls regulations (for human or animal food) is controlling the hazard requiring control in a food. Under § 1.507(a)(2), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer who is subject to the preventive controls regulations to ensure that the identified hazard will be significantly minimized or prevented and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and
- Annually obtains from the customer written assurance, subject to the requirements of § 1.507(c), that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard. Under § 1.507(c), an importer’s customer or a subsequent entity in a food’s distribution chain that provides a written assurance under § 1.507(a)(2), (3), or (4) must act consistently with the assurance and document the actions it takes to satisfy the assurance.

The required disclosure regarding the lack of processing to control hazards is consistent with the suggestions of some comments. The disclosure documents accompanying the food could be the bills of lading or other papers, or disclosure might be made on the label of the food’s container.

Section 1.507(a)(3) of the final rule addresses the situation in which an importer’s customer is *not* subject to the preventive controls regulations (*e.g.*,

because it is a qualified facility or a retail food establishment). Under § 1.507(a)(3), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer who is not subject to the preventive controls regulations to provide assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

- Annually obtains from the customer written assurance, subject to the requirements of § 1.507(c), that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. Because the importer’s customer is not subject to the preventive controls regulations, rather than providing assurance that it is significantly minimizing or preventing a hazard (as required under § 1.507(a)(2)), it is appropriate for the importer’s customer to provide assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. These food safety requirements might include FDA’s food CGMP regulations in subpart B of part 117 or subpart B of part 507 (for qualified facilities), or applicable State or local food safety regulations (for retail establishments).

Section 1.507(a)(4) of the final rule addresses the situation in which an entity in the importer’s distribution chain beyond the importer’s customer is controlling the hazard in a food. Under § 1.507(a)(4), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer to provide assurance that the identified hazard will be adequately controlled by an entity in the distribution chain subsequent to the customer and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

- Annually obtains from its customer written assurance, subject to the requirements of § 1.507(c), that the customer will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is not processed to control an identified hazard. The importer must also obtain written assurance that its customer will only sell the food to another entity that agrees, in writing, that it will either: (1) Follow procedures

(identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the preventive controls requirements) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the preventive controls requirements); or (2) obtain written assurance from its customer similar to that which the importer’s customer must provide.

The final provision in § 1.507 applicable to control of hazards by entities in an importer’s distribution chain, § 1.507(a)(5), allows for the possibility that another approach could ensure the control of an identified hazard in a food. Under § 1.507(a)(5), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it has established, documented, and implemented a system that ensures adequate control, at a subsequent distribution step, of the hazards in a food it distributes, and the importer documents its implementation of that system. We do not have any examples of such a system, but we do not want to preclude the development or use of such systems. If an importer avails itself of this provision, we would evaluate its system during our inspection of the importer.

The provisions allowing for hazards to be controlled by an importer’s customer or an entity in the distribution chain subsequent to the customer accommodate the realities of modern food production. A food might pass through multiple entities in the distribution chain before a control is applied. However, the control must eventually be applied. Under § 1.507(c), the customer or a subsequent entity in the distribution chain for a food that provides a written assurance under § 1.507(a)(2), (3), or (4) must act consistently with the assurance and document the actions it takes to satisfy the written assurance. This requirement is supported by sections 701(a) and 805(c)(2)(B) of the FD&C Act, the latter of which provides that the FSVP regulations must include other requirements the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

In the preventive controls regulations for human and animal food, facilities may also rely on subsequent entities in their distribution chains to apply controls. Those provisions also provide for the combination of (1) disclosure of documentation to a direct customer that the food is “not processed to control

[identified hazard]”; (2) written assurances from the customer regarding appropriate procedures to ensure that the food will receive further processing for food safety; and (3) provisions holding the direct customer accountable for its written assurances. Under those regulations, a facility that provides the written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance. Because the preventive controls regulations hold the customer accountable for its written assurance, the FSVP regulation would not be ensuring that imported food is as safe as domestically-produced food if the FSVP provisions did not do the same.

When a hazard will not be significantly minimized or prevented by an importer’s customer but by some subsequent entity in the distribution chain, the importer’s customer must still pass forward documentation to that subsequent entity disclosing the need to control the hazard. The written disclosure must state that the food has not been processed to address the hazard identified as requiring a control. This requirement is supported by sections 701(a), 805(a)(1), and 805(c)(2)(B) of the FD&C Act. Ordinarily it is not apparent from visual examination of a food whether a hazard has been addressed. Consequently, without labeling, a subsequent entity in the distribution chain might not know that an entity upstream in the supply chain has not significantly minimized or prevented a hazard and is relying on a downstream entity to do so. Therefore, we conclude that information that food has not been processed to address an identified hazard is necessary for an importer to fulfill its obligations under section 805(a)(1) to perform risk-based verification activities to ensure that the imported food meets applicable food safety requirements. We also conclude that the disclosure requirement is consistent with section 805(c)(2)(B) because the preventive controls regulations include a comparable provision, and including this requirement in the FSVP regulation helps ensure that food imported into the United States is as safe as food produced and sold within the United States. In addition, the labeling is necessary for the efficient enforcement of the FD&C Act because labeling is critical for FDA to hold entities responsible for their obligations under this regulatory scheme. Further, when a hazard can cause a communicable disease, we conclude that the labeling requirement, in addition to the requirement that the importer’s

customer or subsequent entity act in accordance with the assurance, is necessary to prevent the spread of communicable disease from one State into another State and is therefore authorized under sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

The overarching goal of the § 1.507 provisions is to reflect that in modern supply and distribution chains, steps to ensure food safety can occur before an importer receives a food or after it distributes a food that it has imported. When those steps are all performed by a subsequent entity in the distribution chain, the requirements for an evaluation of the risk posed by the food and the foreign supplier's performance (under § 1.505), and for the conduct of supplier verification and related activities (under § 1.506), are unnecessary to ensure the safety of the food with respect to those hazards for the ultimate consumer.

These provisions reflect a balance of flexibility and accountability for ensuring the safety of such food. We continue to believe that annual written assurance from an importer's customer is an appropriate mechanism to ensure that its customer is aware of the hazard requiring a control and is taking responsibility for ensuring that the hazard is controlled. We believe that less frequent receipt of assurances would not provide an adequate level of monitoring or accountability. We do not believe that importers' customers or subsequent entities in the distribution chain will need to provide all details of their processes to state in writing the procedures used to control the hazard. For example, a customer could merely state that its processing includes a lethality step for microbial pathogens of concern. The specific assurances that are required when an importer's customer or a subsequent entity in the distribution chain is controlling a hazard are designed to be practical while helping ensure that an entity is held accountable for processing the food to make it safe for consumers. Of course, for any assurance to be meaningful, the importer must understand the substance of the assurance, which must address control of the hazards identified by the importer in accordance with § 1.504.

In response to the comment regarding what importers might need to do with written assurances (such as evaluate a customer's safety procedures), § 1.507 does not require importers to assess whether their customers are controlling hazards in accordance with the assurance they provide. Instead, we may, if necessary, rely on the requirement in § 1.507(c) that the

customer act consistently with the written assurance it provides (and document its actions) to determine whether an importer's customer or a subsequent entity in the distribution chain is in compliance with the requirements in this rule.

Section 1.507(b) of the final rule establishes certain requirements for the written assurances that are required under this section. A written assurance must include the following:

- The effective date of the assurance;
- The printed names and signatures of authorized officials of the entity providing the assurance; and
- The assurance required under the applicable provision of § 1.507(a).

(Comment 227) One comment expresses concern that proposed § 1.504(g) might create confusion regarding what entity is controlling a hazard in a food in circumstances in which imported food is repurposed (redirected to another use) as a result of quality rejection by the customer or for other reasons. To illustrate this, the comment states that an importer might purchase spinach from a foreign supplier to be used in its customer's canning process that includes a validated kill step to control microbiological hazards, but the spinach does not meet the customer's quality specifications. The comment suggests that the customer might repurpose the spinach for use in individually quick frozen (IQF) spinach or spinach dip, each of which is made without a validated kill step. The comment maintains that it is unclear how the importer can bear the responsibility to ensure that appropriate verification activities have been performed because it is likely to be unaware of the customer's repurposed use of the spinach. Alternatively, the comment states that if the customer was subject to supplier verification requirements under the preventive controls for human food regulation, it would need to go back to the importer to ensure that appropriate supplier verification activities had been conducted, resulting in multiple verification activities and processing delays leading to spoiled spinach. The comment therefore asks that we consider mechanisms that could support a requirement for consistent standards on entry of imported foods into the United States, such as creating a repository of audit reports, accessible by multiple importers, to allow sharing of audit costs and reports so that only one annual onsite audit of a foreign supplier is conducted.

(Response 227) We appreciate the safety and economic concerns associated with imported food that is

redirected for a purpose different from its original intended use. As discussed in section III.G.4 of this document, § 1.506(e) of the final rule allows multiple importers to rely on the results of an onsite audit of a foreign supplier, which has the potential to reduce supplier verification costs for both importers and suppliers. We also believe that the ability to import food in accordance with § 1.507(a)(2) when an importer's customer will significantly minimize or preventing the hazards in food could result in reduced burdens on importers because food and supplier evaluation and supplier verification activities are not required in such circumstances.

With respect to the comment's example of "repurposed" spinach, we note that if the importer's customer provided written assurance that it would significantly minimize or prevent biological hazards in the spinach in a canning process in accordance with § 1.507(a)(2), but instead used the spinach to make IQF spinach or spinach dip without significantly minimizing or preventing the hazard, the importer's customer would be in violation of § 1.507(c). However, the assurance requirement in § 1.507(a)(2) does not require that the customer provide assurance as to the specific food it will manufacture or process from the imported food. Instead, it requires that the customer provide assurance that it will significantly minimize or prevent the identified hazard in the food. It is likely that there is more than one way that the customer could act consistently with that assurance. If the customer determines not to manufacture/process spinach in the originally-contemplated canning process, there are likely other foods that the customer could manufacture/process using procedures that would significantly minimize or prevent the identified hazard. Assuming that occurs, there would be no violation of § 1.507(c).

(Comment 228) One comment asserts that the absence of a definition of "customer" could result in requiring an importer that sells food directly to consumers who are expected to cook the food to obtain multiple letters from consumers to comply the requirement in proposed § 1.504(g) to obtain written assurances that customers are controlling hazards. The comment suggests that we define "customer" as a business that purchases the imported food for further processing or distribution, as stated in the preamble to the proposed rule.

(Response 228) We do not believe that it is necessary to include a definition of "customer" in the FSVP regulation.

However, we agree that a “customer” under § 1.507 of the final rule is not an individual consumer of the food. Instead, a “customer” under § 1.507 is an entity that is subject to the preventive controls regulations or is otherwise subject to applicable food safety requirements (e.g., a retail food establishment or restaurant subject to State or local food safety requirements).

I. Corrective Actions and Investigations Into FSVP Adequacy (§ 1.508)

In § 1.507 of the proposed rule, we proposed that importers be required to review complaints of any customer, consumer, or other complaint to determine the adequacy of their FSVPs, conduct investigations into potential adulteration of the food they import, take corrective actions to address foreign supplier non-compliance, and investigate the potential inadequacy of their FSVPs and make modifications when appropriate. As discussed in the following paragraphs, we are making several changes to these proposed requirements. We also are renumbering this section to § 1.508 to accommodate other revisions to the codified provisions.

1. General Comments

(Comment 229) One comment agrees with the requirements in proposed § 1.507 but does not believe that the proposed rule would establish adequate regulatory oversight of importers.

(Response 229) Under § 1.508 of the final rule, importers will be required, under certain circumstances, to take corrective actions and investigate the adequacy of their FSVPs, which we believe will promote more robust and effective FSVPs. However, it is FDA’s responsibility to ensure that importers are in compliance with the FSVP regulation, and we intend to meet this responsibility by conducting regulatory inspections of importers and by providing guidance, outreach, and training to assist importers in meeting the FSVP requirements.

(Comment 230) One comment suggests that we use complaint and investigation data obtained from State and local regulatory agencies. The comment maintains that these agencies play an important role given the local intelligence they maintain and their work with consumer complaints and food product investigations.

(Response 230) We appreciate the significant role that State and local regulatory agencies play in ensuring food safety in the United States. We will continue to work and share data, including investigative and compliance data, with these agencies to help protect

the public health. The purpose of § 1.508, however, is to require importers to perform their own investigations and take their own corrective actions, rather than establish new procedures for FDA compliance and enforcement activities.

(Comment 231) Several comments contend that the recordkeeping associated with proposed § 1.507 would be substantially burdensome.

(Response 231) We do not agree that the recordkeeping requirements in § 1.508 will impose unreasonable burdens on importers. We believe that taking corrective actions is an important responsibility for importers and retaining records of these actions is essential to our ability to oversee importers. Nevertheless, because we are removing certain proposed requirements, as discussed in the following paragraphs, we have reduced the recordkeeping burden associated with § 1.508 of the final rule.

2. Review of Complaints

We proposed to require importers to promptly review any customer, consumer, or other complaint that the importer receives to determine whether the complaint relates to the adequacy of the importer’s FSVP (proposed § 1.507(a)).

(Comment 232) Although some comments support the proposed requirement to review complaints to determine whether they relate to the importer’s FSVP, several comments oppose the requirement or ask that it be modified. Some comments oppose a requirement to review complaints because complaint review is already part of reasonable business practice. Several comments maintain that the proposed requirement would be overly burdensome and that the time and effort to correlate complaints to the adequacy of FSVP would not be justified. Some comments maintain that a majority of complaints concern the quality, rather than safety, of food. Some comments claim that complaints are not always a strong indicator of problems and cannot be used to draw conclusions about the adequacy of an FSVP. Some comments suggest focusing on the importer’s program of review and corrective actions, rather than on individual complaints. One comment contends that the PRIA for the proposed rule does not reflect the complexity of a complaint review.

Some comments state that complaint review is required under the proposed FSVP regulation but not the preventive controls regulations. Some comments assert that the requirement to review complaints may be duplicative given the

reporting requirements related to the RFR.

Several comments suggest limiting the requirement to review complaints to those related to food safety. One comment asserts that complaints unrelated to food safety are not under FDA authority. One comment asks that importers be required to consider whether complaints relate to the adequacy of the FSVP only if specific facts suggest a potential relationship to supplied ingredients. One comment suggests limiting the sharing of complaints with FDA to emergency situations because this exchange could be counterproductive to importers’ proactive efforts to collect and react to complaint information.

(Response 232) We have removed the proposed requirement in proposed § 1.507(a) to review complaints. In the preambles to the proposed rules on preventive controls for human food and animal food, we requested comment on whether and how a facility’s review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards (78 FR 3646 at 3768; 78 FR 64736 at 64809, October 29, 2013). In the preventive controls final rules, we did not establish a requirement for a review of complaints as a verification activity. We determined that, although we agree that reviews of complaints occasionally do uncover food safety issues such as undeclared allergens, complaint reviews are more likely to be useful in providing information and feedback for continuous improvement of the food safety system rather than as a verification of preventive controls. We think that the same reasoning applies to the FSVP regulation.

In addition, removing the complaint review requirement is consistent with our intent, as stated in the FSVP proposed rule and Supplemental Notice, to coordinate the FSVP regulation with any supplier verification provisions that might be included in the regulations on preventive controls for human and animal food (78 FR 45730 at 45740; 79 FR 58574 at 58576 through 58577). As we said in the preambles to the final rules on preventive controls, we nevertheless encourage firms to review complaints as part of standard business practice.

3. Investigation

In proposed § 1.507(b), we proposed to require that, if an importer became aware that an article of food it imported was adulterated under section 402 or

misbranded under section 403(w) of the FD&C Act, either through review of a complaint or by other means, the importer would have to promptly investigate the cause or causes of such adulteration or misbranding and document the investigation.

(Comment 233) Some comments support requiring importers to investigate adulteration of food from foreign suppliers. However, some comments express concern that importers might not have the capacity to conduct an investigation. Some comments suggest limiting the requirement to conduct investigations to those that are related to food safety or, more specifically, to those related to adulteration or misbranding that might pose a risk to public health; the comments assert that not all adulterants pose a food safety risk.

(Response 233) We are deleting the requirement to conduct investigations when importers become aware that food they import is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. We believe that the obligation to respond to negative information about food safety is partly addressed in § 1.505(c)(1) of the final rule, which requires importers to reevaluate the risk posed by a food or a foreign supplier's performance when they become aware of new information about these factors. We believe that a requirement to conduct investigations as specified in proposed § 1.507(b) would be unnecessarily duplicative and would not substantially contribute to the public health. In addition, removing the investigations requirement in proposed § 1.507(b) is consistent with the goal of aligning the FSVP regulation with the supply-chain program provisions in the preventive controls regulations, which do not require investigations in the circumstances identified in proposed § 1.507(b). We note, however, that investigating potential adulteration to determine whether it poses a risk to food safety is prudent, and we encourage importers to undertake such investigations when appropriate.

4. Corrective Actions

We proposed, in proposed § 1.507(c), that importers be required to promptly take appropriate corrective actions if they determined that a foreign supplier of food they import did not produce the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produced a food that was adulterated under section 402 or misbranded under

section 403(w) of the FD&C Act (the standard for FSVPs set forth in FSMA and proposed § 1.502(a) of the FSVP regulation). We proposed that this determination could be based on an investigation into adulteration conducted under proposed § 1.507(b), the supplier verification activities the importer conducted under proposed § 1.506 or § 1.511(c), the FSVP reassessment conducted under proposed § 1.508, or otherwise. Proposed 1.507(c) further stated that the appropriate corrective actions would depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding had been adequately addressed. We further proposed to require that importers document any corrective actions taken in accordance with § 1.507(c).

To reflect changes we are making to other provisions in this final rule, we have revised the requirement to take corrective actions (§ 1.508(a) of the final rule). With respect to the basis for a determination that a corrective action is needed, we are replacing the reference to § 1.508 with a reference to § 1.505(c) to reflect the replacement of FSVP reassessment with reanalysis of the food and foreign supplier. We also are removing the reference to investigations conducted under proposed § 1.507(b) because we are deleting that provision. In addition, § 1.508(a) states that a determination that corrective action is needed could be based on a review of consumer, customer, or other complaints related to food safety. Under the proposed rule, such a determination could also have been based on a complaint, but given our decision to remove the requirement to review complaints, we conclude that it is appropriate to direct importers to the fact that complaints may serve as the basis of the determination. With all of these revisions, § 1.508(a) of the final rule states that a determination that a corrective action is needed could be based on a review of consumer, customer, or other complaints related to food safety, verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risk posed by the food and the foreign supplier's performance conducted under § 1.505(c), or any other relevant information the importer obtains.

(Comment 234) One comment asserts that, because not all adulterants cause an actual food safety risk, the requirement to take corrective actions should be limited to situations in which the foreign supplier's failure causes a risk to public health. Similarly, one

comment requests that the proposed requirement (in § 1.507(d)) to investigate to determine the adequacy of the importer's FSVP be limited to situations in which the foreign supplier's failure causes a risk to public health.

(Response 234) We decline to make changes in response to these comments. To the extent that the comments suggest that importers need not take corrective actions if they believe that the food they import does not cause a risk to public health, we note that section 805(a)(1) of the FD&C Act states that each importer must perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. If a food that an importer imports is adulterated or misbranded with respect to allergen labeling, not taking corrective action would be inconsistent with section 805(a)(1). However, the particular corrective action warranted could differ depending on the circumstances, including the level of risk to public health posed by the particular non-compliance. For example, if non-compliance could cause a serious risk to public health, we would expect an importer to stop importing food from that supplier until the non-compliance was corrected. However, we might not expect this type of corrective action when the non-compliance could be corrected through other measures. All corrective actions are relevant to decisions that an importer may need to make with regard to a supplier. If, for example, a supplier's facility has filthy conditions or the food it supplies is contaminated with filth, an importer may find it inappropriate to approve that supplier even though filth often does not pose a risk to public health.

(Comment 235) One comment maintains that RACs will already have been consumed before responsibility for non-compliance or adulteration can be assigned and corrective actions taken.

(Response 235) We do not agree that RACs in all cases will necessarily have been consumed before an importer has the opportunity to take corrective action. Regardless, under § 1.508(a) of the final rule, importers must promptly take whatever corrective actions are appropriate depending on the circumstances. In some circumstances, the appropriate corrective actions may prevent problems from recurring. For instance, in some cases the appropriate corrective actions might include discontinuing use of the foreign supplier until the cause or causes of non-compliance, adulteration, or

misbranding have been adequately addressed.

(Comment 236) Some comments object to the proposed requirement's reference to discontinuing use of a foreign supplier under certain circumstances, asserting that discontinuing use of a supplier is an extreme response that should be reserved for only the most serious situations. Some comments suggest that if the foreign supplier implements appropriate corrective actions following a nonconformance, the importer should be permitted to continue to source from that supplier.

(Response 236) We decline to delete the reference to possible discontinuation of use of a foreign supplier. Section 1.508(a) of the final rule does not specify conditions under which importers must cease using a foreign supplier; rather, it states that such action, even if only on a temporary basis, might be an appropriate corrective action under certain circumstances. We believe that some supplier actions, such as a failure to promptly or effectively respond to serious safety concerns identified in the food they have supplied, might warrant temporary or even permanent discontinuation of use of that supplier. However, we agree with the comments that responsive actions by a foreign supplier to address its nonconformance could make it unnecessary for the importer to discontinue importing food from the supplier.

(Comment 237) Several comments suggest that an importer's corrective actions need not necessarily require a physical visit to a foreign supplier.

(Response 237) We agree, and the final rule does not require that an importer visit the foreign supplier's establishment as part of any corrective action conducted under § 1.508(a).

(Comment 238) One comment recommends that actions taken to be removed from import alert be considered corrective.

(Response 238) We agree that actions taken to remove a foreign supplier from an import alert might be appropriate corrective actions under § 1.508(a), provided that those actions correct the underlying problem that precipitated the need for corrective actions under that provision.

(Comment 239) Some comments suggest we keep any information and dialogue concerning potential corrective actions confidential.

(Response 239) As discussed in section III.K.6 of this document, § 1.510(f) of the final rule states that records obtained by FDA in accordance with the FSVP regulation (which would

include documentation of corrective actions taken under § 1.508(a)) are subject to the public information regulations in part 20. The provisions in part 20 provide protections from public disclosure for trade secrets and confidential commercial information.

5. Investigations To Assess Adequacy of FSVP

We proposed to require, in § 1.507(d), that if an importer determines, by means other than the verification activities conducted under proposed § 1.506 or § 1.511(c) or the FSVP reassessment conducted under proposed § 1.508, that a foreign supplier of food does not produce food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act, the importer must promptly investigate to determine whether its FSVP is adequate and, when appropriate, modify the FSVP. We also proposed to require that the importer document any investigations, corrective actions, and changes to the FSVP that it undertakes in accordance with this requirement.

To reflect changes we are making to other provisions in this final rule, we have revised the requirement to investigate to determine the adequacy of FSVPs (§ 1.508(b) of the final rule). With respect to the means by which an importer might determine that a foreign supplier does not produce food in accordance with applicable requirements, we are replacing the reference to § 1.508 with a reference to § 1.505(c) (reevaluation of foreign supplier performance and the risk posed by a food).

6. No Limitation of Obligations

In the proposed rule, we proposed to specify (in § 1.507(e)) that § 1.507 does not limit an importer's obligations with respect to other laws enforced by FDA, such as those relating to product recalls. This provision is codified in § 1.508(c) of the final rule.

J. Identification of Importer at Entry (§ 1.509)

We proposed to require that FSVP importers be identified as the importer of the food that they bring into the United States when the food is imported or offered for import. Specifically, we proposed to require that, for each line entry of food product offered for importation into the United States, the importer's name and Dun & Bradstreet

Data Universal Numbering System (DUNS) number identifying the importer be provided electronically when filing entry with CBP. This proposed requirement was intended to ensure that food importers are accurately identified so that we can effectively implement and monitor compliance with the FSVP regulation in a risk-based manner.

In response to comments, we have replaced the proposed requirement that importers obtain a DUNS number and ensure that it is provided when filing entry with a requirement to provide the importer's unique facility identifier recognized as acceptable by FDA. However, as discussed in the following paragraphs, we anticipate that we will issue a guidance document that recognizes DUNS numbers as being acceptable to FDA. The final rule also adds a requirement to provide an electronic mail address for the importer as part of the identification at entry.

1. Provision of Importer's DUNS Number

We proposed to require importers to obtain a DUNS number from Dun & Bradstreet and to ensure, for each line of entry of food product, that the importer's name & DUNS number are provided electronically when filing entry with CBP. We proposed to require the use of a DUNS number because, as a numerical identifier assigned to a specific business location, use of the DUNS number would provide more accurate identification of importers than use of the firm's name and address. We requested comment on the proposed use of DUNS numbers to identify importers under the FSVP regulation as well as comments on the use of alternative identifiers.

(Comment 240) Some comments oppose this proposed requirement generally because they believe it is unnecessary or would not assist FDA in monitoring importers. One comment questions the need for the proposed requirement given Agency statements that it cannot inspect its way to food safety. Some comments oppose the proposed requirement because they assert that we already receive adequate information to establish the identity of the importer in accordance with the prior notice regulation.

(Response 240) We do not agree with the comments. Although the prior notice regulation requires the submission of the name and full address of the importer of a food (21 CFR 1.281(a)(12)), the entity named as the importer for prior notice might not necessarily be the importer of the food for purposes of FSVP, as the term

“importer” is defined in § 1.500. We agree that we cannot ensure the safety of food through our inspections alone, which is why Congress directed us to promulgate these regulations to require importers to conduct foreign supplier verification to ensure that the food they import is as safe as food produced in the United States. Although we cannot inspect each and every food product that is imported into the United States, we can use our authority under section 805 of the FD&C Act to help ensure that importers conduct appropriate foreign supplier verification activities.

We conclude that requiring importers (under § 1.509) to ensure that they are accurately identified at entry will help us efficiently and effectively ensure that importers are complying with the FSVP requirements. For example, we might use this information to create a comprehensive and up-to-date database that will allow us to efficiently and effectively identify and locate importers for inspection. At the same time, knowing the identity of importers will also help us carry out section 421(b) of the FD&C Act. This provision, also added by FSMA, requires FDA to allocate its resources for examining imported products based on certain risk factors, including the rigor and effectiveness of the importer’s FSVP. To effectively implement this provision, we need to know, at the time of importation, who the importer is. While we currently receive information identifying the importer through prior notice submissions in accordance with section 801(m) of the FD&C Act, the entities identified in prior notice submissions are not necessarily the importers for the purposes of FSVP, as discussed previously. Without information identifying the FSVP importer, we would be less equipped to account for the rigor and effectiveness of importers’ FSVPs in allocating our resources for examining food in accordance with section 421(b).

Finally, obtaining the identity of the importer at entry will likely help us meet the requirement, stated in section 805(g) of the FD&C Act, to “publish and maintain on [our] Internet Web site . . . a current list that includes the name of, location of, and other information deemed necessary by [FDA] about, importers participating under [section 805].” For all these reasons, the requirements regarding the identification of importers are consistent with sections 421(b), 805, and 701(a) of the FD&C Act, the last of which authorizes us to promulgate regulations for the efficient enforcement of the FD&C Act.

(Comment 241) Several comments oppose requiring importers to obtain a DUNS number to provide when filing entry of products. Some comments maintain that requiring use of the DUNS number would cause confusion and impose unnecessary costs and burdens on importers because other adequate or even superior means of importer identification exist, such as information required for CBP entry and prior notice. One comment states that the existing facility registration system is sufficient to meet FSMA’s directives, less burdensome, and more secure. One comment maintains that requiring use of DUNS numbers would cause importers to incur costs to create or modify their internal systems and relationships with brokers to establish a new numbering system and index the new identifier to the appropriate documents. Some comments express concern about FDA relying on a privately owned and operated system when government-issued numbers could serve the same purpose. Some comments question whether FSMA gives FDA legal authority to require importers to obtain a DUNS number. Some comments are concerned that requiring use of a DUNS number might raise security and fraud risks because a DUNS number would not have the same protections under the FOIA as an FDA registration number. Some comments express concern that the requirement would give the Agency access to importers’ business information in the DUNS database or otherwise lead to disclosure of confidential information (e.g., through erroneous designation of a company as the importer of a food).

Instead of, or as an alternative to, use of a DUNS number, some comments suggest that importers be allowed to use other identifiers, such as the following:

- The taxpayer identification number (TIN) used with CBP;
- The FDA facility registration number (if the importer is a registered facility);
- The form used to meet the prior notice requirements (modified to allow identification, where appropriate, of a U.S. agent or representative as the importer for FSVP purposes); or
- The CBP importer of record number.

Some comments suggest that instead of requiring identification at entry, we should require importers to register with FDA.

(Response 241) We conclude that it is necessary to establish, in § 1.509(a) of the final rule, an importer identification requirement specifically for the FSVP regulation to ensure that the identified importer at the time of entry is, in fact,

the “importer” of the food as defined in § 1.500 of the final rule. In addition, we conclude that use of a unique facility identifier, such as a DUNS number, is an appropriate mechanism for accurately identifying importers responsible for complying with the FSVP regulation because such identifiers provide unique identification numbers, which will allow us to efficiently and accurately identify importers. The DUNS number system, for instance, is an internationally recognized system that is updated on a regular basis and makes numbers available at no cost. DUNS numbers also provide for site-specific identification of business entities.

We conclude that use of FDA registration numbers would not be appropriate for FSVP importer identification purposes because not all “importers” under § 1.500 will necessarily be facilities required to register under section 415 of the FD&C Act. Likewise, not all importers under § 1.500 will necessarily be “importers of record” for purposes of CBP entry submissions and therefore will not necessarily have CBP importer of record numbers. Any other CBP-required identifying information also would not necessarily identify the FSVP importer because CBP requirements do not incorporate the definition of “importer” under § 1.500. We do not believe that revising the information required for prior notice would be appropriate because the prior notice regulation serves a different purpose than the FSVP regulation. For these reasons, we do not agree that using the alternative identifiers suggested by the comments would allow FDA to accurately identify FSVP importers. Consequently, they would not allow FDA to efficiently enforce section 805 of the FD&C Act in the ways described in response to the previous comments.

With respect to concerns about use of unique facility identifiers leading to the disclosure of confidential information or posing security risks, any confidential information that we obtain regarding importers would be subject to the applicable protections from public disclosure under part 20 of our regulations (see section III.K.6 of this document). Those protections include, among other things, exemptions from public disclosure for trade secret information and confidential commercial information (§ 20.61). As for concerns regarding security risks, we intend to take appropriate measures to secure all electronic data provided to the Agency, including data about the identification of importers.

For these reasons, we believe that requiring unique facility identifiers is the most appropriate way to accurately identify food importers for purposes of monitoring FSVP compliance. To provide additional flexibility beyond what we had proposed, the final rule does not require the submission of DUNS numbers for importers of foods offered for importation into the United States. Instead, it requires the submission of a unique facility identifier recognized as acceptable by FDA. We anticipate that we will issue guidance specifying which unique facility identifier or identifiers FDA recognizes as acceptable, and we expect to state that we recognize DUNS numbers as acceptable identifiers. Although we will allow importers to request the use of different identification numbers, it is possible that our information technology systems will not be able to accommodate any numbers other than those that we may specifically recognize as acceptable in guidance. If that is the case, we would have to manually review entry submissions that include alternate unique facility identifiers.

In addition to the importer's name and DUNS number, the final rule also requires that the importer's electronic mail address be provided as part of the identification at entry. This requirement follows from our request for comment on whether we should require the submission of any additional identifiers for importers. We believe that an electronic mail address is an appropriate additional identifier to require for importers, especially because electronic mail addresses allow for quick and efficient communications between FDA and importers. We anticipate that we might use the electronic mail addresses to notify at least some of the persons listed at those addresses that they have been identified as FSVP importers, including persons who have been designated as the U.S. agent or representative of a foreign owner or consignee for purposes of the definition of "importer." We also might use electronic mail addresses to communicate with importers more generally, including to help us resolve any questions regarding a food offered for importation to potentially facilitate review of that food. Requiring electronic mail addresses is thus grounded in the statutory objective of efficiently enforcing the food safety and FSVP requirements of the FD&C Act. By requiring electronic mail addresses for importers, we would be able to communicate efficiently and effectively with importers regarding their role

under the FSVP regulation and with respect to the food they offer for import.

(Comment 242) Some comments maintain that if an importer has multiple U.S. locations, it will only have a single DUNS number that will not provide information about the food's destination (*i.e.*, a specific importer facility). On the other hand, one comment maintains that having a different DUNS number for each corporate location would be confusing. Some comments suggest that, if we were to require importers to use DUNS numbers, importers should be allowed to use a single DUNS number (*e.g.*, for their corporate headquarters) even if they have multiple U.S. sites.

(Response 242) As discussed in the previous paragraphs, the final rule does not require that an importer's DUNS number be provided for each line of entry of food. Instead, it requires that a unique facility identifier recognized as acceptable by FDA be provided. However, we anticipate that we will issue guidance that will recognize DUNS numbers as acceptable. We understand that DUNS numbers are specific to physical locations; therefore, an importer with more than one physical location likely would have more than one DUNS number. In that circumstance, the importer should generally provide the DUNS number that applies to the location at which the importer retains its records of FSVP activities for the food for which it provides its DUNS number at entry under § 1.509(a), as that typically is the location that FDA investigators would need to visit to inspect the importer for compliance with the FSVP regulation. If an importer elects to retain its FSVP records for the food at its corporate headquarters, we would expect the importer to provide the DUNS number for its headquarters when it provides the information required under § 1.509(a).

(Comment 243) One comment, stating that FDA databases include multiple assigned numbers (*e.g.*, Central File Number (CFN), Firm Establishment Identifier (FEI)) for a firm due to slight changes in names and addresses and fraudulent or misguided submissions, recommends that we take steps to prevent the issuance of multiple DUNS numbers for the same importer.

(Response 243) We are unable to restrict importers' ability to seek DUNS numbers for multiple office or facility locations. However, as stated previously, we will expect importers to provide the unique facility identifier for the location at which the importer retains its FSVP records for the food for which it submits the unique facility identifier.

(Comment 244) Some comments express concern that the process of applying for and receiving a DUNS number can be lengthy and might delay imports.

(Response 244) We do not agree that the process of applying for whatever unique facility identifier that we recognize as acceptable will delay imports. With respect to DUNS numbers, although we understand that it might take up to 45 business days to receive a DUNS number (when obtained at no charge), importers will have more than a year (in some cases much longer) to come into compliance with the FSVP regulation, which will provide importers who do not currently have a DUNS number with ample time in which to obtain one.

(Comment 245) One comment states that there should be an affirmative requirement for the importer of record for a food to provide the name and DUNS number of the FSVP importer on its entry declaration, because the importer of record is responsible for the entry.

(Response 245) The final rule requires that the FSVP importer be identified at the time of entry, so the unique facility identifier for importers will be a mandatory data element in the entry filing process with CBP. However, because a food's importer of record might not necessarily be the food's FSVP importer, we do not think that the requirement to provide the unique facility identifier should fall to the importer of record. Instead, we believe that it is appropriate for the requirement to apply to a person who is subject to the requirements of the FSVP regulation. Depending on who files entry with CBP, an importer of record for a food may or may not be the FSVP importer. Of course, the FSVP importer of a food might arrange to have the importer of record for the food provide the FSVP importer's identification information at entry. In any case, it is the importer's responsibility to ensure that the information identifying the importer is provided at entry by some entity.

(Comment 246) Some comments assert that we should only require information on a line-entry basis when there is more than one importer for a shipment or when the CBP importer differs from the FSVP importer.

(Response 246) We do not agree. We conclude that FSVP importer identification is needed on a line-entry basis because importers are required to establish FSVPs for each food that they import from a particular foreign supplier, and obtaining importer identification information on a line-

entry basis will help us assess compliance with the FSVP requirements in order to efficiently enforce section 805 of the FD&C Act.

(Comment 247) Some comments request that we specify the data elements that will be required at entry, when they must be provided, and in what format. However, the comments ask that we provide this information in guidance rather than the final rule because information systems can change over time.

(Response 247) To the extent that the comments request that we use guidance to provide information on the details of the exact manner and format in which importer identification information should be provided, we agree. Section 1.509(a) of the final rule establishes the requirements that importers ensure that their name, electronic mail address, and unique facility identifier are provided electronically to CBP for each line entry of food product they import. We anticipate that we will provide more detailed formatting and other information through guidance.

(Comment 248) One comment requests that we specify what information will be publicly available under CBP's confidentiality provisions.

(Response 248) For information about the disclosure of records created or obtained by CBP and under the control of CBP, we suggest contacting CBP directly. However, we note that CBP regards confidential commercial information appearing on entry documents as exempt from disclosure under Exemption 4 of the FOIA (5 U.S.C. 552(b)(4)).

(Comment 249) Some comments express concern about the proposed requirement that the importer's name and identification number be provided electronically when filing entry. One comment asserts that this information might be "hacked" or fall into the wrong hands through error, creating a risk of adulteration or potential terrorist acts. One comment suggests that we permit importers to file FSVP information before filing entry with CBP as part of the prior notice form. The comment also urges us to provide timely admissibility determinations about imports shipped under FSVP; the comment maintains that importers often do not file the CBP entry summary until after the arrival of imported products, and release of goods might be delayed if importers must wait to file FSVP-required information. The comment suggests that early submission of FSVP information would give FDA and the importer more time to make admissibility determinations, resolve any perceived failures to comply with FSVP, and, if admission is refused, give

the foreign supplier more time to react to the delivery disruption.

(Response 249) We do not agree that there is any need to change the requirement that FSVP importers be identified electronically when filing entry with CBP. With respect to the concerns about information being "hacked," CBP's electronic filing system is a secure system and CBP takes adequate steps to address security. With respect to the request to permit importers to file FSVP information before submitting entry, we decline this request. We believe that the requirement to submit importer identification information at entry is consistent with the definition of importer in section 805(a)(2)(A)–(B) of the FD&C Act (*i.e.*, the U.S. owner or consignee of an article of food "at the time of entry of such article into the United States" or, if there is no U.S. owner or consignee at the time of entry, the "United States agent or representative . . . at the time of entry"). To ensure that the identified importer is the person who meets this definition, we believe it is appropriate to require that importers file their FSVP information at entry.

With respect to the request to permit importers to file FSVP information as part of the prior notice form, we similarly do not think that doing so would be appropriate. Some entities who submit prior notice information for a food might lack information about the FSVP importer of the food. As a result, we anticipate that there would be technical challenges to allowing the submission of FSVP information during prior notice that could lead to delayed entries. However, we note that because some entities may make a business decision to file prior notice with the entry, there may be some cases in which FSVP information is provided at entry at the same time that prior notice is submitted.

We also do not agree that it is necessary to make any changes to § 1.509 to account for the fact that some importers delay the submission of CBP entry summary information. Although it might be the case that importers often do not file the CBP entry summary until after the arrival of imported products, importers can file entry earlier if they desire. There is no requirement that importers wait until after the arrival of imported products to file entry with CBP. Further, we do not think filing of importer identification information under § 1.509 will ordinarily trigger entry delays.

(Comment 250) Some comments request that we provide guidance to clarify FDA's and CBP's regulatory requirements regarding importer

responsibilities. Some comments ask that we provide a technology platform for industry to use to comply with the importer identification requirements.

(Response 250) The FSVP draft guidance will advise importers on how they can ensure that their name, electronic mail address, and unique facility identifier are provided to CBP when a food is offered for importation in accordance with § 1.509(a).

2. Designation of U.S. Agent or Representative

We proposed to require (in proposed § 1.509(a)) that, before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of "importer" in § 1.500. As discussed in section III.A.13 of this document, we are adding a clarification to the definition of "importer" in § 1.500 stating that for the foreign owner or consignee of the article to validly designate a U.S. agent or representative for the purposes of the definition of "importer," the U.S. agent or representative's role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer for the purposes of the FSVP regulation.

(Comment 251) Some comments suggest that we should have a better database of designated U.S. agents (for FSVP purposes) than exists for U.S. agents named in foreign facility registrations.

(Response 251) Section 415(a)(1)(B) of the FD&C Act provides in relevant part that the registration of a foreign food facility must include the name of the U.S. agent for the facility. As we have discussed in connection with a proposed rule to amend the Agency's regulation on food facility registration, we have learned that in some cases persons identified as U.S. agents in foreign food facility registrations were unaware that they had been so identified, and had not in fact agreed to serve as U.S. agents for foreign food facilities (80 FR 19160 at 19169, April 9, 2015). To the extent that the comment is concerned about the accuracy of designations of U.S. agents who would serve as FSVP importers in accordance with § 1.500, we conclude that the clarification we are making to the definition of "importer" in § 1.500 adequately addresses this concern. Specifically, we conclude that the clarification that any designation of a

U.S. agent or representative as the FSVP importer must be confirmed in a signed statement of consent will help ensure that the U.S. agents or representatives who are so designated have in fact agreed to serve in that role. As discussed in section III.A.13, we might request the foreign owner or consignee that is exporting the food to provide us with the signed statement when and if any questions arise about whether the person designated as the U.S. agent or representative agreed to serve in that role. Although we do not plan to establish a separate database for U.S. agents and representatives responsible for functioning as FSVP importers, we will include these entities in the list of all importers subject to the FSVP regulations that we will maintain on our Web site in accordance with section 805(g) of the FD&C Act, as discussed in section III.J.3 of this document.

(Comment 252) One comment asks that U.S. agents and representatives of foreign owners be excluded from the requirement to identify the importer at entry because agents and representatives have limited information available to them.

(Response 252) We do not agree. Under section 805(a)(2)(B) of the FD&C Act, the importer of a food for purposes of meeting the FSVP requirements must be the U.S. agent or representative of the foreign owner or consignee of the food when there is no U.S. owner or consignee at the time of entry of the food into the United States. Foreign owners or consignees will need to ensure that the persons who agree to serve as their U.S. agent or representative for purposes of functioning as the FSVP importer have or can obtain the information and capability needed to meet their obligations as importers subject to the FSVP regulation.

3. FDA List of Importers "Participating Under" the FSVP Regulation

In the preamble to the proposed rule, we stated that obtaining the identity of the importer at entry could help us meet the requirement, in section 805(g) of FD&C Act, to maintain on our Web site a list of "importers participating under this section," *i.e.*, section 805 regarding FSVPs. We stated that the meaning of the phrase "importers participating under this section" was ambiguous (*e.g.*, it might refer to all importers subject to section 805 or only those importers in compliance with section 805), and we sought comment on the meaning of the phrase and the purpose of section 805(g).

(Comment 253) Some comments suggest that we identify all importers

that are subject to the FSVP regulation. Some comments agree that the meaning of the phrase "participating under this section" is ambiguous but suggest that we focus on only those importers that are in compliance with the FSVP regulation. These comments assert that such a list would be helpful to retailers and others who seek to source from or otherwise employ the services of such importers. Some comments maintain that although section 805(g) was intended to produce a comprehensive list of all importers, FDA's intended use of the list and its plans for maintaining an accurate database are ambiguous. Some comments request clarity regarding what other information about importers we will "deem necessary" under section 805(g). Some comments encourage us to comply with the statute in a manner that does not conflict with CBP's confidentiality regulations, allowing companies to continue protecting sensitive shipping details such as those concerning product sourcing and distribution.

Some comments oppose any listing of importers "participating under" the FSVP regulation. Some comments question the meaning of the phrase "importers participating under this section" and the purpose of the list. Some comments contend that this provision does not belong in section 805 because that section creates requirements for all importers; these comments argue that maintaining a list of importers would be a huge task that would serve no purpose. One comment contends that publishing a list of names and locations of importers appears to be in direct conflict with section 415(a)(5) of the FD&C Act, which exempts facility registration records from public disclosure. Some comments suggest that, before publishing a list of "participating" importers, we should seek clarification from Congress regarding the meaning of section 805(g), or ask Congress to either delete the requirement or move it to the FSMA provisions concerning the VQIP for food importers (set forth in section 806 of the FD&C Act).

(Response 253) In publishing the list of importers "participating" in FSVP, we intend to develop a list that includes importers who are subject to the FSVP regulation (and not exempt from the requirements under § 1.501 of the final rule). Although we agree that a list of importers deemed to be in compliance with the FSVP regulation might be of interest to the public, even importers that are the subjects of enforcement actions for non-compliance with the FSVP regulation are "participating" under the regulations, given that

importer compliance with the FSVP regulation is not voluntary. Moreover, maintaining a list of importers deemed to be in compliance with the FSVP regulation would impose a substantial burden on the Agency. Maintaining a list of importers that are subject to the FSVP regulation, however, would be more administratively manageable, especially because we will be able to use the importer identification information provided under § 1.509(a) to establish and maintain the list.

Besides the name and location of importers, we are uncertain what other information, if any, we will include as part of our list of importers subject to the FSVP regulation. We plan to continue to consider whether we should include any additional information in the list. We will maintain the list on our Web site in accordance with the applicable public disclosure requirements, including the requirements in part 20.

K. Records (§ 1.510)

We proposed several requirements concerning the manner in which FSVP records would be maintained and made available to FDA (proposed § 1.510). In response to comments received and to better align the FSVP records requirements with records provisions in other FSMA regulations, we have revised certain requirements regarding record availability (including offsite storage) and retention, and we have added provisions regarding electronic records, use of existing records, and public disclosure.

1. Records Content and Format

We received some comments of a general nature regarding recordkeeping requirements.

(Comment 254) Some comments suggest that FDA educate itself about the content and format of records that importers and foreign suppliers maintain; the comments state that we should take into account the use of different systems in different countries and not impose a single, restrictive reporting rubric. One comment asks that the records importers are required to keep be based on an importer's risk assessment and not be specified in the regulation.

(Response 254) As discussed elsewhere in this document, we are requiring that importers document certain determinations they make and actions they take to meet the FSVP requirements, including regarding hazard analysis, evaluation of the risk posed by a food and the foreign supplier's performance, and supplier verification. In several areas, such as

onsite auditing of foreign suppliers, testing of imported food, and review of foreign supplier food safety records, we conclude that it is appropriate to require the documentation of specific information to ensure that importers can adequately assess whether their suppliers are producing food consistent with the applicable requirements. In addition, importer maintenance of certain records containing information required under the regulations will help us determine whether importers are taking adequate measures to ensure that they import safe food. However, as stated in section III.G.6 of this document with respect to documentation of foreign supplier verification activities, the regulation generally does not specify a particular form or format for required documentation. In addition, § 1.510(e) of the final rule allows importers to use existing records if they contain the information required by this part (see the response to the following comment).

(Comment 255) Some comments suggest that FDA train its investigators to understand that there will be a wide range of documentation approaches importers take that should be viewed as acceptable. The comments maintain that importers should be allowed to document their program as a whole (e.g., using a tiered or matrix approach to assessing supplier and ingredient risk and determining the corresponding verification activities) rather than maintaining a separate file for each individual supplier or food. The comments assert that importers should not be required to keep a narrative file explaining their reasoning as to which verification activities are appropriate for each supplier and food.

(Response 255) As previously stated, the FSVP regulation generally does not require the use of specific formats for the information that must be included in required records. However, the regulation requires importers to conduct a hazard analysis for each type of food they import, evaluate the risk associated with each food and the foreign supplier's performance, and use that evaluation to approve their foreign suppliers and determine appropriate supplier verification activities.

Although importers may use a risk matrix or risk tier system to help them approve foreign suppliers and determine appropriate verification activities for particular foods and suppliers, importers must document, for each food and its foreign supplier, the evaluation of the food and the supplier and the determination of the appropriate type and frequency of supplier verification activities based on that evaluation. FDA investigators might

not be able to determine whether an importer had met these and other FSVP requirements for a particular food and foreign supplier simply by reviewing an importer's risk matrix or tier system, depending on the level of information and detail provided in the matrix or system. The maintenance of records on a food-and-supplier basis is essential to providing adequate assurance of the safety of foods obtained from each foreign supplier. This is especially important when an importer determines that a method other than annual onsite auditing can provide adequate assurance that SAHOCODHA hazards in food are significantly minimized or prevented.

However, on our own initiative to align the FSVP regulation with other FSMA regulations, we have added to the final rule provisions allowing importers to use existing records under certain conditions to meet FSVP requirements. Section 1.510(e)(1) of the final rule states that existing records (e.g., records kept to comply with other Federal, State, or local regulations) do not need to be duplicated if they contain all of the information required under the FSVP regulation for each food and satisfy the FSVP requirements, including, as described above, that the records are specific to each food. Section 1.510(e)(1) further states that importers may supplement existing records as necessary to include all of the required information and satisfy the FSVP requirements. In addition, under § 1.510(e)(2), importers are not required to keep required information in one set of records. If existing records contain some of the required information, any new information required by the FSVP regulation may be kept separately or combined with existing records.

2. General Requirements

We proposed, in § 1.510(a), that importers be required to sign and date records concerning their FSVPs upon initial completion and subsequent modification.

(Comment 256) Some comments support not specifying which particular qualified individual must sign the FSVP records.

(Response 256) We agree that it is not necessary to specify a particular qualified individual who must sign and date all FSVP records for the importer. However, the qualified individual signing a record on behalf of the importer must have the authority to do so and be qualified to review and assess what he or she is signing.

(Comment 257) One comment suggests that only certain records should have to be signed and dated;

these records would primarily be those concerning the following: compliance status review (a proposed requirement that we deleted in the Supplemental Notice); hazard analysis; supplier verification activities; complaint review, investigations, and corrective actions; FSVP reassessment; dietary supplements; and very small importers and very small foreign suppliers.

(Response 257) We do not agree. The comment did not provide a reason as to why the other records do not need to be signed and dated, and we conclude that to aid in accountability and the efficient enforcement of the requirements in section 805 of the FD&C Act, importers must sign and date all records required under the FSVP regulation.

(Comment 258) One comment asks that we state in guidance that electronic signatures are acceptable.

(Response 258) We agree that electronic signatures are acceptable provided the importer maintains a system for ensuring that the signatures are trustworthy. We discuss electronic records generally in section III.K.5 of this document.

On our own initiative, we have added to § 1.510(a), consistent with other FSMA regulations, a requirement that importers keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. We have also moved the proposed requirement that all records be legible and stored to prevent deterioration or loss from proposed § 1.510(b) to § 1.510(a) of the final rule.

3. Records Availability

a. Records in English

We proposed, in § 1.510(b), that importers retain records in English and make them available promptly to an authorized FDA representative, upon request, for inspection and copying.

(Comment 259) Some comments support the proposed requirement to retain records in English; however, most comments object to the proposal.

Several comments state that foreign supplier records and supplier audit reports usually are created in the native language of the foreign supplier, which often is not English, and some importers do not speak English as their first language. The comments maintain that a requirement to translate all such records into English would be costly, burdensome, and could lead to confusion and misunderstandings that could adversely affect food safety when records are created for the foreign supplier or others in a language other

than English. One comment states that the proposed requirement could mean that native-language speaking foreign suppliers would need to recruit dual-language speaking personnel so they could provide English language records to their importers, or it might require importers to enlist specialized resources to engage in translations. Some comments contend that the proposed requirement is not authorized by FSMA or the FD&C Act. One comment states that translation is not needed to allow FDA to use its resources wisely and conduct efficient investigations. Some comments contend that a requirement to maintain records in English would be inconsistent with industry standards such as those in the British Retail Consortium and Safety Quality Food schemes. Two comments suggest that because the official languages of the WTO are French, Spanish, and English, importers should be allowed to keep records in these languages.

Some comments request that the regulations specify which records must be maintained in English; a few comments suggest that any English requirement should apply only to records created by the importer.

Some comments maintain that the English requirement is unnecessary because some importers have personnel who understand the languages of their foreign suppliers. Instead of requiring that FSVP records be maintained in English, several comments suggest that the regulation require that persons reviewing records for the importer be able to understand the language in which the records were written, including documents written by a foreign supplier or an auditor of a foreign supplier in a language other than English.

Several comments suggest that, as an alternative to the proposed requirement that records be maintained in English, the regulation could require importers to translate records upon FDA request in a reasonable time.

(Response 259) Although existing FDA regulations (§§ 120.14(c) and 123.12(c)) require importers of juice and seafood to maintain records in English, we conclude that it is not necessary to include such a requirement in the FSVP regulation. Although we believe that having records in English would facilitate efficient FDA inspection of importer records, we believe that we can address most of the concerns related to the language of records through other requirements. First, because an importer would not be able to meet its FSVP requirements (e.g., hazard analysis, review of results of supplier verification activities) if it could not understand the

documents that it was reviewing, we have added a requirement, in § 1.503(a) of the final rule, that a qualified individual must be able to read and understand the language of any records that the qualified individual must review in performing activities to meet FSVP requirements.

Second, the final rule requires, in § 1.510(b)(1), that, upon FDA request, importers must provide within a reasonable time an English translation of records maintained in a language other than English. We believe that a “reasonable” time in which to provide translated records would depend on the volume of the records requested but should not be so long as to impair the Agency’s ability to conduct record reviews and follow-up enforcement activities. Without the requirement to translate records in a reasonable time, we would not be able to efficiently enforce section 805 of the FD&C Act.

b. Place of Business or Reasonably Accessible Location

We proposed that importers be required to maintain records at their place of business or at a reasonably accessible location; records would be considered to be at a reasonably accessible location if they could be immediately retrieved from another location by computer or other electronic means (proposed § 1.510(b)).

(Comment 260) Some comments suggest that importers should have the flexibility to store records at any reasonably accessible location, including where the records are created or at a corporate office, import team facility, or offsite facility. Some comments suggest that we align the FSVP regulation with the proposed requirement in the preventive controls regulations permitting offsite storage of records provided that the records can be retrieved and made available onsite within 24 hours of FDA request. These comments maintain that the proposed FSVP approach would be too limiting because it would require importers to store all paper records onsite for the entire retention period because offsite paper documents would not be immediately retrievable by computer or other electronic means. On the other hand, some comments suggest that we apply the term “immediately retrieved” in a practical manner to allow for an employee at another location being in a meeting at the time of a request, and ask that we modify the preventive controls provisions for consistency to provide further flexibility for the storage location. One comment states that, rather than requiring that records be immediately retrieved from another

location, there should be a specific, reasonable interval, such as within 5 business days, but in no case less than 1 business day.

(Response 260) We conclude that it is appropriate, under § 1.510(b)(2) of the final rule, to permit offsite storage of records (including records retained by other entities) if such records can be retrieved and provided by the importer onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location. We believe that this approach, which is consistent with the approach under the preventive controls regulations, gives importers the flexibility to store records at whatever location they deem suitable provided that any records stored offsite can be made available onsite within 24 hours.

(Comment 261) Some comments object to the proposed requirement that retrieval from an offsite location could only be achieved “by computer or other electronic means” because some offsite locations might not have adequate resources and the provision might inadvertently require expensive computer system validation.

(Response 261) We agree. The final rule does not specify the manner in which offsite records must be retrieved and provided onsite, only that the records must be provided onsite within 24 hours.

c. Sending Records to FDA Electronically

We proposed that importers be required, when requested in writing by FDA, to send records to the Agency electronically rather than making the records available for review at the importer’s place of business. On our own initiative, we have modified the requirement so that § 1.510(b)(3) of the final rule states that if requested in writing by FDA, an importer must send records to us electronically, or through another means that delivers the records promptly, rather than making the records available for review at the importer’s place of business. Allowing use of another means that delivers the records promptly provides additional flexibility for all importers in the records review process. We also note that for records that will need to be translated into English, we expect to receive such records promptly after the reasonable time needed for translation.

(Comment 262) Several comments oppose the proposed requirement to send records to FDA electronically upon request. Some comments maintain that neither FSMA nor the FD&C Act (including FDA’s authority to issue

regulations for the efficient enforcement of the FD&C Act under section 701(a)) provides authority for the requirement and that such a requirement would be inconsistent with sections 414 and 704 of the FD&C Act. Some comments state that only one section of FSMA (section 808(c)(3)(B) of the FD&C Act) gives FDA remote records access; some comments contend that the proposed requirement would be inconsistent with FSMA's legislative history (because a similar requirement was included in a House of Representatives version of the FSMA legislation that Congress did not enact). Some comments maintain that the language of section 805(d) of the FD&C Act does not provide authority to require importers to send records to the Agency electronically because the provision only requires that records "be made available promptly" to an FDA representative. Some comments state that a requirement to submit records electronically would not be consistent with the HACCP regulation for juice or the proposed regulations on preventive controls or produce safety.

(Response 262) We disagree with the comments stating that FDA does not have the authority to require records to be sent to us electronically or through another means that delivers the records promptly upon request, as set forth in § 1.510(b)(3). Section 805(d) provides that FSVP records "be made available promptly to a duly authorized representative of the Secretary upon request." Section 805(c)(5)(B) states that the FSVP regulations must "include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States." Section 701(a) provides for the efficient enforcement of the FD&C Act. We conclude that we have the authority under these sections to require that records be made available to us electronically upon written request or through another means that delivers the records promptly. We conclude that this requirement is necessary for the efficient and effective enforcement of section 805 to ensure that importers are adequately verifying the safety of the food they import into the United States. It is important to note that the provisions in § 1.510(b)(1) and (2) describe FDA inspection of records at an importer's place of business, as authorized by section 805 and 701(a). Section 1.510(b)(3), however, provides an alternative means of efficiently reviewing records upon request—electronically or through another means that delivers the records to us promptly.

Several comments refer to the legislative history of FSMA and the "remote access" to records provisions that were included in a separate food safety bill, H.R. 2749, which was not incorporated into FSMA and was not ultimately enacted. The comments maintain that this legislative history indicates that Congress did not intend section 805(d) to mean that records could be reviewed electronically. S. 510, a separate bill with numerous distinct provisions, was passed by the Senate, enacted by both houses of Congress, and became FSMA. While H.R. 2749 does include specific provisions regarding "remote access" to records in certain circumstances, we conclude that the existence of the "remote access" provisions in that bill does not in any way indicate that Congress' decision to enact S. 510 was attributable to its disapproval of requests for records outside of the inspection context.

The decision to enact S. 510 could be attributable to any number of factors. Indeed, H.R. 2749 was a separate bill from S. 510 and differed in many critical respects. Although there is no mention of the term "remote access to records" in any section of S. 510, it is notable that H.R. 2749's section regarding imports did not refer to FSVP at all and consisted only of what became the VQIP program (section 806 of the FD&C Act). It is therefore impossible to draw the conclusion that, in enacting S. 510, Congress rejected the notion of FDA issuing written requests for FSVP records. Indeed, there is no evidence in the legislative record and no evidence provided by the comments that the "remote access" to records provision in H.R. 2749 was even a factor regarding which of the two bills would be enacted as FSMA. What actually occurred was the adoption of an entirely separate bill with many provisions that differed from H.R. 2749, including the requirements for foreign supplier verification.

We agree with the comments stating that the recordkeeping provisions in this rule differ from the recordkeeping provisions in FDA's HACCP regulations, the preventive controls regulations, and the produce safety regulation. Indeed, the difference is intentional. Unlike the recordkeeping provisions in those other regulations, the FSVP records requirements are designed to be specific to the imports context. As to the comments stating that the FSVP proposal is inconsistent with sections 414 and 704 of the FD&C Act, we disagree. We are not relying on those provisions as authority for the records requirements. In enacting section 805, we believe that Congress intended to provide FDA with a type of records

authority that is specific to the FSVP context. Consistent with that intent, we conclude that it is appropriate for the FSVP records provisions in this rule to differ from certain other Agency records provisions. We believe this is appropriate in light of the nature and purpose of FDA record review for the FSVP regulation. Our review of importers' FSVP records serves a distinct purpose from review of a manufacturing/processing facility's records in the context of an onsite inspection of activities at the facility. Importers do not necessarily manufacture, process, pack, or hold food. Instead, they must conduct activities to verify the food safety practices of their suppliers. The FSVP regulation requires that those verification activities be appropriately documented and that records be adequately maintained. Our enforcement of FSVP therefore ordinarily will not hinge on the observation of manufacturing/processing, packing, and holding activities. Rather, it ordinarily will be based on whether importers have conducted adequate verification activities, documented those activities, and maintained appropriate records. The nature of the FSVP requirements therefore allows us to more easily determine compliance by reviewing records. Thus, while several comments refer to being able to put records into context at a manufacturing location, § 1.510 refers only to the importer's FSVP records, and there might not be a manufacturing location to inspect for purposes of assessing FSVP compliance.

The fact that Congress did not intend to limit FSVP records requests to the context of onsite inspections is evidenced by comparing section 805(d) to other FD&C Act records provisions that clearly contemplate onsite inspections. For example, section 414(a)(2), which applies in certain circumstances involving use of or exposure to food of concern, specifies that each person to which the section applies "shall permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article" This is in contrast to the language in section 805(d), which states that FSVP records "shall be made available promptly to a duly authorized representative of the Secretary upon request." Notably, section 805(d) differs from section 414(a)(2) in that it does not refer to copying records, providing

access at reasonable times, or the presentation of credentials—all of which suggest that any records request be preceded by, or be part of, an onsite inspection. In contrast to the language in section 414(a)(2), the language in section 805(d) leaves flexibility regarding the conditions under which FSVP records requests are made.

In addition, section 808(c)(3)(B) regarding accredited third-party audits has a records provision distinct from that for FSVP, requiring accredited third-party certification bodies to “submit to the Secretary” regulatory audit reports and associated documents required under the third-party program. While one comment regards this as evidence that this is the only provision under which FSMA granted “remote records” access, we conclude that this language reflects the nature of audits conducted in accordance with the third-party certification rule and the fact that such audits are conducted by entities other than FDA, thus creating the practical necessity for regulatory audit reports to be submitted to FDA. It does not in any way suggest that Congress did not intend to authorize FDA to review FSVP records electronically or through other prompt means.

In addition, we believe that our records requirements are consistent with section 805(c)(2)(B), which provides that the FSVP regulations must include other requirements as we deem necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold in the United States. Providing records to us electronically or otherwise promptly upon our written request will help ensure that imported food is as safe as domestically-produced food because it will enable us to more efficiently review importers’ FSVP records. More efficient review of FSVP records will allow us to review more FSVP records than would otherwise be possible, which will help us ensure that more importers are importing food that meets U.S. food safety standards. More efficient review of records also will allow us to identify importers that have adequate FSVP records, as well as those that do not. Consequently, our review of FSVP records will help us target our inspection resources towards those importers that present a greater risk to food safety because their records are inadequate and/or raise concerns about compliance with other FSVP requirements. Conversely, our review of records will help us determine which importers present a lower risk because they have adequate records, therefore lessening the need for follow-up inspection. Importers we identify as

lower risk will therefore be less likely to be burdened by an FDA inspection.

The comments’ references to inconsistency with records requirements outside of FSMA, such as section 704 of the FD&C Act and the HACCP regulations, are similarly misplaced. We are not relying on our authority under section 704 to require access to FSVP records. That provision lays out the general parameters for an inspection of a “factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction.” Because FSVP importers do not necessarily manufacture, process, pack, or hold food, section 704 is not necessarily applicable to an FSVP importer and, unlike section 805(d), was not specifically designed to apply to access to records maintained as part of the FSVP program. Further, unlike a facility inspection, where a critical component of the inspection may be viewing the physical plant and observing the conditions in person, we often can evaluate an FSVP importer entirely by reviewing the records that the importer provides to us. Further, the HACCP regulations, like the preventive controls regulations, concern the control of hazards, and viewing records in the context of an onsite inspection of the HACCP processing facility where the actions described in the records occur is similarly important.

(Comment 263) Several comments contend that reviewing records remotely would constitute a significant change from current FDA practice of reviewing records onsite during inspections of regulated entities. The comments maintain that the Agency could not adequately understand importer records except in the course of an onsite inspection, when company experts can answer questions and records can be viewed in the context of the importer’s facility and operations. Some comments express concern that we might make unreasonable and burdensome demands for records, and that the requirement would create the potential for inadvertent disclosure of confidential commercial information and security breaches (including the potential for terrorist acts). One comment states that the proposed provision would essentially require importers to maintain all records electronically, which would be overly burdensome to small businesses. Some comments state that maintaining records submitted electronically would impose a significant burden on FDA. Some comments contend that the proposed

requirement would create the potential for fraud because unscrupulous companies might submit fraudulent records to the Agency.

(Response 263) We disagree with these comments. As previously discussed, the context of record review for the purposes of determining an importer’s compliance with the FSVP regulation can be quite different from a facility inspection. In many cases, depending on the type of importer, we might find that it is more appropriate to perform onsite record inspection, where an FDA official can have in-person, back-and-forth discussions with the importer, and § 1.510(b)(1) and (b)(2) contemplate this type of record review. But § 1.510(b)(3) allows the importer and FDA to avoid the burden of performing that onsite record inspection if it does not make sense given the context. For example, an importer who maintains all records electronically and travels between ports of entry without a traditional “facility” might benefit from the flexibility of being able to demonstrate compliance with FSVP by making records available to us electronically. We also disagree that importers will not be able to provide sufficient and appropriate context for records submitted electronically. Nothing prevents importers from providing explanatory information to accompany requested records or discussing the request by email or telephone. Moreover, because FSVP records will not necessarily address manufacturing/processing, packing, or holding activities that take place at the entity being inspected, we believe that the potential benefits of reviewing FSVP records onsite would be reduced.

We understand concerns that unreasonable demands for records might adversely affect both importers and the Agency. Our need to use our enforcement resources in a risk-based, efficient manner provides incentive for us to limit our requests to those records that will provide sufficient information about an importer’s level of compliance with the FSVP regulation. Targeting our record requests in this way should minimize the burden of these requests on individual importers and avoid unnecessary expenditure of Agency resources, enabling us to evaluate more importers for FSVP compliance.

We do not agree that it would be more likely for importers to maintain or submit fraudulent records if the records are submitted electronically. There have been times when we have encountered fraudulent records located at physical facilities. Although we understand concerns about the security of data submitted electronically to the Agency,

as well as concerns about confidential commercial information and terrorism, we will take appropriate steps to secure communications with importers and to protect any data we receive, whether submitted electronically or otherwise.

We agree with the comment stating that small businesses should not be forced to maintain electronic records, as this might be a disproportionate burden on these importers. For that reason, and to provide more flexibility in the review of records under the FSVP regulation, importers will not be required to provide records electronically to FDA. The final rule allows all importers, regardless of size, to either provide requested records electronically to us or use another means that delivers the records promptly. Therefore, there is no burden on small importers to maintain or make their records available electronically; they will be in compliance as long as they are able to send their records promptly.

4. Records Retention

Under proposed § 1.510(d), we proposed a two-part approach to the requirements for the length of time that records must be retained. For records that would be created and used for an extended or indefinite period, such as the hazard analysis that an importer conducts for a food or the procedures that an importer uses to determine appropriate supplier verification activities, we proposed that records be retained until at least 2 years after use of the records was discontinued (*e.g.*, because the importer no longer imported a particular food, no longer used a particular foreign supplier, or changed its FSVP procedures). For certain records that involved documentation of the implementation of procedures and determinations, such as the performance of supplier verification activities, corrective actions, and FSVP reassessments, we proposed that records be retained for a period of at least 2 years after the records were created or obtained (with certain exceptions). We stated that these proposed requirements were consistent with section 805(d) of the FD&C Act, which requires that FSVP records be maintained for a period of not less than 2 years.

(Comment 264) One comment maintains that some sections of the proposed regulation were not mentioned as having a records retention requirement and asks that we clarify the requirements. Some comments maintain that having two separate record retention specifications would be unnecessarily complicated and confusing. Instead, the comments suggest having the regulation require

that all records be maintained for 2 years after use of the records is discontinued. One comment states that this approach would be consistent with FSMA. One comment suggests that the phrase “after their use is discontinued” be modified because “their” might be seen as referring to use of the foreign supplier or use of the records. If the former, according to the comment this would mean that all records regarding use of the supplier must be kept until 2 years after the supplier is no longer used. However, the comment suggests that “their” should refer to the records, which would mean that importers would be required to keep records 2 years after use of those records was discontinued.

(Response 264) We agree that referencing records retained in accordance with specific sections of the FSVP regulations was unnecessarily confusing. However, we conclude that it is appropriate to distinguish records that are created and remain in use for an extended time (*e.g.*, records of procedures) from records that are created to document the performance of activities under established procedures and are not used on a continuing basis. Therefore, § 1.510(c)(1) of the final rule specifies that importers must retain FSVP records until at least 2 years after the importer creates or obtains the records. This requirement would apply, for example, to results of foreign supplier verification activities that the importer conducts (or obtains documentation of) and documentation of corrective actions taken. However, § 1.510(c)(2) states that importers must retain records that relate to their FSVP processes and procedures, including the results of evaluations and determinations the importer conducts, for at least 2 years after their use is discontinued (*e.g.*, because the importer no longer imports a particular food, no longer uses a particular foreign supplier, has reevaluated the risk posed by a food and the foreign supplier’s performance, or has changed its supplier verification activities for a particular food and foreign supplier). In other words, if the importer continues to rely on certain records to meet an FSVP requirement more than 2 years after the records were created or obtained, the importer must retain those records for at least 2 years after their use is ultimately discontinued.

As stated previously, section 805(d) of the FD&C Act mandates that FSVP records be maintained for a period of not less than 2 years, and § 1.510(c) reflects this statutory timeframe. We note that some food products are stored for longer than 2 years before they are

exported (but after they leave the foreign supplier). In such cases, relevant supplier verification activities (*e.g.*, onsite auditing) might occur long before the food is imported into the United States. Although not required by the final rule, it is good business practice for importers of these foods to retain the FSVP records for these foods at least until the foods are distributed in the United States.

As further discussed in section III.M.2 of this document, we conclude that it is necessary to include a specific requirement for records on which an importer relies to document its status as a very small importer (as defined in § 1.500) in accordance with § 1.512(b)(1) of the final rule. Therefore, § 1.512(b)(5)(iii)(C) specifies that records that an importer relies on during the 3-year period preceding the applicable calendar year to support its status as a very small importer must be retained for at least 3 years.

5. Electronic Records

We did not specify requirements for the retention of electronic records in the proposed rule. However, we received several comments regarding the potential application of the requirements for electronic records in part 11 (21 CFR part 11) to FSVP records.

(Comment 265) Several comments ask that we not apply the part 11 requirements to FSVP records. Several comments maintain that requiring importers to comply with part 11 would be costly, burdensome, and discourage the use of electronic records without significantly benefitting public health. One comment states that most electronic systems currently used by importers do not meet the stringent requirements of part 11 and would need to be recreated or redesigned at considerable expense if importers were required to comply with part 11. Some comments note that FDA exempted from part 11 electronic records established or maintained to satisfy the requirements of the Bioterrorism Act records regulation (21 CFR 1.329(b)). Some comments suggest that, rather than require compliance with part 11, the FSVP regulation should include more simplified, practical requirements to have appropriate systems to ensure the integrity and security of electronic records.

(Response 265) We agree that it would be unnecessarily burdensome to require that FSVP records meet the requirements in part 11. Therefore, § 1.510(d) of the final rule states that records that are established or maintained to satisfy the FSVP

requirements and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. Section 1.510(d) further specifies that records that satisfy the FSVP requirements, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. Consistent with these provisions, we are making a conforming change in part 11 to specify in § 11.1(l) that part 11 does not apply to records required to be established or maintained under the FSVP regulation, and that records that satisfy the requirements of the FSVP regulation, but that also are required under other statutory provisions or regulations, remain subject to part 11.

Although FSVP records are not subject to part 11, we will expect importers to maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

6. Public Disclosure

In the proposed rule, we did not specify requirements regarding the public disclosure of records created and retained to meet FSVP requirements.

(Comment 266) Several comments request that the regulations include provisions to protect FSVP records from public disclosure. The comments maintain that FSVP records will contain much commercially sensitive information and information that terrorists could use to overcome an importer's or foreign supplier's food defense measures. Some comments assert that the regulation should regard all information about foreign suppliers as confidential commercial information by default. Some comments assert that viewing and redacting FSVP records would overburden FDA FOIA staff and result in inadvertent disclosure of trade secrets and confidential information. Several comments ask that the regulation specify that FSVP records have the same level of protection from public disclosure under FOIA as juice and seafood HACCP records (which, under §§ 120.12(f) and 123.9(d), are exempt from disclosure unless previously disclosed or the records relate to a product or ingredient that has been abandoned and the records no longer represent a trade secret or confidential commercial or financial information). One comment states that it prefers the HACCP disclosure language to the provision included in the proposed regulation on preventive controls for human food, which

specifies that records are subject to the disclosure requirements in part 20.

(Response 266) We agree that many FSVP records retained by importers will contain confidential commercial information and trade secrets that will be exempt from public disclosure under current law. Therefore, § 1.510(f) of the final rule specifies that records obtained by FDA pursuant to the FSVP regulation are subject to the disclosure requirements under part 20. This means, for example, that certain information in records such as evaluations of foreign supplier performance and the results of onsite audits of suppliers likely would be exempt from disclosure under FOIA because, under § 20.61(b), such information is likely to be regarded as commercial or financial information that is privileged or confidential that is submitted or divulged to FDA and therefore not available for public disclosure under § 20.61(b) and (c).

We conclude that it is not necessary to use the disclosure provision contained in the HACCP regulations. The regulations in part 20 regarding public information apply to all Agency records, regardless of whether a particular recordkeeping requirement says so. In the case of the recordkeeping requirements for our HACCP regulations for juice and seafood, we framed the public disclosure provisions by providing specific details about how particular provisions in part 20 (*i.e.*, § 20.61 (concerning trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (concerning data and information previously disclosed to the public)) would apply to the applicable records because we recognized that such details were of particular interest to the regulated industries. In the case of the recordkeeping requirements for this rule, we framed the provisions regarding public disclosure by more broadly referring to all the requirements of part 20, consistent with our approach in the recently issued preventive controls regulations. For example, provisions such as § 20.20 (concerning the policy on disclosure of FDA records) apply to all records that we have in our system, including HACCP records, even though the HACCP regulations do not specify that this is the case.

(Comment 267) Several comments request that we train our investigators and staff regarding FSVP information that is confidential commercial information or trade secrets and therefore should be protected from disclosure under the FOIA.

(Response 267) We agree. We intend to include disclosure issues in the FSVP training that we will provide to Agency

investigators. We will evaluate the training currently provided to our FOIA personnel and, if necessary, make modifications to address FSVP records.

7. Relationship to Records Required Under Customs Regulations

(Comment 268) One comment asks whether any FSVP documents are considered "A1A" documents that must be maintained under CBP regulations, specifically 19 CFR 163.5(b)(2).

(Response 268) We encourage the commenter to contact CBP about whether and under what circumstances CBP regulations apply to FSVP documents.

(Comment 269) One comment asks whether FSVP documents will need to be accessible by entry number.

(Response 269) Documents that importers create and maintain to meet FSVP requirements, such as hazard analyses, evaluations of the risk posed by food and of foreign supplier performance, and documentation of supplier verification activities, will not have to be linked to a particular entry number for an imported food. However, FDA investigators might refer to entry documents for particular food products when requesting records concerning such products during an inspection to assess an importer's compliance with the FSVP requirements. (Comment 270) One comment recommends that FDA collaborate with CBP on the portion of the FSVP guidance that addresses importer identification at entry.

(Response 270) We intend to work with CBP on implementing the importer identification at entry provisions. We also intend to consult with CBP as appropriate in drafting FSVP guidance on compliance with these requirements.

L. Dietary Supplements and Dietary Supplement Components (§ 1.511)

We proposed to adopt modified FSVP requirements for dietary supplements and dietary supplement components in § 1.511 of the proposed rule. We noted that facilities making these foods are exempt from the preventive controls requirements in section 418 of the FD&C Act when the facilities are in compliance with statutory provisions concerning dietary supplement CGMP requirements (section 402(g)(2) of the FD&C Act) and adverse event reporting (section 761 of the FD&C Act (21 U.S.C. 379aa-1)). We stated that the proposed FSVP requirements for dietary supplements and dietary supplement components reflected the food safety regulations applicable to those products (*i.e.*, the dietary supplement CGMP regulation in part 111 (21 CFR part 111)), rather than focusing on

verification of hazard control, as we had proposed under the “standard” FSVP requirements.

1. Dietary Supplements for Further Processing

We proposed certain limited FSVP requirements for dietary supplements and dietary supplement components that will undergo further processing by the importer or its customer in accordance with certain dietary supplement CGMP regulations. We did this because we believe that the dietary supplement CGMP regulation, through its specification requirements, contains provisions that already require supplier “verification” tailored to dietary supplements. Specifically, these provisions require a dietary supplement manufacturer to verify that the ingredients they are using are identified properly, have the appropriate purity, strength, and composition, and do not contain contaminants that adulterate or can lead to adulteration of the dietary supplement. Therefore, imposing additional verification requirements under the FSVP regulation would be redundant and unnecessary.

Under proposed § 1.511(a), if an importer was required to establish specifications under § 111.70(b), (d), or (f) of the dietary supplement CGMP regulation with respect to a food and the importer was in compliance with the regulations for determining whether the specifications had been met, the only FSVP requirements that the importer would have to meet would be those concerning identification of the importer at entry and recordkeeping. Section 111.70(b), (d), and (f) concern specification requirements for (1) dietary supplement components, (2) dietary supplement labels and packaging that may come into contact with dietary supplements, and (3) products received for packaging or labeling as a dietary supplement and subsequent distribution, respectively.

We proposed (in § 1.511(b)) similar requirements for importers whose customer was required to establish such specifications and was in compliance with the regulations for determining whether the specifications were met, except that the importer also would be required to annually obtain written assurance that the customer was in compliance with those requirements. We tentatively concluded that these specification and verification provisions in the dietary supplement CGMP regulation would provide adequate assurances that the foreign supplier of the dietary supplement or dietary supplement component produced the food in compliance with the FD&C Act.

We also proposed that importers of dietary supplements and dietary supplement components acting in accordance with § 1.511(a) or (b) would not be subject to the proposed requirement to use a qualified individual to perform FSVP activities. As discussed in section III.D of this document, we conclude that it is appropriate to require these importers to use a qualified individual to perform the tasks required under these provisions.

Several comment express support for the proposed modified approach for dietary supplements and dietary supplement components under proposed § 1.511(a) and (b). However, as discussed in the following paragraphs, some comments suggest changes to the proposed requirements and some request that the FSVP regulation not include these requirements. In the final rule, we have removed the reference to § 111.70(f), as discussed in response to those comments in the following paragraphs.

(Comment 271) One comment suggests that, instead of referring to a “food” that is imported, § 1.511(a) and (b) should refer to a “food that is a dietary supplement or dietary supplement component . . . import[ed] for further manufacturing, processing, packaging, and/or labeling as a dietary supplement.”

(Response 271) We agree and have revised § 1.511(a) and (b) of the final rule accordingly, except that we have not included the suggested reference to labeling, consistent with our deletion of the reference to § 111.70(f) from those provisions.

(Comment 272) One comment objects to exempting from most FSVP requirements importers of dietary supplement components that are determined to meet specifications established by the importer in accordance with § 111.70(b). The comment maintains that conformance to specifications under § 111.70(b) would not provide adequate assurance that the component was in compliance with part 111 and not adulterated. The comment requests that importation of such dietary supplement components be subject to the standard FSVP requirements for conventional food.

(Response 272) We do not agree. Section 111.70(b) of the dietary supplement CGMP regulation and the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met are intended to ensure that:

- A component used in the manufacture of a dietary supplement has the proper identity;

- A dietary supplement manufactured using the component has the appropriate purity, strength, and composition; and
- The limits on the types of contamination that may adulterate or lead to adulteration of a finished batch of a dietary supplement are not exceeded.

To import a dietary supplement component in accordance with § 1.511(a) of the final rule, the manufacturer of a dietary supplement using an imported component will be required to determine whether the specifications for the component that the manufacturer has established under § 111.70(b) are met in accordance with §§ 111.73 and 111.75. We conclude that compliance by the importer/manufacturer with these CGMP specification provisions would provide adequate verification that the imported dietary supplement component was produced in accordance with the relevant CGMP requirements. We also note that, in addition to determining whether specifications for the dietary supplement component are met in accordance with §§ 111.73 and 111.75, the manufacturer of the dietary supplement using the imported component must comply with all other applicable CGMP requirements in producing the dietary supplement.

On our own initiative, to provide clarity we have added to the regulation references to the specific CGMP provisions (*i.e.*, §§ 111.73 and 111.75) concerning determination of whether established specifications are met for an imported dietary supplement or dietary supplement component.

(Comment 273) One comment objects to exempting from most FSVP requirements importers of dietary supplements for whose labels or packaging the importer has established specifications in accordance with § 111.70(d) and determines whether the specifications are met. The comment finds the reference to § 111.70(d) confusing. The comment maintains that the reference might suggest that FDA regards labels and packaging as food; if this is the case, the comment does not believe that confirming that those materials meet specifications would provide adequate assurance of their safe manufacture. On the other hand, the comment asserts that if the Agency does not regard labels and packaging as food, the reference to § 111.70(d) is misplaced because confirming that labels or packaging met specifications would not provide adequate assurance that the imported food was produced in compliance with U.S. law. The comment states that we should not

consider labels and packaging to be food and asks that we delete the reference to § 111.70(d) from proposed § 1.511(a) and (b).

(Response 273) We do not agree with the comment that the reference to § 111.70(d) in § 1.511(a) and (b) is inappropriate. Section 111.70(d) is relevant to the extent that it covers packaging that may come in contact with dietary supplements. The definition of food under the FSVP regulation includes food contact substances and § 111.70(d) refers to establishing specifications for packaging that may come in contact with dietary supplements. Section 111.70(d) specifies that packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement. This requirement makes the verification of specifications for these materials relevant for a dietary supplement manufacturer under § 1.511(a) and (b). The domestic manufacturer is responsible for appropriate labeling of the dietary supplement made from the imported component in accordance with its own obligations under part 111.

(Comment 274) Some comments oppose the proposed exemption from the standard FSVP requirements for importers of dietary supplements who, in accordance with § 111.70(f), establish specifications to provide assurance that the product they receive for packaging or labeling (such as bulk capsules or tablets) is adequately identified and is consistent with the purchase order, and who determine whether these specifications are met. The comments maintain that this provision would be inconsistent with FDA's statement, in the preamble to the final rule on dietary supplement CGMP (see 72 FR 34752 at 34851, June 25, 2007), that a firm that only packages and labels a product may rely on information about the content of the product that it receives from the manufacturer. The comments assert that under proposed § 1.511(a), an importer that packages or labels an imported dietary supplement would have no obligation to verify that the imported dietary supplement was produced in compliance with part 111. One of the comments contends that retaining the reference to § 111.70(f) in proposed § 1.511(a) and (b) would incentivize dietary supplement manufacturers to use foreign manufacturing followed by domestic labeling or packaging instead of having the complete manufacturing occur either inside or outside the United States.

(Response 274) We do not agree with the assertion in the comment that an importer that receives a dietary supplement from a supplier for packaging and labeling would not be obligated to verify that the imported dietary supplement was produced in compliance with part 111. We believe that this statement mischaracterizes the obligations that apply to a firm that packages and/or labels a finished dietary supplement to which § 111.70(f) applies. Section 111.70(f) applies when the product received by the packager or labeler has left the control of the person who manufactured the product. Although the packager/labeler does not manufacture the product, it is responsible for ensuring that the product it places into interstate commerce is not adulterated (see sections 402(g) and 301(a) of the FD&C Act). The specifications that a packager/labeler would establish under § 111.70(f) must provide sufficient assurance that the received finished dietary supplement product is adequately identified and is consistent with the purchase order (see 72 FR 34752 at 34844 to 34845). The level and nature of information a packager/labeler requires as "sufficient assurance" under § 111.70(f) may vary based, for example, on the finished dietary supplement and the supplier from which it is received.

The verification activities that a packager/labeler might conduct in accordance with § 111.70(f) may not need to include, for a given supplier, verification that the manufacturer of the dietary supplement complied with all applicable requirements related to the manufacture of a finished dietary supplement. However, the verification requirements contemplated by section 805 of the FD&C Act would require that level of verification of the manufacturer. Specifically, section 805(a)(1) of the FD&C Act requires importers of dietary supplements, like importers of all foods, to perform risk-based foreign supplier verification activities for the purpose of verifying that the food they import is not adulterated under section 402. For importers of dietary supplements, this means that they are required to perform supplier verification activities for the purpose of verifying that the dietary supplements they import are in compliance with section 402(g), which deems dietary supplements adulterated if they fail to meet the CGMP requirements established in part 111.

Given this potential difference in required verification activities, we conclude that it is not appropriate to apply the modified requirements in § 1.511(a) and (b) of the final rule to importers of dietary supplements who

establish (or whose customers establish) specifications under § 111.70(f) and ensure they are met. Instead, firms who import dietary supplements for packaging and labeling in the United States (by themselves or their customers) will need to comply with § 1.511(c) and verify that the imported product was produced in compliance with the applicable requirements of part 111 for the manufacture of the dietary supplement. These importers may be able to use documentation provided under § 111.70(f) (as well as §§ 111.73 and 111.75 regarding determination that specifications are met) to fulfill some of the requirements under § 1.511(c) (e.g., regarding the performance of supplier verification activities).

(Comment 275) Two comments request that we broaden proposed § 1.511(a) and (b) to include not just importers that are subject to, and in compliance with, the specified dietary supplement CGMP requirements, but also importers that are not required to comply with those requirements in manufacturing certain products but voluntarily do so. The comments maintain that some facilities that are not subject to part 111 choose to comply with the requirements in that part for various reasons (e.g., a facility that manufactures only dietary ingredients but does so in compliance with part 111 at the request of their customer or at FDA's recommendation). Therefore, the comments ask that we revise proposed § 1.511(a) and (b) to include importers who voluntarily comply with § 111.70(b), (d), or (f).

(Response 275) We decline this request. Attempting to enforce compliance with the dietary supplement CGMP regulation by firms that are not legally required to comply with the regulation could present problems for the Agency if we sought to take an enforcement action against an importer for failure to comply with § 1.511(a) of the final rule because we determined that the importer was not in compliance with § 111.70(b) or (d).

(Comment 276) One comment objects to the requirement in proposed § 1.511(b) that an importer of a dietary supplement or dietary supplement ingredient obtain written assurance of compliance when the importer's customer is required to establish specifications under § 111.70(b), (d), or (f) and the customer is in compliance with the requirements for determining whether the specifications are met. The comment maintains that the written assurance requirement would impose a significant burden on importers (because importers might have hundreds or even thousands of

customers) without protecting public health because importers would not be in a position to audit their customers or otherwise confirm their compliance with part 111. The comment suggests that the exemption from most of the FSVP requirements under proposed § 1.511(b) should apply if either of the following occurs:

- The importer annually obtains written assurance of its customer's compliance with § 111.70(b), (d), or (f) (as applicable); or
- The importer verifies (such as through publicly available information) that its customer manufacturers, packages, and/or labels dietary supplements and the importer provides a disclosure in labels or commercial documentation accompanying the dietary supplement or dietary supplement component stating that the food was not imported under the standard FSVP requirements and is intended only for use in the manufacture, processing, packaging, or labeling of dietary supplements in compliance with part 111 (except as may be allowed under the customer's food safety plan).

(Response 276) We decline to make the suggested change. We acknowledge that obtaining written assurance from the customer of compliance with the applicable specification requirements would provide less definitive assurance of the customer's compliance than some other measures (such as onsite auditing or review of records); however, annually obtaining the assurance would necessitate the importer's ongoing consideration of its customer's compliance status. On the other hand, the disclosure to the customer suggested by the comment likely would not communicate any additional information to the customer that the customer would not already have learned through providing the required assurance.

2. Other Importers of Dietary Supplements

For finished dietary supplements (packaged and labeled dietary supplements that will not be subject to further processing) and other dietary supplements not subject to proposed § 1.511(a) and (b), we proposed to establish FSVP requirements that were similar to the proposed "standard" FSVP requirements applicable to most imported foods. Under proposed § 1.511(c), if a dietary supplement was imported other than in accordance with proposed § 1.511(a) or (b), the importer would not be required to comply with the standard FSVP requirements concerning hazard analysis but it would

be required to comply with requirements concerning the following:

- Use of a qualified individual (proposed § 1.503);
- Evaluation of risks (except hazard analysis) (proposed § 1.505(a)(2) through (6) and (b));
- Certain supplier verification activities, including use of approved foreign suppliers, establishment of written procedures, and determination and performance of appropriate verification activities to provide adequate assurances that the foreign supplier produced the dietary supplement in compliance with part 111 (proposed § 1.511(c)(2) through (8));
- Complaint review, investigations, corrective actions (proposed § 1.507);
- FSVP reassessment (proposed § 1.508);
- Identification of importer at entry (proposed § 1.509); and
- Recordkeeping (proposed § 1.510).

The comments generally support the proposed FSVP requirements for finished dietary supplements and other dietary supplements not imported in accordance with proposed § 1.511(a) or (b). We respond to comments on these requirements in the following paragraphs. We also discuss the changes that we have made to these requirements in accordance with several changes to the standard FSVP requirements discussed previously in this document and the updated references to these other sections (and, as previously discussed, this provision now includes dietary supplements imported for packaging and labeling in the United States). Section 1.511(c)(1) of the final rule states that if the food imported is a dietary supplement and neither § 1.511(a) or (b) is applicable, the importer must comply with § 1.511(c) and the requirements in §§ 1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but is not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. In addition to the changes discussed in the following paragraphs, we have made minor wording changes to several subsections.

a. Evaluation for Supplier Approval and Verification

Proposed § 1.511(c)(1) specified that importers of finished dietary supplements would be required to comply with the requirements in proposed § 1.505 related to consideration of the entity that will control the hazards in a food and evaluation of the foreign supplier's performance (but not evaluation of the risk posed by a food, *i.e.*, the hazard

analysis). The applicable provisions of § 1.505 are now § 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d) rather than § 1.505(a)(2) through (6) and (b). The changes that we have made to § 1.505(a) concerning the factors for the entity controlling the hazards and foreign supplier performance, discussed in section III.F.1 of this document, are also applicable to importers of finished dietary supplements under § 1.511(c)(1) of the final rule.

b. Corrective Actions

Proposed § 1.511(c)(1) specified that importers of finished dietary supplements would be required to comply with the requirements in proposed § 1.507, including those concerning review of complaints, investigations, corrective actions, and modification of the FSVP (when necessary). As discussed in section III.I of this document, the section of the regulation regarding corrective actions, § 1.508 of the final rule, does not require importers to review complaints or conduct investigations into possible adulteration, and includes certain changes to the corrective action requirements. Finished dietary supplement importers will need to comply with these final provisions of § 1.508.

c. Identification of Importer at Entry

As discussed in section III.J of this document, we have revised the requirements related to importer identification at entry in § 1.509 of the final rule; these changes apply to the importation of finished dietary supplements under § 1.511(c)(1).

d. Recordkeeping

As discussed in section III.K of this document, we have revised several recordkeeping requirements in § 1.510 of the final rule; these changes apply to the importation of finished dietary supplements under § 1.511(c)(1) of the final rule.

e. Use of Approved Foreign Suppliers

Section 1.511(c)(2) of the final rule finalizes the proposed requirement to establish and follow written procedures to ensure the importation of dietary supplements from approved foreign suppliers (and in limited circumstances from unapproved suppliers) and codifies the requirements taken from revised § 1.506 that allow an entity other than the finished dietary supplement importer's foreign supplier to establish and follow such procedures, provided the importer reviews and assesses the other entity's procedures and activities (see the discussion of

these matters with respect to foods other than dietary supplements in section III.G.1 of this document).

f. Determination of Appropriate Foreign Supplier Verification Activities

Section 1.511(c)(4) of the final rule finalizes the requirement (in proposed § 1.511(c)(5)) to determine appropriate foreign supplier verification activities before importing a dietary supplement from a foreign supplier, as well as the frequency with these activities must be conducted. (We deleted the separate reference to the “purpose” of supplier verification activities stated in proposed § 1.511(c)(4)—*i.e.*, to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111—and added it to the provision requiring determination of appropriate supplier verification activities (§ 1.511(c)(4) of the final rule.) Section 1.511(c)(4) specifies that this determination must be based on the evaluation conducted under § 1.505, lists the possible appropriate verification activities, and permits the importer to rely on a determination of appropriate verification activities made by an entity other than the foreign supplier, provided the importer reviews and assesses the entity’s determination (see the discussion of these matters with respect to foods other than dietary supplements in section III.G.4 of this document).

g. Performance of Foreign Supplier Verification Activities

Section 1.511(c)(5) of the final rule finalizes the proposed requirement to conduct verification activities for foreign suppliers of finished dietary supplements. Among the changes to the verification activity provisions that match changes to proposed § 1.506 are the following:

- Section 1.511(c)(5)(i)(A)(2) specifies that when the foreign supplier of a dietary supplement is in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, an onsite audit of the supplier may consider the relevant laws and regulations of that country instead of the requirements of part 111.

- Section 1.511(c)(5)(i)(A)(3) specifies that if an onsite audit of a foreign supplier of a dietary supplement is conducted solely to meet the FSVP supplier verification requirements by an audit agent of a certification body accredited in accordance with FDA’s regulations on the accreditation of third-

party certification bodies, the audit itself is not subject to the requirements for audits conducted under those regulations.

- Section 1.511(c)(5)(i)(A)(5) broadens the scope of inspections on which an importer of a dietary supplement may rely instead of an onsite audit of the foreign supplier to include appropriate inspections for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal agencies (such as the USDA), and representatives of State, local, tribal, or territorial agencies, in addition to inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted (see the discussion of these provisions with respect to foods other than dietary supplements in section III.N of this document).

(Comment 277) One comment suggests that, instead of allowing an importer to rely on the results of an inspection of a foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted, the importer should be allowed to rely on the results of such an inspection conducted within “approximately” 1 year of when the audit would have been required. The comment maintains that it is not always possible to obtain audit documentation within an annual timeframe (asserting that it might take several weeks or more to obtain an updated certificate of compliance following completion of an audit).

(Response 277) We decline to make this change. We are concerned that extending beyond 1 year the time period for which an importer could rely on inspection results would substantially weaken the likelihood that those results would accurately reflect the foreign supplier’s current state of compliance with applicable regulations and therefore diminish the assurance of food safety that such inspection results might provide.

- Section 1.511(c)(5)(i) includes other relatively minor changes to the requirements for documentation of foreign supplier verification activities.

- Under § 1.511(c)(5)(ii) and (iii) of the final rule, an importer of a dietary supplement may rely on supplier verification activities conducted by an entity in its supply chain provided that it reviews and assesses the results of those activities. However, the importer may not rely on the foreign supplier to conduct these activities except with respect to sampling and testing of a dietary supplement.

h. Verification of Customers and Other Subsequent Entities

Section 1.507 of the final rule contains provisions regarding verification when an importer imports a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation. Section 1.511(c)(1) states that this section does not apply to dietary supplements. This is because § 1.507 is based on the hazard analysis performed by importers. Specifically, importers can only avail themselves of the distribution chain provisions in § 1.507 if they identify the specific hazards that require control, thus enabling them to ensure either that the food could not be consumed without the application of an appropriate control or that the hazard will be appropriately controlled after importation. Because the FSVP regulation does not require hazard analysis by importers of dietary supplements, the provisions of § 1.507 are not suitable for dietary supplements.

(Comment 278) One comment suggests that if we do not delete the proposed requirement to obtain written assurance from customers subject to certain dietary supplement CGMP requirements under proposed § 1.511(b), then proposed § 1.511(c) should specify that the requirements under that paragraph, rather than the standard FSVP requirements, will apply when an importer is “unable to obtain the required written assurance” from the customer.

(Response 278) Although we agree with the comment that an importer of a dietary supplement or dietary supplement component that fails to obtain written assurance from its customer in accordance with § 1.511(b) of the final rule would be subject to the requirements in § 1.511(c), we conclude that it is not necessary to change § 1.511(c) as requested. The FSVP draft guidance will reiterate that when a dietary supplement is imported and neither § 1.511(a) nor (b) is applicable (including because the importer elects not to annually obtain the appropriate written assurance from its customer), the importer must comply with § 1.511(c).

3. Mixed-Use Food/Drug Ingredients

(Comment 279) One comment asks that we exempt from the preventive controls regulations certain ingredients that are used in the manufacture of both food and drugs, and also asks that we establish separate modified FSVP requirements for these ingredients. The comment states that there are many ingredients that are used in the United States as conventional foods, dietary supplements, and drugs, and many ingredients that can be used as drugs in foreign countries but only as foods in the United States. The comment maintains that if an ingredient is made in compliance with the United States Pharmacopeia (USP)/National Formulary (NF) or other official monographs and internationally recognized drug CGMP standards, it would be superfluous for the facility to be required to comply with proposed subparts B and C of the regulation on preventive controls for human food (proposed part 117). (The comment suggests that we include in the preventive controls regulation a definition of “monograph ingredient,” defined as an ingredient that is allowed for food use in the United States, meets certain criteria related to compliance with certain official monographs, and is manufactured in accordance with certain pharmaceutical CGMP standards or guidelines.) The comment asserts that because the construction, equipment, recordkeeping, training, and quality control operations of an establishment making a “monograph ingredient” will already be conducted in a manner that meets or exceeds the standards for CGMP in subpart B of part 117, it would be unnecessary to require the establishment to comply with that subpart. The comment also asserts that hazard analysis and preventive controls requirements in subpart C of part 117 also should not apply to monograph ingredients because official monographs and pharmaceutical CGMPs already provide preventive controls for harmful contaminants in these ingredients.

The comment also requests that we establish separate modified FSVP requirements for monograph ingredients. These modified requirements, which would be mandatory for monograph ingredients used as a conventional food and optional for monograph ingredients used as a dietary supplement or dietary supplement component, would be tailored toward providing adequate assurances that the food is in compliance with the applicable monograph and/or that the monograph ingredient was produced in accordance

with the requirements of the applicable pharmaceutical CGMP standards.

The comment asserts that requiring manufacturers of “monograph ingredients” to comply with the preventive controls regulation and failing to adopt the comment’s suggested modified FSVP requirements for these ingredients would be inconsistent with U.S. obligations under WTO agreements. The comment also maintains that the suggested modified FSVP provisions would be consistent with the intent of Congress because they would help ensure that imported food is as safe as food produced in the United States and they take into account differences among types of imported food and their level of risk.

(Response 279) We are not responding to the comments suggesting revision of the proposed regulation on preventive controls for human food as those comments are beyond the scope of this rulemaking. We decline to establish separate FSVP requirements for “monograph ingredients” as defined by the comment. We do not believe that the proposed definition of “monograph ingredient” is feasible given its references to multiple and in some cases unspecified official monographs and CGMP standards and guidelines. In addition, because the FSVP regulation applies to importers of food, we conclude that it would not be appropriate to establish FSVP provisions that would require importers of certain products to conduct activities to provide assurances that the food is specifically in compliance with a pharmaceutical monograph and/or that the foreign supplier was in compliance with certain pharmaceutical CGMP requirements.

Importers of ingredients that are dietary supplements will be required to comply with § 1.511(c) of the final rule; importers of such ingredients that are dietary ingredients will be required to comply with the “standard” FSVP requirements. However, in either case, importers might be able to rely on records regarding conformance to a foreign country’s drug standards or compliance with a foreign country’s drug regulations if such records also contain the information required under § 1.511(c) or the standard FSVP provisions (as applicable). Those requirements are for verification of the same level of public health protection as required under part 111, not strict compliance with the regulation. In our records provision in § 1.510(e), we state that an importer does not need to duplicate existing records it has (*e.g.*, records retained to comply with other Federal, State, or local regulations) if

they contain all of the information required by the FSVP regulation, and that an importer may supplement any such existing records as necessary to include all of the required information. If, as the comment states, these products are produced at higher standards than the relevant FDA requirements, then it should not pose a significant burden to demonstrate that the relevant FDA standards are met using existing records.

With respect to the comment’s WTO-related assertion, we do not agree that our WTO obligations compel us to establish special FSVP requirements for producers of “monograph ingredients.” As we stated in the preceding paragraph, the FSVP requirements are to obtain assurances that the foreign supplier is producing food in compliance with processes and procedures that provide the same level of public health protection as required by the relevant FDA regulations. To the extent that the information regarding the production of foods in compliance with foreign pharmaceutical monograph specifications is relevant, importers may be able to use that information.

4. Dietary Supplements Regulated in Foreign Countries as Drugs

(Comment 280) One comment requests that we exempt from the dietary supplement CGMP regulation and subparts B and C of the preventive controls for human food regulation certain finished food products that are imported as dietary supplements but regulated as drug products in the countries in which they are manufactured. The comment also requests that we adopt separate modified FSVP requirements for these products. The comment proposes to call such products “foreign registered products,” which it proposes to define as products that are allowed for sale in the United States as dietary supplements and that meet the following criteria:

- The product is manufactured in a foreign jurisdiction and is registered as a drug product, medicine, therapeutic good, or natural health product by the government of that jurisdiction.
- The product complies with a standard setting forth required physical, chemical, and/or biological characteristics, including limits on any harmful contaminants likely to occur, such as a product registration, market authorization, or official monograph in a national pharmacopeia, codex, or formulary.
- The product is manufactured at a facility that is registered with FDA as a food facility and registered with the

government of the jurisdiction in which it is located, and the facility is regularly inspected for compliance with applicable CGMP requirements.

- The product is manufactured in accordance with one or more of several specified drug CGMP regulations or guidelines.

The comment states that many finished products imported into the United States as dietary supplements are regulated as drugs in their country of manufacture and generally must comply with an official monograph, product registration, or market authorization that sets forth required attributes, and must be manufactured under CGMP requirements. The comment contends that application of parts 111 and 117 (or equivalent foreign regulations) to suppliers of foreign registered products would pose a burden without any benefit because the standards and CGMPs applicable to these suppliers exceed the U.S. requirements for dietary supplements. The comment therefore maintains that importers of such products should have the option to verify the product against any applicable monograph, product registration, or market authorization and/or to verify the supplier's compliance with the applicable CGMP requirements, rather than its compliance with part 111 or 117 (or equivalent foreign regulations). The comment also asks that importers of foreign registered products be provided the option of complying with the FSVP requirements in proposed § 1.511 or complying with separate modified FSVP requirements tailored toward providing adequate assurances that the food is in compliance with the requirements of the applicable monograph, product registration, or market authorization and/or that the supplier is producing the product in accordance with the applicable CGMP requirements of the foreign jurisdiction.

The comment asserts that requiring manufacturers of "foreign registered products" to comply with the dietary supplement CGMP or preventive controls regulations, and failing to adopt the comment's suggested modified FSVP requirements for these products, would be inconsistent with U.S. obligations under WTO agreements. The comment also maintains that the suggested modified FSVP provisions for foreign registered products would be consistent with the intent of Congress because the provisions would help ensure that imported food is as safe as food produced in the United States and they take into account differences among types of imported food and their level of risk.

(Response 280) We decline to establish separate FSVP requirements for "foreign registered products" as defined by the comment for the reasons we stated in declining to adopt separate FSVP requirements for monograph ingredients. In particular, because the FSVP regulation applies to importers of food, we conclude that it would not be appropriate to establish FSVP provisions requiring importers of certain products to conduct activities to provide assurances that the food is in compliance with the requirements of an applicable pharmaceutical monograph, product registration, or market authorization and/or that the supplier is producing the product in accordance with the applicable drug CGMP requirements or guidelines. Importers of finished dietary supplements that are used as drugs in foreign countries will be required to comply with § 1.511(c) of the final rule. However, importers of such products might be able to rely on records of conformance to drug standards or compliance with other drug regulations if such records contain the information required under § 1.511(c) or the standard FSVP provisions (as applicable). In the FSVP draft guidance, we intend to address how importers of such products might use information related to foreign supplier compliance with drug monographs, product registrations, market authorizations, and drug CGMP regulations and guidelines to meet their FSVP requirements.

For the reasons stated in our response to the comment regarding "monograph ingredients," we do not agree that the failure to adopt the suggested modified FSVP requirements for so-called "foreign registered products" would be inconsistent with U.S. obligations under WTO agreements.

5. Location of FSVP Regulations Applicable to Dietary Supplements

In the proposed rule, we sought comment on whether we should add the proposed foreign supplier verification requirements applicable to dietary supplements to the regulation on dietary supplement CGMP in part 111, rather than include them in the FSVP regulation in subpart L of part 1.

(Comment 281) Two comments support including the FSVP requirements for importers of dietary supplements in the FSVP regulation because they believe that the FSVP regulation should be comprehensive, but they suggest that the dietary supplement CGMP regulation include a reference to the FSVP requirements applicable to dietary supplement importers. Two comments suggest that

taking the opposite approach would facilitate clarity and compliance with the requirements for verification of foreign suppliers of dietary supplements.

(Response 281) We conclude that it is appropriate to locate the FSVP requirements applicable to importers of dietary supplements and dietary supplement components in the FSVP regulation in part 1, subpart L, in part because the requirements for the importation of finished dietary supplements in § 1.511(c) are very similar to the "standard" FSVP requirements and include cross-references to some of those requirements. However, we are adding, to § 111.5 in the dietary supplement CGMP regulation, a statement that importers of dietary supplements and dietary supplement components can find the FSVP requirements in part 1, subpart L.

M. Very Small Importers and Importers of Food From Certain Small Foreign Suppliers (§ 1.512)

In the proposed rule, we proposed modified FSVP requirements for importers that are very small importers and for importers of food from very small foreign suppliers. We proposed some changes to these modified requirements in the Supplemental Notice. An importer following the proposed modified requirements would still be subject to the requirements in §§ 1.502 (concerning the scope of an FSVP), 1.503 (concerning the use of qualified individuals), and 1.509 (concerning identification of the importer at entry), but it would not be required to comply with the proposed requirements in §§ 1.504 through 1.508 or § 1.510. This means that very small importers and importers obtaining food from very small foreign suppliers would not have to meet many of the standard FSVP requirements, including those for hazard analysis and supplier verification.

Under the proposed modified requirements, an importer would need to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign suppliers are producing food in compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. The written assurance would be required to include a brief description of the processes and procedures that the foreign supplier is following to ensure

the safety of the food. An importer would be required to promptly take appropriate corrective actions, as necessary, maintain relevant records, and make those records available to FDA upon request.

1. Modified Requirements for Very Small Importers and Importers of Food From Certain Small Foreign Suppliers

We received many comments both for and against the proposed modified FSVP requirements for very small importers and importers of food from very small foreign suppliers. As discussed in the following paragraphs, we conclude that it is appropriate to include in the final rule modified requirements for very small importers as well as for importers of food from certain small foreign suppliers. We are making changes to the proposed requirements in response to comments and to align with requirements applicable to the verification of certain suppliers of raw materials and other ingredients under the supply-chain program provisions of the preventive controls regulations.

(Comment 282) Some comments agree with the proposal to have modified requirements for very small importers and importers of food from very small foreign suppliers. The comments assert that applying special and fewer requirements to these entities would assist small businesses that create jobs and innovate without creating public health concerns. These comments argue that application of the detailed and technical requirements of the FSVP regulation would be overly burdensome for very small businesses given the administrative and related costs. Some comments state that FDA should recognize that the vast majority of recent foodborne illness-related public health incidents were caused by large U.S. companies, not small businesses or foreign suppliers of processed food.

Other comments object to the proposed modified requirements, asserting that food safety risks are not limited to any particular business size and that food produced by very small foreign suppliers or imported by very small importers could still be high risk. Some comments argue that no producer of food, whether foreign or domestic, should be exempt from good food safety practices. Some comments assert that inherent risk factors associated with smaller farms due to economic challenges increase the likelihood of food safety compliance problems. Some comments maintain that foods imported from very small operations have been the source of significant illness outbreaks in the past. One comment

points to spices in particular, arguing that a single very small supplier can have a huge negative effect on the food supply. Another comment argues that certain microbial contamination issues in imported food most likely would involve a very small importer or very small supplier. Some comments contend that the costs of outbreaks, including the costs associated with a loss of consumer confidence that are borne by firms not responsible for the outbreak, would be greater than the costs to very small foreign suppliers and very small importers of complying with the full FSVP requirements. Some comments assert that adopting FSVP requirements based on the size of the importer or foreign supplier, rather than the hazards in the imported food, might be inconsistent with international trade agreements.

Some comments express concern that a significant percentage of imported food would be eligible for the modified requirements under our proposed definitions of very small importer and very small foreign supplier. These comments cite the PRIMA of the original proposal, which estimated that 59 percent of processed food suppliers and 93 percent of raw produce suppliers would fall under the very small foreign supplier category.

Some comments maintain that the modified requirements should only be adopted if very small producers in the United States are treated in the same way. Other comments state that the definitions of very small importer and very small foreign supplier should correspond with the definitions of similar terms in the preventive controls regulations to align the requirements, comply with WTO obligations, and avoid confusion.

(Response 282) We agree with three main concerns expressed by the comments on very small importers and importers of food from very small suppliers. First, we recognize that some very small entities might have great financial difficulty complying with this rule. Second, while we recognize that small entities are not immune from food safety problems, their operations typically involve a relatively low volume of food, which, in most cases, should reduce consumers' exposure to, and thus potential risk from, such food. We are not aware of data conclusively demonstrating that small or large firms are more likely to be responsible for foodborne illness outbreaks. Third, we agree that the scope of any modified FSVP requirements for very small entities should align with the scope of modified requirements under the supply-chain program provisions of the

preventive controls regulations, to the extent appropriate and feasible.

With respect to the comments concerning the consistency of the modified requirements with U.S. international obligations, we believe that the requirements are proportionate to the risk posed by food imported by or from these smaller entities but will still provide adequate assurances of the safety of the food, and therefore are consistent with our international trade obligations. We also conclude that aligning the FSVP and preventive controls regulations to the extent feasible and appropriate regarding food from small suppliers helps provide parity in supplier verification requirements for domestic and foreign food producers and is therefore consistent with the national treatment provisions in international trade agreements to which the United States is a party.

In response to comments, we are finalizing modified requirements for certain very small entities, but we are changing the scope of the entities to which the modified requirements will apply. As discussed in section III.A.23 of this document, we have changed the definition of very small importer to better align with the definitions of very small business under the regulations on preventive controls for human food and for animal food.

In addition, we are convinced by the comments to reconsider whether all food from "very small foreign suppliers" as we defined the term in the Supplemental Notice (*i.e.*, suppliers with less than \$1 million in annual food sales) should be eligible for modified requirements. We agree that making a large percentage of imported produce not subject to the full FSVP requirements by adopting such a definition would be concerning. We also recognize that the produce safety regulation excludes from coverage farms with \$25,000 or less in annual produce sales (while also providing for qualified exemptions in certain other circumstances), which is clearly a lower monetary ceiling than the proposed \$1 million ceiling for very small foreign suppliers.

In addition, we note that there is no analogous "very small supplier" category in the supply-chain program provisions of the preventive controls regulations. However, those regulations include modified supplier verification requirements (in §§ 117.430(c), (d), and (e) (for human food) and 507.130(c), (d), and (e) (for animal food)) applicable to raw materials or other ingredients from the following suppliers (both domestic and foreign):

- Qualified facilities;
- Farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) (the farm has 3-year average annual produce sales of \$25,000 or less) or in accordance with §§ 112.4(b) and 112.5 (the farm satisfies the requirements for a qualified exemption under the produce safety regulation and associated modified requirements in § 112.6); and

- Shell egg producers not subject to part 118 because the supplier has fewer than 3,000 laying hens.

In each case, the underlying food safety regulations (*i.e.*, the regulations on preventive controls, produce safety, and the production, storage, and transportation of shell eggs) exclude or provide modified requirements for entities based at least in part on their size. To verify such suppliers, the receiving facility must obtain written assurance, at least every 2 years, of the supplier's compliance (or acknowledgement that it is subject to the adulteration provisions of the FD&C Act). The verification requirement varies depending on the type of small supplier as follows:

- Written assurance from a qualified facility must attest to the facility's compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States), and the assurance must include either a brief description of the supplier's preventive controls for a hazard or a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

- Written assurance from a farm that grows produce and is not a covered farm in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, or a shell egg producer with fewer than 3,000 laying hens, must attest that the farm or shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

In addition to these modified requirements for supplier verification activities, receiving facilities obtaining raw materials or other ingredients from these small suppliers are subject to other modified supply-chain program

requirements. Rather than having to conduct a full review of a supplier's performance in accordance with § 117.410(d)(1)(iii) or § 507.110(d)(1)(iii), these receiving facilities need only consider the small supplier's compliance history under § 117.410(d)(1)(iii)(B) or § 507.110(d)(1)(iii)(B). However, these receiving facilities still must approve these suppliers and include them in the procedures the receiving facilities establish and follow to ensure that they obtain raw materials and other ingredients from approved suppliers (see §§ 117.420 and 507.120).

We conclude that the FSVP regulation should include analogous modified requirements for food imported from these same types of small suppliers. (In § 1.506(d)(4) of the proposed rule as revised by the Supplemental Notice, we had already proposed parallel provisions for food from certain small farms; we respond to comments on proposed § 1.506(d)(4) later in this section of the document.) Therefore, under § 1.512(a)(2) of the final rule, the FSVP regulation includes modified requirements for importers of food from the following small foreign suppliers:

- Qualified facilities under the regulations on preventive controls for human food or for animal food (§ 117.3 or § 507.3, respectively);
- Farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) (the farm has 3-year average annual sales of \$25,000 or less), or in accordance with §§ 112.4(b) and 112.5 (the farm satisfies the requirements for a qualified exemption under the produce safety regulation and associated modified requirements in § 112.6); and
- Shell egg producers that are not subject to part 118 because they have fewer than 3,000 laying hens.

For both human food (under § 117.3) and animal food (under § 507.3), a qualified facility is (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a "very small business," or a facility to which both of the following apply:

1. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

2. The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year

was less than \$500,000, adjusted for inflation.

For human food, under § 117.3, a very small business is a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). For animal food, under § 507.3, a very small business is a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale). More information about qualified facilities and very small businesses appears in the preventive controls final rules.

For produce, produce farms that are not "covered farms" under § 112.4 of the forthcoming produce safety rule have less than \$25,000 in annual sales averaged over the previous 3-year period, or satisfy the requirements for a qualified exemption in § 112.5 and associated modified requirements in § 112.6, based on average monetary value of all food sold (less than \$500,000) and direct farm marketing (during the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of the food sold to all other buyers). In the Supplemental Notice, we erroneously referred to these farms as farms "not subject to the requirements in part 112." While produce farms that make less than \$25,000 annually are not subject to the requirements in part 112, produce farms that satisfy the requirements for a qualified exemption are not subject to the full requirements of part 112, but they do have certain modified requirements that they must meet, as described in § 112.6. In the Supplemental Notice we further erroneously described the types of farms that are not subject to the requirements in part 112 under § 112.4 as including farms that do not grow and harvest "produce" and certain farms that grow and harvest produce that is not covered under the proposed produce safety regulation (*i.e.*, produce that is rarely consumed raw and produce for personal consumption or consumption on the farm). Although the produce rule does not apply to food from such farms, § 112.4 does not establish this. Rather, §§ 112.3 and 112.2 of the produce safety

final rule define what constitutes produce and specify what produce is not covered by part 112, respectively.

For shell eggs, we considered the regulations on production, storage, and transportation of shell eggs in part 118. Section 118.1(a) states that the regulations in part 118 apply only to shell egg producers with 3,000 or more laying hens at a particular farm that do not sell all of their eggs directly to consumers and that produce shell eggs for the table market. Therefore, any shell egg producer with fewer than 3,000 laying hens is not subject to the requirements in part 118. The reasoning behind this cutoff, that producers with fewer than 3,000 layers do not contribute significantly to the table egg market (see the final rule on the production, storage, and transportation of shell eggs, 74 FR 33030 at 33036, July 9, 2009), is consistent with our basis for establishing modified requirements when suppliers are farms that are not covered farms under the produce safety regulation or qualified facilities under the preventive controls regulations. As a result, we are including shell egg producers with fewer than 3,000 laying hens among the small foreign suppliers from which an importer could import food subject to the modified requirements in § 1.512.

As with the importation of food by very small importers, we conclude that modified FSVP requirements are appropriate for the importation of food from these small foreign suppliers because they provide a relatively low volume of food imported into the United States, resulting in less consumer exposure and potential risk. To align the FSVP regulation with the supply-chain program provisions of the preventive controls regulations, the modified requirements in § 1.512 include certain different requirements for importers of food from the specified small foreign suppliers compared to the requirements for very small importers.

One such difference concerns the applicable standard of compliance for written assurance from the foreign supplier. Under § 1.512(b)(3)(i) of the final rule, a very small importer must obtain written assurance, before importing a food and at least every 2 years thereafter, that its foreign supplier is producing the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act. However, consistent with the analogous

requirements in the supply-chain program provisions of the preventive controls regulations, importers of food from small foreign suppliers must obtain written assurances as follows:

- If the foreign supplier is a qualified facility as defined by § 117.3 or § 503, the written assurance must attest that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either (1) a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food or (2) a statement that the supplier is in compliance with State, local, county, tribal or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries (§ 1.512(b)(3)(ii)).

- If the foreign supplier is a farm that grows produce and is not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the written assurance must attest that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) (§ 1.512(b)(3)(iii)).

- If the foreign supplier is a shell egg producer that is not subject to the requirements of part 118 because it has fewer than 3,000 laying hens, the written assurance must attest that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) (§ 1.512(b)(3)(iv)).

We believe that these requirements for supplier verification appropriately reflect the laws and regulations applicable to the relevant type of foreign supplier in the different circumstances, such that the specified foreign suppliers need only provide assurances that their food is in compliance with, or is subject to, applicable food safety requirements. With respect to the written assurances from certain farms that are not covered farms (as specified in § 1.512(b)(3)(iii)) and shell egg producers with fewer than 3,000 laying hens, we believe that the

acknowledgement that the producer's food is subject to the adulteration provisions of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) provides adequate and proportional assurance of safety given the lower risk to U.S. consumers posed by the lesser volume of food from such suppliers. Any business that introduces food into interstate commerce, including these small suppliers, is subject to the prohibited acts provisions in section 301 of the FD&C Act and is accountable if it produces food that is adulterated under section 402. We therefore conclude that the written assurances required from such suppliers provide adequate assurance of safety while minimizing the burden that providing the assurances to importers may indirectly impose on these suppliers.

Consistent with these requirements, we have correspondingly revised the requirement (§ 1.512(b)(4) of the final rule) for a very small importer or importer of food from one of the specified types of small foreign suppliers to take corrective actions if the foreign supplier does not produce the food in accordance with the applicable standards just discussed to make clear that corrective action is only required if an importer determines that the foreign supplier of the imported food does not produce the food consistent with the assurance provided under § 1.512(b)(3)(i) through (iv).

Paragraph (c) of § 1.512 of the final rule sets forth certain requirements that apply to importers of food from the specified small foreign suppliers but not to very small importers. We believe that these provisions provide an additional level of food safety assurance that should be part of the standard operations for most food importers, except for very small importers. This approach to FSVP requirements for importers of food from certain small suppliers is consistent with the supply-chain requirements applicable to receiving facilities that obtain raw materials or other ingredients from these types of suppliers under the preventive controls regulations.

Section 1.512(c)(1)(i) requires that in approving foreign suppliers, importers of food from the specified small foreign suppliers must conduct (and document) a limited evaluation of a potential foreign supplier by considering the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those

regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety. Section 1.512(c)(1)(i) also states that the importer may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (a)(1)(iii)(C) (*i.e.*, a foreign supplier's food safety processes, procedures, and practices and its food safety history).

Section 1.512(c)(1)(ii)(A) requires the importer to promptly reevaluate the concerns associated with the foreign supplier's compliance history when the importer becomes aware of new information about the supplier's compliance history and to document the reevaluation. If the importer determines as a result of the reevaluation that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. However, § 1.512(c)(1)(ii)(B) requires that if, at the end of any 3-year period, an importer has not reevaluated the concerns associated with the foreign supplier's compliance history, the importer must reevaluate those concerns and take other appropriate actions, if necessary, and document the reevaluation and any subsequent actions taken.

The potential burden of reviewing a small foreign supplier's compliance history may be reduced because the regulation permits the importer to review another entity's evaluation or reevaluation of a foreign supplier's compliance history. Under § 1.512(c)(1)(iii) of the final rule, if another entity (other than the foreign supplier) has, using a qualified individual, performed the supplier compliance evaluation or the reevaluation, the importer may meet its requirements by reviewing and assessing the evaluation or reevaluation conducted by that entity. If an importer chooses to do this, it must document its review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

Under § 1.512(c)(2) of the final rule, importers of food from certain small foreign suppliers must approve these suppliers on the basis of the compliance history evaluation the importer either conducts or reviews and assesses, and the importer must document the approval.

Finally, § 1.512(c)(3)(i) requires these importers of food from certain small foreign suppliers to establish and follow

written procedures to ensure that they import foods only from foreign suppliers approved based on the compliance history evaluation (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities before importing the food). The importer must document its use of these procedures. However, under § 1.512(c)(3)(ii), the importer may rely on another entity (other than its foreign supplier) to establish these procedures and perform and document the required activities, provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer documents its review and assessment.

Having discussed the principal changes the final rule makes to the proposed modified requirements for very small importers and importers of food from very small foreign suppliers, in the following paragraphs we respond to comments on various aspects of the proposed requirements and, in doing so, note other changes included in the final rule.

a. Comments Regarding the Proposed Modified Verification Requirements for Certain Farms

(Comment 283) Some comments state that the produce safety regulation excludes farms with annual sales of \$25,000 or less but the FSVP regulation does not include an analogous exclusion. The comments ask that we delete the exclusion from the produce safety regulation because they believe that mandating importers to hold foreign operations to standards that domestic operations are not required to meet would invite a WTO challenge.

(Response 283) As previously stated, importers obtaining produce from farms with annual sales of \$25,000 or less are subject to modified requirements under the FSVP regulation. While these requirements do not constitute an exclusion from FSVP, they significantly decrease the burden of the regulation for these importers. Because farms with \$25,000 or less in annual sales are not subject to the produce safety regulation, the modified requirements do not mandate that an importer of produce from such a farm obtain assurance that the farm is in compliance with section 419 of the FD&C Act, as the produce safety regulation would not apply.

In addition, we have aligned the supplier verification provisions in the FSVP regulation with the supply-chain program provisions of the preventive controls regulations, to the extent

appropriate and feasible, including the eligibility criteria for the modified requirements for produce imported from suppliers that are farms that are not covered farms under the produce safety regulation in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5. Therefore, receiving facilities subject to the preventive controls regulations that obtain produce from domestic farms are not subject to less burdensome supplier verification requirements for that produce than importers importing produce from foreign farms.

(Comment 284) One comment suggests that we not provide modified requirements for certain farm suppliers and delete proposed § 1.506(d)(4) because modified requirements would not give importers the tools they need to assure that they are addressing safety issues with food from such farms. On the other hand, one comment asks that we apply the proposed modified requirements to all farms that are not subject to the produce safety regulations.

(Response 284) We stated in the preamble to the Supplemental Notice that proposed § 1.506(d)(4) would have provided modified verification requirements with respect to food from the following:

- Farms that grow or harvest crops such as grains that are not "produce," as defined in § 112.3(c) of the proposed produce safety regulation.
- Farms that grow and harvest produce that is not covered by the proposed produce safety regulation in accordance with proposed § 112.1. Such "non-covered produce" includes produce that is rarely consumed raw, produce that is produced for personal consumption or for consumption on the farm or another farm under the same ownership.
- Farms that are not "covered farms" because they produce an average annual monetary value of produce of no more than \$25,000.

- Farms that are not covered farms because they satisfy the requirements for a qualified exemption from the proposed produce safety regulation under proposed § 112.5 and the exemption has not been withdrawn.

Although § 1.512 of the final rule provides modified verification requirements for the latter two types of farms, it does not provide modified verification requirements for the former two types of farms. That is, final § 1.512 does not provide modified verification requirements for farms that grow and harvest crops such as grains that are not "produce" as defined in proposed § 112.3(c), and does not provide

modified requirements for farms that grow or harvest produce that is not covered by the proposed produce safety regulation in accordance with proposed § 112.1 (e.g., because such produce is rarely consumed raw or is produced for personal or on-farm consumption). We believe that this approach is appropriate.

With respect to crops such as grains that are not “produce” as defined in the produce safety regulation (and thus are not subject to the regulation), much of this imported food likely will not be consumed without processing that provides for the application of an appropriate kill step or control. Rather than provide for modified verification requirements for such food under § 1.512, we think it is more appropriate to allow importers to rely on the provisions of § 1.507 discussed in section III.H of this document, as applicable. Under those provisions, if the hazards have not been significantly minimized or prevented before importation, an importer may determine and document that the food could not be consumed without application of an appropriate control (e.g., cooking or other treatment of the food for grains for human consumption) or could obtain assurances from its customer that the customer or a subsequent entity in the distribution chain will process the food for food safety. This approach allows the hazard control to be applied after importation while also providing the importer with flexibility as to which entity will apply the appropriate control. In addition, importers of some grains may appropriately determine through their hazard analysis that there are no hazards requiring control. In such cases, the importer would document that determination in its written hazard analysis but would not be required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and would not be required to conduct foreign supplier verification activities under § 1.506. Importers of other grains might determine that the only way to ensure that identified hazards are significantly minimized or prevented would be to conduct verification activities in accordance with § 1.506.

For similar reasons, the final rule requires importers of produce rarely consumed raw to comply with the provisions in §§ 1.505, 1.506, and 1.507, as applicable, instead of providing modified provisions for such produce. For some produce rarely consumed raw, an importer might determine it is appropriate to conduct supplier verification activities to ensure that hazards in the food have been

significantly minimized or prevented before importation. For other produce in this category, we believe that the requirements in § 1.507 are suitable to ensuring the safety of such produce because the food will be subject to the application of a control after importation, and § 1.507 provides flexibility as to which entity will apply the control. With respect to produce for personal or on-farm consumption, this produce would either never be exported to the United States (because it is consumed on the farm) or could be eligible for the personal consumption exemption from the FSVP regulation under § 1.501(d). We therefore do not see any need to establish modified requirements applicable to this category.

We are not certain whether the comment requesting that the modified requirements apply to all farms not subject to the produce safety regulation contemplates any other food or farms being subject to the modified verification requirements in § 1.512. To the extent that the comment requests that food produced by such operations as dairy farms be covered by the modified requirements in § 1.512, we do not agree. Safety problems may arise in food produced by such operations. Providing modified requirements for such operations would increase the volume of imported food subject to modified requirements, and would therefore also increase consumers’ risk of exposure to such food. Consistent with Congress’ intent that we implement the FSVP requirements based on the level of risk posed by the imported food (see section 805(c)(3) of the FD&C Act), we believe it is appropriate that importers of food from such farms be subject to the standard supplier verification requirements. Indeed, we have designed the modified verification requirements in § 1.512 so they apply only to operations that expose consumers to less risk because the operations export a relatively small volume of food to the United States. We also believe that our treatment of produce and food from other farms not subject to the produce safety regulation is consistent with the coverage of the supply-chain program provisions in the preventive controls regulations.

In the context of the nature of the imports for which we are providing modified verification requirements in § 1.512, we continue to believe that the modified requirements would be adequate to provide assurances from these particular suppliers that the food is produced in compliance with the applicable standards in this rule. In addition, the foods covered by the modified requirements in § 1.512 are

and will continue to be covered under the adulteration provisions of the FD&C Act and applicable implementing regulations, irrespective of the modified verification requirements under the FSVP regulation.

(Comment 285) Several comments request that importers not be required to obtain written assurance of compliance with the FD&C Act from the farms specified in proposed § 1.506(d)(4). The comments assert that obtaining written assurance would be unnecessary or inappropriate because FDA has already determined that these foods are of minimal or no risk. The comments also state that, with respect to a RAC that is not subject to the produce safety regulations, the importer might not know the identity of the farmer who grows the RAC (e.g., RACs that are consolidated before export to the United States).

(Response 285) As stated previously, the fact that we are allowing importers to obtain written assurance, instead of requiring importers to determine and conduct what might be more burdensome supplier verification activities, reflects our view of the risk to public health attributable to produce from these farms. To the extent that the comments believe that requiring assurances is inconsistent with the risk to public health posed by these suppliers, we disagree. Obtaining assurances is an appropriate verification activity because it requires importers to obtain from suppliers information about the safety of the imported food. For produce RACs consolidated before export to the United States from farms described in § 1.512(a)(2)(ii) of the final rule, the regulation does not prohibit an importer from enlisting the consolidator to help obtain the necessary written assurances.

(Comment 286) One comment contends that obtaining written assurances from grain farmers is not feasible because FDA has not established safety standards for grain.

(Response 286) As finalized and as previously discussed, § 1.512 does not establish any modified requirements specific to the importation of grain. However, we expect that the risk-based framework of this rule will still generally result in a relatively low verification burden for the importation of grain. As described in the previous paragraphs, importers may be able to take advantage of the flexibility in § 1.507 for imported grains for which hazards will be controlled after importation.

b. Other Comments Related to the Appropriateness or Implementation of Modified Provisions for Small Entities

(Comment 287) Some comments assert that Congress did not provide an exemption for very small importers and food from very small foreign suppliers and FDA should not create one.

(Response 287) As discussed in the proposed rule, section 805(c)(3) of the FD&C Act directed FDA to, as appropriate, take into account differences among importers and types of imported food, including based on the level of risk posed by the imported food. We have not created an exemption from the FSVP regulation for very small importers or very small foreign suppliers. Instead, as discussed previously, we are adopting modified requirements that generally apply to situations that involve a relatively low volume of imported food, which should reduce consumers' exposure to, and thus potential risk from, the food (see 78 FR 45730 at 45765). We think this approach is commensurate with the risk to public health posed by these importers and suppliers, consistent with section 805(c)(3), because the food affected by these provisions constitutes a relatively low volume of imported food, which should reduce the risk to consumers posed by this food.

(Comment 288) Some comments agree with the idea of having modified requirements for very small importers and very small foreign suppliers, but state that the modified requirements should be different from what we proposed. Some comments maintain that we should require a third-party audit by a qualified individual for very small importers and importers of food from very small foreign suppliers. Some comments argue that these importers should be subject to the full requirements of the FSVP regulation, but that we should address the challenges for these entities in complying by giving them additional time to comply.

(Response 288) Although an importer may determine that a third-party audit is the most appropriate verification activity for a given food and foreign supplier, the FSVP regulation does not mandate a third-party audit of a foreign supplier for any imported food. We do not see the logic in creating more stringent requirements for very small importers and importers of food from small suppliers than for all other importers subject to the FSVP regulations.

(Comment 289) Some comments support modified requirements for very small foreign suppliers but state that

importers' requirements should be the same regardless of the size of the importer or its supplier.

(Response 289) The FSVP regulations apply to importers; they do not impose direct requirements on foreign suppliers. The size of the importer is relevant to its ability to comply with the FSVP requirements and to the volume of food imported by the importer (and thus consumers' exposure to the food). We therefore believe it is appropriate to adopt modified requirements for very small importers.

(Comment 290) Some comments state that very small foreign suppliers may already be exempt from the preventive controls or produce safety regulations and do not need a duplicative exemption from importers' verification requirements.

(Response 290) We did not propose and are not finalizing an exemption for food from qualified facilities or certain small farms. We are establishing modified, risk-based verification requirements for importers of such food.

(Comment 291) Some comments express concern that these provisions will allow businesses to alter their structures to ensure that the imported food is exempt from the regulation. Some comments assert that businesses would assign the FSVP importer responsibility to the entity most likely to be exempt. Comments also maintain that large exporters of food to the United States might break shipments into smaller units to avoid application of the full FSVP requirements.

(Response 291) While this rule does not prevent various business arrangements from developing, we do not believe that it would be cost-effective for an importer to alter its entire supply chain to only import food from many small facilities or farms to meet its needs instead of from its usual large suppliers. We understand that many large importers that import food from large suppliers are already performing supplier verification activities of some kind. We believe they are much more likely to simply modify their current practices, if such modification is needed, rather than adopt entirely new supply structures to evade application of the full requirements of the rule.

We do not agree that large exporters of food to the United States are likely to break shipments into smaller units to avoid the full FSVP requirements. An importer of food from a large exporter would not be eligible for modified requirements just because the particular shipment the importer received happened to be small. To make its products eligible for application of the

modified requirements, an exporter would have to divide itself into smaller, distinct businesses, which could create significant costs for the underlying business.

(Comment 292) Some comments assert that if FDA believes the modified requirements are sufficient, those requirements should apply to all importers regardless of size.

(Response 292) As previously stated, FSMA directed FDA to, as appropriate, take into account differences among importers and types of imported food, including based on the level of risk posed by the imported food. The modified requirements are designed to specify verification activities that take into account the risk to overall public health posed by the low volume of food from these entities imported into the United States. The modified requirements would not be appropriate for all importers regardless of risk.

(Comment 293) Some comments express concern that eligibility reporting and verification activities will create additional work for FDA. They assert that verification of sales data might be possible for importers through interagency cooperation with the Internal Revenue Service but not for foreign suppliers. The comments maintain that without verification, importers might fraudulently document that an entity meets the very small foreign supplier definition as well as assurances of compliance.

(Response 293) When we review records of importers who are following modified requirements in accordance with § 1.512, we will expect to review documentation supporting their determination that the food they import is eligible for the modified requirements. Importers should expect that we will use information available to us to verify the truthfulness and accuracy of this information. Falsely reporting eligibility criteria to FDA could subject importers to penalties under 18 U.S.C. 1001.

(Comment 294) Some comments ask what course of action FDA would have in the event of a foodborne illness outbreak if an outbreak is traced back to a very small foreign supplier or food imported by a very small importer.

(Response 294) If a foodborne illness outbreak is traced back to food subject to modified requirements under the FSVP regulation, we will be able to use our enforcement tools to address the issue in the same manner as we would with importers subject to the "standard" FSVP requirements, including, if appropriate, placing the foreign supplier or importer on import alert.

(Comment 295) Some comments state that the modified requirements do not solve the problems associated with having to verify thousands of farms, including maintaining a list of approved suppliers, conducting compliance status reviews, and documenting the entities' eligibility for the modified requirements. Some comments question whether compliance status review for thousands of small farms that do not directly sell food to the United States is a good use of resources.

(Response 295) The final modified requirements do not include maintaining a list of approved suppliers; they do include documenting eligibility for the modified requirements and, for importers of food from the specified small foreign suppliers, evaluating their potential suppliers' compliance history. If an importer wants to follow the modified requirements, it must make a determination about its eligibility through reviewing its own annual sales information or obtaining written assurance from a foreign supplier. Maintaining the record of that determination allows the importer to show that it meets the eligibility criteria and enables us to verify the importer's eligibility.

Regarding the comments on compliance status review, § 1.512 of the final rule does not require very small importers to conduct a compliance status review of potential foreign suppliers, as we had originally proposed. As previously discussed, § 1.512(c)(1) does require importers of food from certain small foreign suppliers to evaluate their foreign suppliers' compliance history. With respect to produce imported from a farm that grows produce and is not a covered farm in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, under § 1.512(c)(1)(iii), an importer of such produce could rely on another entity (other than the foreign supplier) to evaluate the compliance history of a potential foreign supplier.

2. Provisions of the Modified Requirements for Very Small Importers and Importers of Food From Certain Small Suppliers

Some comments address particular aspects of the proposed modified requirements for very small importers and importers of food from very small foreign suppliers. We respond to these concerns in the following paragraphs.

a. Calculating Eligibility

Under proposed § 1.512(b)(1), an importer seeking to import food under the modified requirements would have to document, at the end of each calendar

year, that it meets the definition of "very small importer" in § 1.500 or that the foreign supplier meets the definition of "very small foreign supplier" in § 1.500. For the purpose of determining whether the definitions were satisfied, the baseline year for calculating the adjustment for inflation would be 2012. Proposed § 1.512(b)(1) further states that if the importer or foreign supplier conducts food sales in currency other than U.S. dollars, the importer would have to use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

The final rule includes changes to § 1.512(b)(1) to clarify how importers must determine their eligibility for the modified provisions for very small importers and importers of food from certain small foreign suppliers. To import food as a very small importer, an importer must document its eligibility as a "very small importer" (as defined in § 1.500) with respect to human food and/or animal food before initially importing food and thereafter on an annual basis by December 31 of each calendar year (§ 1.512(b)(1)(i)(A)). For the purpose of determining whether the importer satisfies the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which the importer intends to import food as a very small importer (§ 1.512(b)(1)(i)(B)). To align the very small importer requirements with the requirements for qualified facilities in the preventive controls regulations, the baseline year for calculating the adjustment for inflation is 2011 rather than 2012 as proposed. If the importer conducts any food sales in currency other than U.S. dollars, it must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

To import food under the modified provisions for food from small foreign suppliers, an importer must obtain written assurance that its foreign supplier meets the criteria for one of the types of small suppliers in § 1.512(a)(2)(i), (ii), or (iii) before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(Comment 296) One comment seeks clarification as to who will determine the monetary value of an importer and how such criteria will be enforceable.

(Response 296) Under § 1.512(b)(1)(i) of the final rule, the importer itself must determine the dollar amount of its sales of human or animal food and the market value of any human or animal food imported, manufactured, processed, packed, or held without sale. Importers must retain documentation of eligibility for the modified requirements and make it available for FDA review.

b. Written Assurances

We proposed (in § 1.512(b)(3)) that an importer seeking to import food under the modified requirements be required to obtain written assurance, before importing a food and at least every 2 years thereafter, that the foreign supplier is producing food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. The written assurance would have to include a brief description of the processes and procedures that the foreign supplier is following to ensure the safety of the food.

As previously discussed, the final rule contains revised written assurance requirements for very small importers and importers of food from certain small foreign suppliers.

(Comment 297) Some comments agree with the proposed requirement to obtain written assurances from foreign suppliers. Other comments argue that we should allow greater flexibility by allowing a very small supplier to provide records, like a commercial invoice, a certification of safety by the supplier's regulatory authority, a HACCP plan/certification, or a private certification, to meet the verification requirements. These comments also state that if a food is specifically named as high risk by FDA, or food from the foreign supplier was rejected twice at the border for its food safety performance, then additional proof of safety could be demanded according to FDA guidance developed in consultation with small food companies.

(Response 297) We believe that the requirement to obtain written assurances from foreign suppliers will not be more burdensome than obtaining records from those suppliers. Recognizing the variety of business practices that currently produce safe food, the final rule provides a significant amount of flexibility concerning the form of written assurances. The modified requirements do not specify the particular form of

documentation that must be used as written assurance for FSVP purposes. Some records suggested by the comments, such as a certification of safety by a supplier's regulatory authority or a private certification, might be sufficient for written assurance purposes if they satisfy the applicable requirements for written assurance in § 1.512(b)(3). However, for food from qualified facilities, the written assurance must include the information required by § 1.512(b)(3)(ii).

We believe that basing supplier verification requirements for a particular food on whether it had been refused admission, as suggested by some comments, would be too administratively burdensome for both importers and the Agency. As to the issue of basing the level of supplier verification on whether a food is high risk, we generally agree that supplier verification should be risk-based and this rule applies a risk-based framework. In general, the rule allows importers to tailor the supplier verification activities they conduct based on the hazards applicable to the food and the characteristics of the supplier. For very small importers, however, we believe that the modified requirements, including the requirement to obtain supplier assurances, are appropriate given the reduced risk to consumers posed by the relatively low volume of food imported by these firms.

c. Corrective Actions

We proposed (in § 1.512(b)(4)) that very small importers be required to promptly take corrective actions if they determine that a foreign supplier of food they import does not produce the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act. The appropriate corrective actions would depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of non-compliance, adulteration, or misbranding have been adequately addressed. We further proposed that importers be required to document any corrective actions they take to meet this requirement.

We have revised the corrective action requirements in § 1.512(b)(4) to reflect the revised requirements for written assurances for very small importers and importers of food from certain small foreign suppliers by specifying that appropriate corrective actions would be

required if the importer determines that its foreign supplier does not produce food consistent with the assurance provided in accordance with § 1.512(b)(3).

(Comment 298) Some comments ask that the provision be revised to specify that corrective actions are only necessary when non-compliance causes a risk to public health. The comments assert that this would be consistent with FDA's statement in the preamble to the proposed rule that regulations should focus on foreseeable food safety risks identified through a hazard assessment process, rather than all risks covered by the adulteration provisions in section 402 of the FD&C Act.

(Response 298) For the reasons stated with respect to the corrective action provisions in § 1.508 of the final rule (see section III.I.4 of this document), we disagree that corrective actions are only necessary when non-compliance causes a risk to public health.

d. Records

We proposed certain requirements (in § 1.512(b)(5)) related to the availability, quality, and retention of records of activities under the modified requirements for very small importers and importers of food from very small foreign suppliers. We proposed to require importers to maintain records, in English, and to make them available promptly to an authorized FDA representative, upon request, for inspection and copying. We also proposed that importers be required to maintain records at their places of business or at a reasonably accessible location; records would be considered to be at a reasonably accessible location if they could be immediately retrieved from another location by computer or other electronic means.

The final rule includes several changes to the proposed requirements to align the recordkeeping requirements in § 1.512(b)(5) of the final rule with the changed recordkeeping requirements in § 1.510 (discussed in section III.K of this document) as well as for consistency with the supply-chain program provisions in the preventive controls regulations. Section 1.512(b)(5)(ii)(A) of the final rule does not require that records be maintained in English. Instead, upon FDA request, importers must provide within a reasonable time an English translation of records maintained in a language other than English.

The record retention provisions in § 1.512(b)(5)(iii) require importers to retain records for at least 2 years after records are created or obtained. However, records of importers who

obtain food from certain small foreign suppliers that relate to the importers' processes and procedures (e.g., evaluations of supplier compliance history under § 1.512(c)(1), approvals of suppliers under § 1.512(c)(2)) must be retained for at least 2 years after their use is discontinued. Also, records relied on to support an importer's status as a very small importer must be retained for at least 3 years.

Section 1.512(b)(5)(iv) specifies that records of very small importers and importers of food from certain small foreign suppliers obtained by FDA in accordance with the FSVP regulations are subject to the disclosure requirements under part 20. In addition, under § 1.512(b)(5)(v)(A), these importers do not need to duplicate their existing records if they contain all of the information required under the FSVP regulation, and importers may supplement any existing records as necessary to include all required information. Under § 1.512(b)(5)(v)(B), importers are not required to keep required information in one set of records; if existing records contain some of the required information, any new information required by the FSVP regulation may be kept separately or combined with existing records.

(Comment 299) Some comments suggest that records should be considered to be at a reasonably accessible location if they can be retrieved within 5 business days from another location, rather than immediately retrieved by computer or other means. The comments state that "immediately" is subject to misinterpretation, and FDA should replace the term with a specific, reasonable time interval. The comments suggest that 5 days is adequate, but in no case should FDA impose an interval of less than 1 business day. Some comments object to the requirement that only computer or other electronic means are suitable for record retrieval because some locations of offsite records might not have adequate resources, and a requirement to use electronic means might inadvertently require expensive computer system validation.

(Response 299) Consistent with changes to proposed § 1.510 discussed in section III.K.3.b of this document, we have changed § 1.512(b)(5)(ii)(B) to specify that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Under the final rule, electronic records are considered to be onsite if they are accessible from an onsite location. We believe that the 24-hour deadline is important because records must be

available to FDA investigators during inspections. We do not believe it is reasonable for an inspection to be put on hold for 5 business days so that an importer can acquire the necessary records. However, the provision no longer specifies retrieval by computer or other electronic means; an importer could use a non-electronic means (e.g., courier service) to retrieve and provide records onsite.

(Comment 300) Some comments request that the regulations specify that there is no requirement for compliance with any part of part 11.

(Response 300) The final rule includes a provision (§ 1.512(b)(5)(iv)) specifying that electronic records that are established or maintained to satisfy the requirements of § 1.512 are exempt from the requirements of part 11.

3. Other Concerns Regarding the Modified Requirements

a. Withdrawal of Eligibility

(Comment 301) One comment expresses concern that the modified requirements for very small importers do not include a provision on withdrawal of eligibility for the exemption, as there is in the preventive controls regulations. The comment asks that we consider adding the ability to withdraw eligibility from an importer that imports food that causes an illness outbreak.

(Response 301) We do not believe such a provision is necessary, given the risk-based nature of the eligibility criteria for these modified requirements and our existing enforcement tools in the imports arena. For example, if an importer imports food that causes an illness outbreak, we can place the importer on import alert, as appropriate, among other options to ensure the safety of the food.

b. Identifying Very Small Importer Eligibility at the Time of Entry

(Comment 302) Some comments say that exemptions and exceptions to the FSVP requirements, including the proposed modified requirements for very small importers and importers of food from very small foreign suppliers, should be identified at the time of entry by using an exemption/exception code, similar to the structure in place under the prior notice regulations.

(Response 302) We are planning to establish data elements that can be submitted at the time of entry to identify shipments that are exempt from the FSVP regulation or, as with very small importers and importers of food from certain small foreign suppliers, subject to modified FSVP requirements.

c. Compliance Period

(Comment 303) Some comments ask that we consider giving very small importers and importers of food from very small foreign suppliers more time, beyond the 3 years proposed, to comply with the requirements. Some comments suggest 5 years.

(Response 303) We do not believe that the modified requirements are sufficiently onerous to justify a longer compliance period for very small importers or importers of food from small suppliers. With respect to the compliance period for all importers, we are aligning the FSVP regulation with the compliance dates of the supply-chain program provisions in the preventive controls regulations, to the extent feasible. For more discussion about the applicable compliance dates, see section IV of this document.

d. Outreach

(Comment 304) Some comments ask that we commit to engaging in capacity building and education to help improve the knowledge and performance of very small entities, particularly for very small importers.

(Response 304) We are committed to stakeholder engagement throughout the implementation of FSMA. We plan to issue several guidance documents to assist entities in complying with the new FSMA regulations, including a general guidance document on FSVPs. We intend for this guidance to include recommendations on compliance with the modified requirements for very small importers and importers of food from small foreign suppliers. We will develop and issue these guidances in accordance with our good guidance practice regulation, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate (21 CFR 10.115(g)). In addition, we plan to develop training materials to assist importers in complying with the requirements of this rule.

With respect to capacity building, we issued a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries in countries from which foods are exported to the United States in accordance with section 305 of FSMA in 2013 (Ref. 15). We anticipate that this plan will provide a strategic framework for our capacity-building efforts over the next several years.

N. Importing a Food From a Foreign Supplier in a Country With an Officially Recognized or Equivalent Food Safety System (§ 1.513)

We proposed to establish alternative FSVP requirements for food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States, when certain conditions are met. These provisions would allow the importation of such food without being subject to most of the standard FSVP requirements.

Proposed § 1.513(a) specified that the importation of food from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable to that of the United States, or that FDA has determined to be equivalent to that of the United States, would be subject to modified FSVP requirements when certain conditions are met and documented. The proposed conditions (stated in proposed § 1.513(b)(1)) were the following:

- The foreign supplier must be in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States; and
- The food must be within the scope of the relevant official recognition or equivalency determination.

Proposed § 1.513(b)(1) also specified that these conditions be documented before importing a food from the foreign supplier and annually thereafter.

Under proposed § 1.513(b)(2), when those conditions were met, the importer would have the option of complying with modified FSVP requirements. Under such modified requirements, the importer would be required to determine and document whether the foreign supplier of the food was in good compliance standing with the food safety authority of the country in which the foreign supplier is located. Importers would be required to continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicated that food safety hazards associated with the food are not being adequately controlled, we proposed that the importer would be required to take prompt corrective action, which would depend on the circumstances but could include discontinuing use of the foreign supplier. We also proposed to require that these importers document any corrective actions. If an importer met

those conditions and requirements for a food, the importer would not be required to comply with most of the proposed FSVP requirements (e.g., for hazard analysis, compliance status review, supplier verification activities). (However, for the reasons stated in section III.D of this document, we conclude that it is appropriate to require these importers to use a qualified individual to perform the tasks required under § 1.513 of the final rule.) But we proposed that these importers would be required to comply with the requirements concerning identification of the importer at entry and recordkeeping.

In the preamble to the proposed rule, we discussed how these proposed modified requirements were consistent with a risk-based approach to food safety, which includes leveraging the regulatory efforts of food safety authorities in foreign countries. We discussed our systems recognition initiative, under which we are conducting assessments of foreign food safety systems to determine whether they provide similar protections to those offered under the U.S. system and a similar level of oversight and monitoring. The systems recognition process, which is described on our Web site at <http://www.fda.gov/food/internationalinteragencycoordination/ucm367400.htm> (Ref. 16), involves a comprehensive review of a country's food safety system by FDA scientists, auditors, and investigators, along with use of a food safety authority self-assessment tool (currently in draft form) called the International Comparability Assessment Tool (ICAT), to determine whether a country has a food safety system that is comparable to that of the United States.

As stated in the preamble to the proposed rule, the systems recognition review process consists of two principal stages. After satisfactory completion of a review of a country's ICAT submission, audit teams from FDA, including persons specializing in particular high-risk commodities, will perform an in-country assessment to verify the implementation of programs and measures as outlined in the ICAT submission. The assessment provides an objective and comprehensive means of assessing the foreign food safety system. FDA will only enter into a systems recognition arrangement with a foreign government if we are confident that the oversight of the foreign food safety authority is sufficiently rigorous and reliable that it can ensure that food produced in that country is as safe as food produced in the United States.

After FDA enters into a systems recognition arrangement with another food safety authority, we will maintain an ongoing dialogue and hold annual consultations to determine whether any substantial changes in the country's food safety system have developed to ensure that the country's food safety system continues to be comparable. Although we are still developing the systems recognition process, we plan to reevaluate the operation and status of each arrangement every 5 years, including reviewing changes in a country's food safety system and conducting system audits as needed.

We requested comment on the appropriateness of our proposed modified FSVP requirements for food imported from a country with a comparable or equivalent food safety system, including the proposed conditions and modified FSVP requirements that would be applicable to such imported food. In addition, in light of the possible inclusion of supplier verification provisions for raw materials and other ingredients in the preventive controls regulations, we requested comment on whether the modified requirements should apply to the importation of raw materials and other ingredients.

1. Appropriateness of the Modified Requirements

We received comments supporting and opposing the proposed modified FSVP requirements for food from foreign suppliers in countries with comparable or equivalent food safety systems. As discussed in the following paragraphs, we conclude that the modified provisions are an appropriate component of risk-based foreign supplier verification requirements. However, for the reasons described in the following paragraphs, we conclude that it is appropriate to limit the scope of the modified provisions to imported food that will not be further manufactured/processed in the United States, including packaged food products and fresh produce intended for consumption without further commercial manufacturing/processing. This change will ensure that food from foreign suppliers in countries whose food safety systems we have officially recognized as comparable or determined to be equivalent to that of the United States will be subject to supplier verification under the FSVP regulation in the same circumstances that food from domestic suppliers will be subject to supplier verification under the preventive controls regulations.

(Comment 305) Several comments express support for the application of

modified FSVP requirements for importing a food from a country with a comparable or equivalent food safety system. These comments maintain that the requirements are consistent with a risk-based approach to food safety that avoids unnecessary expenditure of verification resources by incorporating the regulatory efforts of foreign food safety authorities. With respect to the importation of raw materials and other ingredients, some comments support applying the modified requirements to these products.

On the other hand, some comments oppose the modified provisions, asserting that supplier verification is needed to provide adequate assurance of safety regardless of the regulatory environment in the country in which a food is produced. The comments assert that just because a country's food safety system has been deemed comparable does not mean that the system operates perfectly all the time. The comments express concern that under the modified provisions not all foreign suppliers would be held to the same standards that apply to domestic producers.

(Response 305) We conclude that the application of the modified FSVP requirements for imports of food from foreign suppliers in countries with a food safety system officially recognized as comparable or determined to be equivalent is consistent with a modern, risk-based approach to food safety. As previously stated, the systems recognition process provides for a thorough and rigorous assessment of whether the food safety system in a foreign country provides similar protection to that provided to consumers under the U.S. system. We believe that the production of food by a foreign supplier in good compliance standing with a food safety authority implementing a system that FDA has deemed comparable or equivalent to the U.S. system will provide adequate assurance of safety and make supplier verification by importers unnecessary. Thus, importation of food under these modified provisions should reduce the regulatory burden on importers while still providing assurance that the food will be produced consistent with U.S. standards.

However, we conclude that the scope of the modified requirements for food from countries with comparable or equivalent food safety systems must be revised with respect to raw materials and other ingredients. Supplier verification for raw materials and other ingredients is an important part of a preventive approach to food safety. Through supplier verification, the entity receiving raw materials or other

ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented controls to significantly minimize or prevent known or reasonably foreseeable hazards in the raw material or other ingredients. As a result of these considerations, we have finalized requirements for supplier verification in the preventive controls regulations—even for suppliers that operate under the U.S. food safety system. Under the preventive controls regulations, receiving facilities that obtain raw materials or other ingredients from either domestic or foreign suppliers will, under certain circumstances, need to have a supply-chain program that includes the performance of supplier verification activities.

We believe that verifying foreign suppliers of raw materials and other ingredients is as important to food safety as verifying domestic suppliers, and that where the supplier operates and the nature of government oversight does not change the need for supplier verification requirements. In other words, supplier requirements are important when food is produced in the United States, when it is produced in foreign countries whose food safety systems FDA has not officially recognized as comparable or determined to be equivalent, and when it is produced under food safety systems that FDA has found to be comparable or equivalent. When a supplier has not controlled a hazard requiring a control, the entity receiving that food can help ensure that the hazard is controlled before there is a finished product to be distributed to consumers—regardless of whether the supplier is located domestically or in a foreign country.

The U.S. food safety system requires that hazards be significantly minimized or prevented in finished food products, and the same will be the case for the food safety system in any country that FDA officially recognizes as comparable or determines to be equivalent. When food that does not require further manufacturing/processing is imported from foreign suppliers in good compliance standing in those countries, we do not believe that there will be significant public health benefit in an importer conducting verification that the supplier's hazards have been significantly minimized or prevented. In those circumstances, we will have confidence that the food safety system of the foreign supplier's country adequately requires the control of hazards for which controls are needed. Furthermore, we do not see a reason for the FSVP regulation to permit imports of raw materials and other ingredients

under the modified requirements for food from countries with comparable or equivalent food safety systems while raw materials and other ingredients would be subject to supplier verification under the preventive controls regulations. Therefore, § 1.513(a)(2) of the final rule specifies that the modified provisions apply only to food that is not intended for further manufacturing/processing, including packaged finished food products and RACs that will not be commercially processed further before consumption.

(Comment 306) Several comments maintain that we should exempt U.S. producers that are in good compliance standing with FDA from the supplier verification requirements in the preventive controls regulations. These comments assert that if domestic manufacturers are subject to supplier verification requirements under the preventive controls regulations while importers of food from countries with comparable or equivalent food safety systems are exempt from most FSVP requirements, this would result in imported food being subject to less oversight than domestic food.

(Response 306) As discussed previously, § 1.513(a)(2) of the final rule provides that supplier verification of raw materials and other ingredients is treated the same under the FSVP and preventive controls regulations by limiting the applicability of the modified provisions on food from countries with comparable or equivalent food safety systems to food that will not be subject to further manufacturing/processing. Further, we believe, as stated previously, that supplier verification of raw materials or other ingredients is important regardless of whether the food is produced by domestic or foreign suppliers. Such verification allows the facility receiving the raw material or other ingredient to take steps, when necessary, to control hazards requiring a control that have not been controlled by the supplier.

(Comment 307) Some comments suggest that there is an inconsistency with the provisions of proposed §§ 1.513 and 1.506(d)(5). As discussed in section III.G.4 of this document, proposed § 1.506(d)(5) would permit an importer to rely on an inspection of a foreign supplier that is conducted by the food safety authority of a country whose food safety system we had officially recognized as comparable or determined to be equivalent, as a substitute for conducting a required onsite audit of the foreign supplier. The comments assert that this provision is superfluous because proposed § 1.513 would relieve

the importer of the obligation to conduct an onsite audit of the foreign supplier.

(Response 307) We do not agree. As stated previously, the modified provisions in § 1.513 of the final rule apply only to food that will not be commercially processed further in the United States. However, under § 1.506(e)(1)(i)(E)(2) of the final rule, an importer of a raw material or other ingredient from a country with a comparable or equivalent food safety system may substitute an inspection by the food safety authority for an onsite audit of the foreign supplier of the raw material or other ingredient provided that certain conditions are met. In addition, the provisions allowing substitution of an inspection for an onsite audit do not require documentation that the foreign supplier is in good compliance standing with the food safety authority in a country with a comparable or equivalent food safety system, which is required for importing food under the modified provisions in § 1.513. Consequently, we conclude that there are circumstances under which an importer of food from a country with a comparable or equivalent food safety system might wish to rely on the results of an inspection conducted by the food safety authority of that country in accordance with § 1.506(e)(1)(i)(E)(2).

2. Systems Recognition Process

Several comments request changes to, or clarification of, our systems recognition process, while some comments request a change to proposed § 1.513 to address a concern about the systems recognition process.

(Comment 308) Some comments request that we clarify and simplify the process of making systems recognition determinations. Some comments, noting their understanding that the systems recognition approach will allow FDA to prioritize its inspection and surveillance activities according to risk, ask that we more clearly show the benefits for exporting countries under the approach to increase the incentive for participation in systems recognition.

(Response 308) The systems recognition initiative is a food safety regulatory cooperation program and it is not intended to be a program for the promotion of trade or market access. Systems recognition is a regulator-to-regulator program that allows FDA to take into account the role of food safety systems of exporting countries in our risk-based decision making regarding inspections, monitoring, admissibility, and follow-up when food safety incidents occur. As a regulatory coordination program, systems recognition embraces cooperation in

many areas such as research, capacity building with third countries, and outbreak response.

We are using systems recognition as a tool to determine when we can rely on the implementation of science-based food safety programs by foreign regulatory authorities and take action based on information provided by such authorities. However, we note that the systems recognition program is based on the principle that foreign food producers can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country whose food safety system we have found to be comparable or equivalent. Therefore, it is appropriate, under § 1.513 of the final rule, to exempt from the application of most FSVP requirements certain food from foreign suppliers that are in good compliance standing with the food safety authority of a country whose food safety system we have found to be comparable to ours as a result of a systems recognition assessment.

(Comment 309) One comment requests that we revise proposed § 1.513(b) to replace “country” with “country or entity” in the phrase “country with an officially recognized or equivalent food safety system” to recognize that, in addition to individual countries, entities such as the EU might also be the subject of a food safety systems recognition agreement. This comment also asks that we establish a transition program or grace period for countries that are undergoing systems recognition evaluation so that exports from those countries are not subject to the full range of FSVP requirements while FDA conducts its evaluation.

(Response 309) We appreciate that the EU plays an important role in coordinating the food safety policy of its Member States. However, within the EU the food safety agencies of the national governments of the Member States are responsible for enforcing the feed and food safety laws and implementing official controls for food safety through all stages of production, processing, and distribution (Ref. 17). In that context, we are continuing to evaluate and consider how to best address the functions and processes of both the EU and its Member States. We do not believe that it is necessary to revise § 1.513(b)(1) as requested to address this aspect of our systems recognition review.

We also decline to apply modified FSVP requirements to importers of food from countries that are undergoing, but have not completed, a systems recognition assessment. Applying such requirements to systems recognition

candidates before we have completed the evaluation process would prejudice the outcome of the process.

(Comment 310) Some comments request that we rapidly expand the list of countries participating in the systems recognition program so that it includes the major trading partners of the United States. These comments assert that a systems recognition program covering the United States’ largest trading partners would significantly reduce burdens on food importers.

(Response 310) We are transitioning the systems recognition program from the pilot phase to the implementation phase. During this transition we will be addressing modifications of our internal procedures and training of FDA personnel involved in systems recognition determinations. As a result, we will be applying more resources to the program in response to requests for recognition from additional countries. As we gain more experience with the systems recognition program, we expect to improve the efficiency of the review process. However, because there is variation in the level of maturity of food safety systems in countries around the world, not all countries are likely to qualify to participate in the systems recognition program.

(Comment 311) One comment asserts that in selecting countries to review under the systems recognition process, FDA will be biased towards countries with legal systems and official languages that are similar to those of the United States, making it difficult for other countries to obtain systems recognition status.

(Response 311) We do not agree. We are administering the systems recognition pilot program through a transparent and objective science-based evaluation of the food safety systems of the candidate countries. We will continue to provide information and opportunities for stakeholder input as the program transitions from the pilot stage to the full implementation stage.

(Comment 312) Some comments assert that FDA should only make equivalency determinations and not systems recognition determinations. One of these comments maintains that equivalency determination is a more robust approach than systems recognition for determining whether the United States can rely on another country’s food safety system.

(Response 312) We do not agree. Both equivalence and systems recognition have unique aspects, but both can be considered robust enough to satisfy the objectives of the FSVP regulations, which include several methods for an importer to achieve compliance.

Systems recognition, in particular, involves a sufficiently rigorous analysis of the food safety system of the foreign country so that it is appropriate to include it as an alternative.

3. Commodity-Specific Arrangements With FDA

In the proposed rule, we requested comment on what FSVP requirements might be appropriate for food imported from countries whose food safety authorities have entered into commodity-specific arrangements or agreements with FDA.

(Comment 313) Several comments support the idea of having commodity-specific systems recognition arrangements. These comments assert that there are certain countries with excellent food safety systems for specific products. The comments suggest that limiting compliance assurance to these specific products rather than requesting equivalence for all food products should be sufficient and appropriate in certain cases. The comments ask that we publish a listing of all commodity/country arrangements for specific food sectors within countries that can demonstrate equivalent public health protection with respect to the listed commodities. Some comments ask that we consider products that are already covered under bilateral memoranda of understanding (MOUs), such as FDA’s agreement with Mexico regarding cantaloupe, as subjects for future commodity-specific systems recognition agreements.

(Response 313) We are considering whether and how best to develop commodity-specific recognition programs. In considering the best path forward, we are aware that, although a country’s overall food safety system may not be comparable to that of the United States for FDA-regulated products, the country might be able to successfully demonstrate that a specific production practice or set of practices for a particular food or foods provides the same level of public health protection for a specific measure or a set of measures as described in FDA regulations. At the same time, we know that an evaluation of an overall food control system allows for intensive and extensive review of many components of that safety system. We will provide opportunities for stakeholder input as we continue to consider whether and how to recognize programs for specific commodities when a country demonstrates that their programs provide the same level of public health protection as those being applied to food production in the United States. If we establish commodity-specific

arrangements in the future, we will provide information about such arrangements on our Web site.

(Comment 314) One comment suggests that FDA base an equivalence determination on an evaluation of the official food safety control system of the exporting country by investigating the food safety control systems of a specific number of suppliers in the exporting country.

(Response 314) We agree that consideration of the food safety control systems of exporting suppliers might be a relevant factor in an equivalence determination. However, more important to this determination would be the quality and strength of the foreign authority's food safety operations.

O. Consequences of Failure To Comply With FSVP Requirements (§ 1.514)

We proposed to codify in the FSVP regulation certain FSMA provisions related to the consequences of failing to comply with the FSVP requirements. In accordance with section 801(a) of the FD&C Act, we proposed to specify, in § 1.514(a), that an article of food is subject to refusal of admission under section 801(a)(3) of the FD&C Act if it appears that the importer of the food fails to comply with the FSVP regulations with respect to that food. Proposed § 1.514(a) further states that if an article of food has not been sold or consigned to a person in the United States at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has designated a U.S. agent or representative as the importer for the purposes of the definition of "importer" in § 1.500. In accordance with section 301(b) of FSMA, we proposed to specify, in § 1.514(b), that the importation or offering for importation into the United States of an article of food by an importer without having an FSVP that meets the requirements of section 805 of the FD&C Act, including the FSVP regulation, is prohibited under section 301(zz) of the FD&C Act.

In the final rule, we are making certain changes to the regulatory text for these provisions. Specifically, in § 1.514(a) we are changing the phrase "has not been sold . . . to" to "is not owned by" in accordance with the changes we made to the definition of "importer" in § 1.500. Another change we are making to § 1.500 also is relevant to these provisions. As discussed in section III.A.11 of this document, we are adding a clarification to the definition of importer in § 1.500 stating that a designation of a U.S. agent or representative by a foreign owner or

consignee of a food (when there is no U.S. owner or consignee at the time of entry) must be confirmed in a signed statement of consent that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. In cases where there is no such signed statement of consent, there would not be a valid designation of a U.S. agent or representative for purposes of the definition of importer in § 1.500. In those circumstances, food offered for entry into the United States may be refused admission under § 1.514(a). We might ask the foreign owner or consignee that is exporting the food to provide us with the signed statement if any questions arise about whether the person designated as the U.S. agent or representative in fact agreed to serve in that role.

(Comment 315) One comment states that FDA should share with port officials from relevant agencies information on refusals of admission due to an importer's failure to comply with the FSVP regulation. The comment also suggests that we take steps to ensure that importers do not "port shop" to gain entry after previously being denied.

(Response 315) We currently post information related to all admission refusals on our Web site. In addition, we share information on refusals with CBP, relevant partner government agencies (PGAs), and State officials as appropriate. Once compliance with the FSVP regulation is required, this information might include refusals related to non-compliance with the regulation.

In addition, we believe that the FSVP regulation will provide us with tools to respond to any inappropriate "port shopping." Under § 1.509(a) of the final rule, the name, electronic mail address, and unique facility identifier identifying the importer must be provided electronically when filing entry with CBP for each line entry of food product offered for importation into the United States. Because we will have information about individual importers, we will be able to identify shipments linked to those importers. We plan to use this information to respond to any inappropriate "port shopping" that importers might attempt. In addition, in appropriate situations, when we identify violations with respect to products, shippers, and/or importers, we may place the products, shippers, and/or importers on import alert. Import alerts provide guidance to FDA field staff that future shipments appear violative within the meaning of applicable FD&C Act provisions. Based on information in an import alert, field

staff might detain products in shipments without physical examination. Detention without physical examination places the burden on the importer to demonstrate that each shipment is in compliance. When products, shippers, and/or importers are included on an import alert, this prompts the FDA district office to flag relevant shipments involving these products and entities. Flagging such shipments makes "port shopping" less likely to be successful.

(Comment 316) One comment asks that we provide importers with a means to pose questions or request secondary consideration of shipment refusal due to FSVP non-compliance. One comment suggests that we develop procedures for informing foreign suppliers (and presumably importers) how they can obtain entry for future shipments following an admission refusal.

(Response 316) Importers will be able to use existing procedures to resolve matters related to non-compliance with the FSVP regulation. Under § 1.514(a), an article of food is subject to refusal of admission under section 801(a)(3) of the FD&C Act if it appears that the importer of that food fails to comply with the FSVP regulation with respect to that food. If there appears to be a violation, we might issue a Notice of Detention and Hearing specifying a place and period of time in which testimony may be introduced either verbally or in writing concerning the detention to prove compliance with the regulatory requirements. Throughout this process, the importer may contact the local District compliance office to ask questions.

To the extent that the second comment is asking about procedures for removal of food from detention without physical examination under an import alert due to FSVP non-compliance, existing procedures are likely to be applicable. An importer is placed on detention without physical examination because information indicates the appearance of a violation of an applicable provision of the FD&C Act. Our decisions to remove an importer from an import alert are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future entries will be in compliance with the relevant FD&C Act requirements. FDA import alerts often provide guidance about removal from the import alert, in particular how to remove the appearance of a violation. If we place any importers on import alert for FSVP violations, we plan to provide information in the import alert about achieving removal from the alert.

Depending on the nature of the violations at issue, that guidance may specify that we might require reviewing the records of the importer before granting removal. However, this review might not always be necessary.

(Comment 317) One comment states that FDA might sample an imported food and determine that it is adulterated or misbranded even though the importer is meeting all FSVP requirements. The comment states that although the food itself would be subject to detention or refusal, it is not clear what action the Agency would pursue regarding the importer's FSVP. The comment suggests that we explain what action we might take, such as conducting a follow-up inspection of the importer or directing the importer to revise its FSVP as needed to address inadequacies.

(Response 317) We agree that it is possible that we might find, based on an examination of samples or otherwise, that an importer's food appears to be adulterated, even in circumstances in which we had found the importer to be in compliance with the FSVP requirements during our most recent review of the importer's records. In such circumstances, we may take appropriate action in response to any such finding of an appearance of a violation, including, where appropriate, detention and subsequent refusal of admission of the food. Any finding that imported food appears to be adulterated may require the importer to take appropriate corrective action under § 1.508 to ensure that its foreign supplier produces food consistent with the applicable requirements of the FD&C Act. The importer also might need to modify its FSVP for the food to provide adequate assurance of the food's safety.

Depending on the circumstances, we might determine that we should inspect the importer to assess its compliance with the FSVP regulation and, potentially, place the importer, the food, and/or its foreign supplier on import alert. However, we realize that there are circumstances in which the finding of adulteration in any particular shipment might not necessarily mean that the importer is in violation of the FSVP regulation.

To the extent that the comment is addressing circumstances in which the hazards in a food are controlled after importation, those circumstances are addressed, in part, in section III.H.2 of this document. As explained in that section, under § 1.507 in the final rule, importers are not required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506 under specified circumstances. For instance, importers are not required to

conduct § 1.505 evaluations or § 1.506 activities if they demonstrate and document that they rely on their customer to ensure that the identified hazard will be significantly minimized or prevented, or that they rely on a customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer, and that other specified requirements are satisfied (§ 1.507(a)(2) through (4)). In addition, § 1.502(c)(1) deems in compliance with most of the FSVP requirements an importer that is a facility subject to the preventive controls regulations that is implementing preventive controls for the hazards in the food in accordance with those regulations.

(Comment 318) One comment suggests that food from a foreign supplier for which FDA has refused admission under § 1.514(a) should be located and placed under embargo or "stop sale," adding that FDA should work with State and local government authorities in this effort whenever possible.

(Response 318) Under section 801(a)(3) of the FD&C Act, food that is refused admission under section 801(a) must be exported or destroyed within 90 days after its refusal. If, after a reasonable time, FDA has not received notification of exportation or destruction of articles refused admission, FDA guidance for import operations recommends that FDA district offices investigate the status of the disposition. Because of the requirement to either export or destroy such food, we do not agree that there is any general need to embargo the food or place it on "stop sale." However, if the need arises, we may work with State counterparts in connection with use of their "embargo" authority under State and/or local law. Our ability to work with States in this manner is one of the reasons we agree with the suggestion that we work with State and local government authorities when appropriate.

(Comment 319) Some comments state that, although it will be very easy for FDA to find technical infractions of the FSVP regulation, the Agency should focus more on infractions that may be linked to food safety problems rather than violations related to paperwork or recordkeeping procedures.

(Response 319) As with all of our FSMA-related enforcement efforts, we intend to apply our FSVP enforcement resources in a risk-based manner, placing greater emphasis on violations of the regulation that are more likely to result in harm to the public health. In

considering what enforcement actions, if any, are appropriate, we expect to consider factors including the severity of the violation, the risk to public health, and the willingness of the importer to cooperate and take corrective actions. In addition, we plan to provide guidance and technical assistance to assist importers in achieving compliance.

(Comment 320) Some comments request that we establish an appeals process for disputes regarding compliance with the FSVP regulation.

(Response 320) Importers will be able to use existing procedures to challenge FDA findings regarding non-compliance with the FSVP regulation. If we cite violations of the FSVP regulation upon inspection of an importer, the importer will have the opportunity to respond to the inspectional observations, and any such inspectional observations will not represent a final Agency determination regarding compliance. In addition, if we issue a warning letter to an importer, the importer will likewise have the opportunity to respond. Generally, FDA warning letters request corrective actions and a written response within a specified period of time after the date of receipt of the letter, usually 15 working days. At our discretion, the recipient of a warning letter may be offered an opportunity to discuss the letter with FDA district officials or, when appropriate, with other FDA officials.

(Comment 321) Some comments request that we provide information on the measures we will use to assess an importer's compliance with the FSVP regulation.

(Response 321) FDA investigators may conduct inspections of importers and review importers' records. In conducting such inspections and reviews, we might consult any information and/or Agency guidance that is relevant and appropriate.

P. Other Issues

We received comments on several matters related to FDA implementation and enforcement of the FSVP regulation as well as Agency outreach and training. We respond to the comments in the following paragraphs.

1. Implementation and Enforcement

As discussed in the following paragraphs, we received comments concerning FDA inspections of importers, the role of States in enforcing the FSVP regulation, and other implementation and enforcement issues.

a. How should FDA conduct FSVP inspections?

(Comment 322) We received many comments addressing how we should conduct FSVP inspections. Several comments ask that we provide companies with flexibility to develop their supplier verification programs. Some comments assert that FDA inspections of supplier verification programs should focus on ensuring that importers establish strong, risk-based programs that are consistently implemented and documented.

Some comments assert that FDA inspectors should focus on whether the qualified individuals responsible for developing the FSVPs have the necessary education and experience.

Some comments recommend that we assess the evaluation of hazards and suppliers, consider whether the importer properly used the evaluation to determine the appropriate supplier verification activities, and verify that the importer conducted the appropriate activities. Some comments assert that unless there is cause, we should not routinely question an importer's determinations about individual suppliers or review the food and supplier evaluations and determinations of appropriate verification activities. One comment suggests that we defer to importers in our inspection and enforcement relating to supplier verification activities.

(Response 322) We understand the need for both flexibility and accountability when conducting records reviews for compliance with the FSVP regulation. The regulation is written to provide importers with flexibility in meeting the requirements, including by determining appropriate supplier verification activities based on the risk posed by a food and the foreign supplier's performance. However, the regulation requires importers to document their procedures, determinations, and activities to allow us to assess importers' compliance.

We disagree that we should not review any particular aspect of an importer's FSVP. Because the final rule allows importers flexibility in meeting the requirements, we must assess the choices the importer makes to ensure that its FSVP adequately protects U.S. consumers from unsafe imported products. It is not our practice to defer to regulated entities in our implementation and enforcement of regulations.

However, we realize that no method of supplier verification can provide complete assurance against the emergence of foodborne illness, and

there might be circumstances in which the failure to detect or control a hazard might not necessarily mean that the importer has incorrectly analyzed the hazards, selected a "wrong" method of verification, or has otherwise violated the FSVP regulation. In such circumstances, however, an importer might be required to revise its procedures to be in compliance with the requirements.

(Comment 323) Some comments recommend that we conduct our inspections of FSVP activities at the central locations where such activities are carried out. Some comments suggest that we conduct targeted inspections at corporate headquarters that focus only on the importer's FSVP, because most supplier verification programs are managed at the corporate level.

(Response 323) Because the FSVP regulation requires documentation of an importer's implementation of its FSVP, our inspections will be records-based. Therefore, in the event of an in-person inspection, the inspection generally will take place where the majority of FSVP records are kept. That might be at the importer's corporate headquarters or another central location. Although § 1.509(b)(2) permits offsite storage of records, those records must be retrieved and provided onsite within 24 hours of FDA's request for review.

b. Role of States in Enforcement

(Comment 324) Some comments ask how we will coordinate our FSVP enforcement activities with State and local agencies. Some comments assert that State and local authorities can play an important role in ensuring the effectiveness of this verification system through the inspection and surveillance of imported food products marketed to establishments routinely inspected by State and local agencies. Some comments ask that we communicate early and often with States and local authorities regarding anticipated roles, options, and resources that will be available for the implementation of this rule. Other comments suggest that we establish cooperative agreements with States explaining what type of enforcement actions we will support, how States should respond to discovered food hazards, and how we will use information reported by States. Some comments ask whether we will provide funding to State agencies to assist them in meeting inspection mandates.

(Response 324) We agree that State and local food safety regulatory authorities play an important role in helping to protect consumers from unsafe food. As previously stated, we

are working through the Partnership for Food Protection to develop and implement the IFSS consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA). We are currently developing our compliance strategy for the FSVP regulation and are considering the role that State and local authorities can play in helping to achieve compliance.

(Comment 325) Many comments ask us to be more open and transparent with records of imported foods distributed within the States. Some comments assert that State agencies must have access to all relevant import records when a State agency discovers an adulterated product. Some comments ask that we develop a formal mechanism through which States can supply surveillance information to us so that we can better target import inspections and review problem products, companies, and countries. Other comments ask us to develop a method to allow States to efficiently access FDA records.

(Response 325) In general, we work with our State partners in enforcement actions, including coordinating actions or deferring to each other when one department has authority to act swiftly to protect the consumer. As previously stated, we are still determining the appropriate role of our State partners in FSVP implementation and enforcement.

c. Decreased Border Sampling for Food Subject to FSVP

(Comment 326) Some comments ask that we consider decreasing the sampling frequency of regular border inspections for chemical, physical, and radiological contamination of imported foods if the importer is in compliance with the FSVP regulation. These comments assert that chemical, physical, and radiological hazards are not increased during transport, unlike biological hazards.

(Response 326) We agree that the results of FSVP inspections should factor into our operations at ports of entry. We plan on incorporating data from the inspections into our PREDICT system to help better target food imports based on risk, which could include risks associated with different types of hazards.

2. Outreach and Training

(Comment 327) Some comments support the efforts of the FSPCA and encourage supplier verification-specific training as part of Alliance programs. Some comments offer recommendations for the content, delivery, and timing of education and training for FDA and

industry. These comments suggest that materials be designed for simplicity of understanding but also completely address all requirements, that FDA take advantage of the wide range of methods available for distribution and dissemination of educational and instructional materials (e.g., workshops, webinars, publications/media, and onsite trainings/consultations), and that we begin training efforts as soon as the final rule is published.

(Response 327) We agree that the FSVP materials we develop for industry need to be comprehensive and understandable to importers and other stakeholders. We also agree that our outreach methods for distribution and dissemination of educational and instructional materials should vary and be easily accessible. We have solicited input on how to best reach all affected stakeholders and will continue to do so. We intend to begin external outreach soon after we issue the final rule.

(Comment 328) Some comments request that we provide “special and differential treatment” along with technical assistance to help exporters from developing countries meet the requirements of the FSVP regulation. One comment also states that providing training will be particularly useful for addressing how implementation of FSMA will impact developing countries.

(Response 328) The concept of special and differential treatment is incorporated in the WTO agreements. Article 10.2 of the SPS Agreement states: “Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction . . . longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports” (Ref. 4). At the 2001 WTO Ministerial Conference in Doha, WTO Members issued a Ministerial Decision that interpreted the special and differential obligations of the SPS Agreement (Ref. 18). The Ministerial Decision defined “longer time-frame for compliance” with regulatory measures to normally mean a period of not less than 6 months.

As discussed in section VI.B of this document, we proposed that importers generally would be required to come into compliance with the FSVP regulation 18 months after the publication date of the final rule. For importation of foods subject to the preventive controls or produce safety regulations, importers would be required to comply with the FSVP regulation 6 months after their foreign

suppliers were required to comply with the applicable regulations.

However, recognizing that smaller businesses may need more time to comply with the requirements, the preventive controls and produce safety regulations contain extended compliance deadlines for very small businesses and small businesses. For example, in the final rule on preventive controls for human food, we are allowing 2 years for small businesses and 3 years for very small businesses to comply with that regulation. We anticipate that these extended implementation periods for small businesses and very small businesses will apply to many firms that would be foreign suppliers for FSVP purposes, including suppliers in developing countries. We believe these implementation periods are sufficient to address the needs of producers in developing countries, particularly for small and very small producers in such countries.

In addition to the extended time periods for compliance for small and very small businesses, we have also established modified supplier verification requirements for importers of food from three types of small foreign suppliers. These foreign suppliers are: (1) Qualified facilities under the preventive controls regulations for human food or animal food, (2) certain smaller farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, and (3) shell egg producers not subject to the shell egg production regulation because they have fewer than 3,000 laying hens. Each of these types of suppliers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly if not wholly because of the size of the entity.

In addition to the 18-month time periods for compliance for all firms, extended compliance dates for small and very small businesses subject to the preventive controls and produce safety regulations, and modified requirements for very small businesses, we intend to work with the food industry, educational organizations, the USDA, the United States Agency for International Development, and foreign governments to develop the tools and training programs needed to facilitate compliance with these new food safety regulations by exporters, including those from developing countries. In addition, as previously stated, we have issued a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign

governments and their respective food industries in countries from which foods are exported to the United States.

(Comment 329) Some comments assert that effective implementation of the FSVP regulation will require comprehensive FDA inspector training, and they recommend that we begin developing such a training program. Some comments ask us to establish a dedicated cadre of supplier verification inspectors who are specially trained to efficiently and effectively ensure that importers’ FSVPs are subject to careful and thoughtful inspections. These comments assert that inspectors who are only familiar with food facility operations will lack the necessary insight and understanding to effectively inspect supplier verification programs unless they are given considerable training. Some comments maintain that inspectors should be trained to understand what is required of the FSVP regulation, how inspections should be conducted, and what types of observations are appropriate to include on FDA-Form 483s issued to importers.

Some comments assert that inspector calibration will be essential to ensure that the regulations are enforced consistently from one region to another by both Federal and State officials. These comments suggest that internal guidance and measures as well as extensive training and education will help ensure that Federal and State inspection and enforcement programs are applied consistently.

(Response 329) We agree that training is an important component of implementation of the FSVP regulation. We are currently developing a comprehensive training program for our inspectional and compliance staff with the goal of ensuring that our FSVP inspections are effective, efficient, and consistent. Our goal is to provide real-time communication between our field investigators and our subject matter experts at Agency headquarters so that questions can be resolved quickly and consistently. This will be important not only for the FSVP regulation but also for the supplier verification components of the preventive controls regulations.

While we agree that our FSVP inspections, which will be records based, will be different from our food facility inspections, we believe that many of the skills needed to conduct these inspections will overlap. For example, an investigator looking at an importer’s FSVP will have to understand the hazard analysis and food and supplier evaluation on which the importer relies to assess the effectiveness of the importer’s FSVP. We are currently exploring ways to leverage

the work done by the FSPCA to aid FSVP compliance efforts.

(Comment 330) Some comments assert that border agents should be appropriately trained in applying FSVP requirements to avoid delays in entry of imported food.

(Response 330) We intend to provide education and training on the FSVP regulation to all FDA staff. We note, however, that FSVP inspections will not occur at entry. These inspections will more likely occur at the offices of importers, their corporate headquarters, or other places where FSVP records are kept. Entry decisions will only be affected if we find problems with an importer's FSVP that remain uncorrected or pose a risk to public health.

(Comment 331) One comment expresses concern that we may not have adequate knowledge and appreciation of foreign food safety practices and asks that we train our inspectors to take these differences into account and adopt a flexible approach to inspections. The comment asserts that this concern is heightened by the FSMA mandate to increase inspections of foreign food facilities.

(Response 331) Because the FSVP regulation applies to importers, we generally will not be inspecting foreign facilities as part of our implementation and enforcement of this regulation. However, we appreciate the differences in food safety practices among different countries and will take them into account when implementing the FSVP regulation. FSMA mandates that importers provide adequate assurances that their foreign suppliers produce food using processes and procedures that provide the same level of public health protection as those required under applicable regulations in the United States. We will need to train our investigators and compliance staff to properly apply this standard when inspecting importers. Ensuring real-time communication between our field staff and subject matter experts at FDA headquarters will help provide consistency in interpretation and judgment.

(Comment 332) Some comments assert that we should design and develop a functional scheme to ensure that States receive needed funds and training to assist in implementing the FSVP regulation if they decide to do so. Some comments assert that we should pursue funding to invest in State agencies that can assist in meeting inspection mandates.

(Response 332) As stated previously, we are currently developing our compliance strategy for FSVP and are

considering the role that State and local authorities can play in helping to achieve compliance.

IV. Effective and Compliance Dates

A. Effective Date

We proposed that any final rule on FSVPs would become effective 60 days after the date on which it is published in the **Federal Register**.

(Comment 333) Some comments support the proposed effective date while others assert that the effective date should be a minimum of 6 months to 1 year after the publication of the final FSVP guidance.

(Response 333) We decline the request to extend the effective date for this rule beyond 60 days after publication. Sixty days is a customary effective date period for significant rules. To the extent that the comments would like importers to have additional time to comply with the final rule, compliance dates are more relevant than the rule's effective date. As discussed in section IV.B of this document, we are providing more time for importers to comply with the FSVP regulation. We intend to issue guidance in a timely manner to facilitate compliance with the new requirements.

B. Compliance Dates

We proposed that generally importers would be required to come into compliance with the FSVP regulation 18 months after the publication date of the final rule. We believed that this would give importers enough time to make changes to their business practices that would be needed to come into compliance with the various requirements we proposed. We proposed exceptions to this approach to take into account the different compliance dates suggested in the proposed rules on preventive controls for human food, preventive controls for animal food, and produce safety.

We proposed that with respect to foods subject to the preventive controls regulations, the importer would be required to comply with the FSVP regulation 6 months after the foreign supplier of the food is required to comply with the preventive controls regulations.

With regard to foreign suppliers that are farms, we proposed to stagger the compliance dates for FSVP activities for RACs from farms as follows:

- The compliance date for an importer to comply with the FSVP regulation with respect to a RAC from a farm would be 18 months after the publication date of the final rule or 6 months after the date on which the

supplier must be in compliance with the produce safety regulation, whichever is later.

- If the foreign supplier is not subject to the produce safety regulation, the compliance date for the importer to comply with the FSVP regulation with respect to a RAC received from a farm would be 18 months after the publication date of the final rule or 6 months after the effective date of the produce safety final rule, whichever is later. This approach would ensure that the receiving facility would be able to know whether the farm supplier was subject to the produce safety regulation before choosing any appropriate verification activities.

(Comment 334) Some comments support the proposed general compliance date of 18 months after publication of the final rule. Some comments assert that the proposed compliance period is too short and ask that the compliance date be extended to 30 months, 3 years, or 5 years after the publication of the final rule. Some comments ask us to coordinate uniform compliance dates for all the FSMA implementing rules to provide certainty and allow businesses to plan for the extensive changes that will be mandated.

(Response 334) We agree that we should coordinate compliance dates for the FSMA implementing rules that are interrelated. We continue to believe that 18 months is a reasonable timeframe for certain importers to begin complying with the requirements. In addition, we continue to strive to minimize the likelihood that an importer will be required to comply with the FSVP regulation before its supplier is required to comply with other FSMA food safety regulations. Finally, we see value in having the compliance dates of this rulemaking align with the compliance dates of the supply-chain program provisions in the preventive controls regulations, to the extent feasible. Therefore, we conclude that the date that importers must comply with the FSVP regulation is the latest of the following dates:

- 18 months after the publication of this final rule;
- For the importation of food from a supplier that is subject to the preventive controls regulations for human food or animal food or the produce safety regulation, 6 months after the foreign supplier of the food is required to comply with the relevant regulations; or
- For an importer that is also subject to the supply-chain program provisions in the preventive controls regulations for human food or animal food, the date the importer, as a receiving facility, is

required to comply with the supply-chain program provisions of the relevant regulation.

(Comment 335) Some comments assert that there should be an informed compliance or transition period after the end of the pre-compliance period during which importers would be expected to comply gradually with the FSVP regulation without the threat of full enforcement and associated penalties. Some comments specify 12 months as the appropriate time for such an informed compliance or transition period. Some comments ask that we give developing countries longer transition periods.

(Response 335) We decline these requests for an informed compliance period because we conclude that we are providing importers with adequate time in which to come into compliance with the FSVP regulation. However, we intend to conduct outreach, training, and engagement activities to help importers understand the new requirements and enable them to comply with the requirements by the applicable compliance dates.

V. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal governmental officials regarding this rulemaking. We have prepared a Tribal Summary Impact Statement that includes a summary of tribal officials' concerns and how we have addressed them (Ref. 19). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.fda.gov/fsvprule> or at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

VI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory

options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to adopt FSVPs or conduct additional verification activities, we conclude that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We expect this final rule to result in a 1-year expenditure that would meet or exceed this amount.

The final analyses conducted in accordance with these Executive Orders and statutes will be made available in the docket for this rulemaking and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/> (Ref. 20).

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the paragraphs that follow with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.

Description: FDA is finalizing its regulation on FSVPs for food for humans and animals. The regulation is intended to help ensure that food

imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as the processes and procedures required for production of food in compliance with section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g or 350h), if either is applicable, and in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act (21 U.S.C. 342 and 343(w)).

Description of Respondents: We estimate that currently there are approximately 56,800 persons who meet the definition of importer set forth in this final rule (and are not exempt from the rule) and are therefore subject to its information collection requirements. The rule exempts from these requirements the importation of certain foods, including the following: Certain juice and seafood products and ingredients; food for research or evaluation; food for personal consumption; certain alcoholic beverages and ingredients imported for use in alcoholic beverages; food that is transshipped through the United States; food that is imported for processing and future export; food that is produced in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country; and meat, poultry, and egg products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). The final rule also specifies that importers who are in compliance with the supply-chain program provisions in the preventive controls regulations, who implement preventive controls for the hazards in the food they import, or who are not required to implement a preventive control under certain provisions of the preventive controls regulations, are deemed in compliance with most of the FSVP requirements. Certain exceptions to the standard FSVP requirements would apply to importers of food for which the importer's customer or a subsequent entity in the distribution chain controls a hazard. In addition, the final rule establishes modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from certain small foreign manufacturers/processors and farms, and importers of

certain food from suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

In the **Federal Register** of July 29, 2013 (78 FR 45729), we published a notice of proposed rulemaking including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the proposed regulation. In the **Federal Register** of September 29, 2014 (79 FR 58573), we published a supplemental notice of proposed rulemaking also including a PRA analysis. While we received some comments regarding

recordkeeping requirements generally, which are discussed in section III.K of this document, we did not receive specific comments addressing the four information collection topics solicited in both the original and supplemental proposed rules. We are, therefore, retaining the estimates provided in our supplemental notice of proposed rulemaking, except to the extent that revisions are necessary to address changes to the proposed regulation included in the final rule, as discussed in the following paragraphs. For more information on our original calculations of the information collection burden associated with this rulemaking, you

may refer to the PRA analyses found under Docket No. FDA-2011-N-0143 at www.regulations.gov.

We estimate the burden for this information collection as follows:

Reporting Burden

Table 4 shows the total estimated annual reporting burden associated with this final rule. This estimate is consistent with the reporting estimates found in the supplemental notice of proposed rulemaking published on September 29, 2014 (79 FR 58573 at 58590), except where revisions are necessary to reflect new requirements included in the final rule.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.501(c); exemption for food for research	36,360	40	1,454,400	0.083 (5 minutes)	120,715
1.509(a), 1.511(c), 1.512(b)(2); importer identification information for filing with CBP.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

A. Exemption for Food for Research or Evaluation

Section 1.501(c) of the FSVP regulation exempts food that is imported for research or evaluation purposes, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public.
- The food is labeled with the statement “Food for research or evaluation use.”
- The food is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of.
- When filing entry for the food with CBP, the customs broker or filer for the food provides an electronic declaration that the food will be used for research

or evaluation purposes and will not be sold or distributed to the public.

As shown in Table 4, we estimate that annually there will be 36,360 persons for whom a declaration that a food will be used for research or evaluation purposes will be submitted, and that about 40 declarations will be submitted for each such person annually. We further estimate that submission of this declaration should take approximately 0.083 hours, resulting in a total annual burden of 120,715 hours.

B. Importer Identification at Entry

Section 1.509(a) requires importers to ensure that, for each line entry of food product offered for importation into the United States, its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA is provided electronically when filing

entry with CBP. As shown in Table 4, we estimate that each of the estimated 56,800 importers would need to ensure that this information is provided for an average of 157 line entries each year. We further estimate that each such submission would require 0.02 hours, resulting in a total annual burden of 178,352 hours.

Recordkeeping Burden

Table 5 shows the total estimated annual recordkeeping burden associated with this final rule. While this estimate is consistent with many of the recordkeeping estimates found in our previous analyses, we have revised certain estimates to reflect changes to the proposed requirements included in the final rule and adopted additional requirements under § 1.507(a) and have revised our calculations accordingly.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Controls for LACF—1.502(b)	2,443	4	9,772	1	9,772
Determine and document hazards—1.504(a)	11,701	1	11,701	3.5	40,954
Review hazard analysis—1.504(d)	11,701	7	81,907	0.33	27,029
Evaluation of food and foreign supplier—1.505(a)(2), 1.511(c)(1)	11,701	1	11,701	4	46,804
Approval of suppliers—1.505(b), 1.512(c)(1)(iii)	8,191	1	8,191	12	98,292
Reevaluation of food and foreign supplier—1.505(c), 1.512(c)(1)(ii)(A)	11,701	365	4,270,865	0.25	1,067,716

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Confirm or change requirements of foreign supplier verification activity—1.505(c), 1.512(c)(1)(ii)(A)	2,340	1	2,340	2	4,680
Review of other entities assessments—1.505(d), 1.512(c)(1)(iii)	3,510	1	3,510	1.2	4,212
Written procedures for use of approved foreign suppliers—1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i)	11,701	1	11,701	8	93,608
Review of written procedures—1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii)	11,701	1	11,701	1	11,701
Written procedures for conducting verification activities—1.506(b), 1.511(c)(3)	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities—1.506(d)(1)–(2) 1.511(c)(4)(i)	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determination by another entity—1.506(d)(3) 1.511(c)(4)(iii) ...	11,701	2	23,402	0.33	7,723
Conduct/review audits—1.506(e)(1)(i), 1.511(c)(5)(i)(A)	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing—1.506(e)(1)(ii), 1.511(c)(5)(i)(B)	11,701	2	23,402	1	23,402
Review records—1.506(e)(1)(iii), 1.511(c)(5)(i)(C)	11,701	2	23,402	1.6	37,443
Document your review of supplier verification activity records—1.506(e)(3), 1.511(c)(5)(iii)	11,701	6	70,206	0.25	17,552
1.507(a)(1)	11,701	3.17	37,082	1.25	46,353
Written assurances—1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)	11,701	8.72	102,038	0.50	51,019
Disclosures that accompany assurances—1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)	102,038	1	102,038	0.50	51,019
Document assurances from customers—1.507(c)	36,522	2.8	102,262	0.25	25,566
Document corrective actions—1.508(a) and 1.512(b)(4)	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy—1.508(b), 1.511(c)(1)	2,340	1	2,340	5	11,700
Written assurances for food produced under dietary supplement CGMPs—1.511(b)	11,701	2.88	33,664	2.25	75,744
Document very small importer/certain small foreign supplier status—1.512(b)(1)	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier—1.512(b)(3)	50,450	2.8	141,084	2.25	317,439
Total					

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

A. Documentation of Production of LACF in Accordance With Part 113

Section 1.502(b)(1) requires importers of LACF to verify and document that, with respect to microbiological hazards that are controlled under part 113, the food was produced in accordance with those regulations, and for all matters not controlled under part 113, to have an FSVP as specified in § 1.502(a). As shown in Table 5, we estimate that there are 2,443 importers of LACF importing an estimated 4 LACF products annually. We further estimate that it would take each LACF importer 1 hour to document that a food was produced in accordance with part 113. This results in a total annual burden of 9,772 hours.

B. Hazard Analysis

Section 1.504(a) requires importers, for each food they import or offer for import, to have a written hazard analysis. We have updated our estimates. We estimate that 11,701

importers would need to spend an average of 3.5 hours each determining and documenting hazard analyses for imported foods, resulting in an estimated burden of 40,954 hours (13,651 hours annualized).

Section 1.504(d) permits importers to identify the hazards that are reasonably likely to occur with a food by reviewing and evaluating the hazard analysis conducted by another entity (including the foreign supplier). If the importer selects this approach to hazard analysis it must document the determination it makes based on its review and evaluation of the foreign supplier's hazard analysis. As shown in table 5, we estimate that 11,701 importers would take this approach to hazard analysis for about 7 products each, and that evaluating the supplier's hazard analysis and documenting each evaluation would require about 1 hour on average. This results in a total

burden of 27,029 hours (9,010 hours annualized).

C. Evaluation for Supplier Approval and Verification

Section 1.505(a)(2) requires importers to document their evaluation of the risk posed by a food and the foreign supplier's performance. As shown in table 5, we estimate that it will take 12 hours for each of an estimated 11,701 importers to conduct and document their evaluation under §§ 1.505(a) and 1.511(c), resulting in a total burden of 46,804 hours (15,601 hours annualized).

Section 1.505(b) requires importers to document the approval of their foreign suppliers on the basis of the food and supplier evaluation the importer conducts under § 1.505(a). As shown in table 5, we estimate that it will take 12 hours for each of an estimated 8,191 importers to approve their foreign suppliers and document their approval of the suppliers, resulting in a total

burden of 98,292 hours (32,764 hours annualized).

Section 1.505(c) requires that the importer reevaluate factors associated with the food and foreign suppliers when the importer becomes aware of new information. Recognizing that some importers may choose to spend more time less often, we estimate it would take about 15 minutes per day to maintain and follow these procedures by reviewing information regarding hazards and suppliers. This results in a burden of 1,067,716 hours annually.

Section 1.505(c) also requires that if an importer determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted need to be changed. We estimate that 2,340 importers will need to determine and document whether they need to change their supplier verification activities 1 time per year, resulting in a total burden of 4,680 hours.

Section 1.505(d) allows importers to review another entity's evaluation or reevaluation of the risk posed by a food and the foreign supplier's performance and requires the importer document the review and assessment or reassessment. As shown in table 5, we estimate that it will take 1.2 hours for each of an estimated 3,510 importers to review and assess or reassess documentation provided by another entity, resulting in a total burden of 4,212 hours (1,404 hours annualized).

D. Foreign Supplier Verification and Related Activities

Under § 1.506(a)(1), importers must establish and follow adequate written procedures to ensure that they import foods only from foreign suppliers that they have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods importers subject to adequate verification activities before using or distributing), and document the use of those procedures. As shown in table 5, we estimate that it would take each of 11,701 importers 8 hours to establish procedures resulting in a burden of 107,112 hours (35,749 hours annualized) and 4 hours annually to document the use of such procedures resulting in an annual burden of 93,608 hours, for a grand total of 31,203 hours annualized.

Under § 1.506(a)(2), an importer may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.506(a)(1) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer document its review and assessment. As shown in table 5, we estimate that it would take each of 11,701 importers 1 hour to review and assess another entity's procedures, resulting in a burden of 11,701 hours (3,900 hours annualized).

Under §§ 1.506(b) and 1.511(c)(3), importers must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted. As shown in table 5, we estimate that it would take each of 11,701 importers 2 hours to establish procedures resulting in a total burden of 23,402 hours (7,801 hours annualized).

Section 1.506(d) requires importers to determine and document which supplier verification activities are appropriate in order to provide adequate assurances that the hazards requiring a control in the food the importer bring into the United States have been significantly minimized or prevented. Under § 1.506(d)(2), when a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the importer must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer makes an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances that the hazards requiring a control in the food are significantly minimized or prevented. As shown in table 5, we estimate that it would take an estimated 11,701 importers 3.25 hours to determine and document appropriate supplier verification activities under either § 1.506(d)(1) or (2) or § 1.511(c)(4)(i) for 4 food and foreign supplier combinations per importer, resulting in a total burden of 152,113 hours (50,704 hours annualized).

Under §§ 1.506(d)(3) and 1.511(c)(4)(iii), instead of determining the verification activities themselves, importers can review and document that they have reviewed and assessed the supplier activities determinations made

by another entity. As shown in table 5, we estimate that it would take an estimated 11,701 importers 0.33 hours to review and document review of another entity's determination of the appropriate supplier verification activities 2 food and foreign supplier combinations per importer, resulting in a total burden of 7,723 hours (2,574 hours annualized).

Under § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A), an importer may conduct (and document) or obtain documentation of an onsite audit of the foreign supplier. As shown in table 5, we estimate that 32,402 such audits would be conducted (or documentation obtained for) annually, with each audit requiring an average of 3 hours each, resulting in a total annual burden of 70,206 hours.

Under § 1.506(e)(1)(ii) or § 1.511(c)(5)(i)(B), an importer may conduct (and document) or obtain documentation of sampling and testing of a food for a hazard. As shown in table 5, we estimate that 11,701 importers each year would determine that this approach to verification is appropriate for an average of two products they import. We further estimate that each incidence of sampling and testing and corresponding documentation will require 1 hour. This results in an estimated annual burden of 23,402 hours.

Under § 1.506(e)(1)(iii) or § 1.511(c)(5)(i)(C), an importer may conduct (and document) or obtain documentation of a review of its foreign supplier's food safety records to verify control of a hazard. As shown in table 5, we estimate that 11,701 importers each year would determine that this approach to verification is appropriate for an average of two products they import. We further estimate that documentation of food safety record review would require 1.6 hours, resulting in a total annual burden of 37,443 hours.

Under § 1.506(e)(1)(iv) or § 1.511(c)(5)(i)(D), an importer may use a different verification procedure that it has established as being appropriate based on an evaluation of the risk posed by a food and the foreign supplier's performance; the importer must document such use. We have not identified any alternative verification procedure nor included an estimated cost, nor have we estimated any associated burden for revised § 1.506(e)(1)(iv).

Section 1.506(e)(3) requires importers to promptly review and assess the results of the verification activities that they conduct or obtain documentation of under § 1.506(e)(1), or that are

conducted by other entities in accordance with § 1.506(e)(2), and to document the review and assessment of the results. However, importers are not required to retain documentation of supplier verification activities conducted by other entities, provided that the importer can obtain the documentation and make it available to FDA in accordance with § 1.510(b). As shown in table 5, we estimate that 11,701 importers will review and assess the results of 70,206 supplier verification activities annually, and that each review and assessment will take 0.25 hours. This results in a total annual burden of 17,552 hours.

E. Requirements for Food That Cannot Be Consumed Without Hazards Being Controlled or for Which Hazards Are Controlled After Importation

Section 1.507 of the final rule includes provisions for activities that were partially addressed under the proposed rule and the supplemental notice of proposed rulemaking. Under § 1.507(a)(1) of the final rule, an importer is not required to conduct a food and foreign supplier evaluation under § 1.505 or conduct supplier verification activities under § 1.506 if it determines and documents that the type of food it is importing could not be consumed without application of an appropriate control. As shown in table 5, we estimate that each year 11,701 importers will determine that 37,082 foods cannot be consumed without application of a control and that it will take 1.25 hours, on average, to make the determination, resulting in a total annual burden of 46,353 hours.

Under § 1.507(a)(2), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer who is subject to subpart C of part 117 or part 507 (the regulations on hazard analysis and risk-based preventive controls) to ensure that the identified hazard will be significantly minimized or prevented, and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]”; and
- Annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

Under § 1.507(a)(3), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer who is not required to implement preventive controls under part 117 or part 507 to

provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]”; and
- Annually obtains from its customer written assurance that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

Under § 1.507(a)(4), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]” and
- Annually obtains from its customer written assurance that the customer will disclose in documents accompanying the food that the food is “not processed to control [identified hazard]” and will only sell to another entity that agrees, in writing, it will: (1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to subpart C of part 117 or part 507) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not required to implement preventive controls under part 117 or part 507); or (2) obtain a similar written assurance from the entity’s customer as required under § 1.507(a)(4)(ii)(A) or (B).

As shown in table 5, we estimate that 11,701 importers will obtain such a written assurance from 102,038 customers annually in accordance with § 1.507(a)(2), (3), and (4), collectively, and that it will take 0.50 hours to document the written assurance. This results in an estimated annual burden of 51,019 hours. We estimate that the disclosure burdens under these provisions will also take 0.50 hours each and will be done for each of the 102,038 assurances identified resulting in an annual burden of 51,019 hours.

Under § 1.507(a)(5), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it establishes, documents, and implements a system that ensures control, at a subsequent distribution step, of the hazards in a food and the importer documents its implementation of that system. We did not include an estimate for compliance with this

provision because we do not know any examples of such a system for hazard control.

Under § 1.507(c), the customer of an importer or some other subsequent entity in the distribution chain for a food that provides a written assurance under § 1.507(a)(2), or (3), or (4) must document its actions taken to satisfy the written assurance. As shown in table 5, we estimate that 36,522 customers of importers or other subsequent entities in the distribution chain will need to document its actions in accordance with § 1.507(c) 2.8 times annually and that this documentation will require 0.25 hours, resulting in a total annual burden of 25,566 hours.

F. Investigations, Corrective Actions, and Investigations Into FSVP Adequacy

Proposed § 1.507(b) would have required an importer, if it became aware that an article of food that it imported was adulterated or misbranded, to promptly investigate the cause or causes of such adulteration or misbranding and to document any such investigation. As previously discussed, this requirement was not included in the final rule and we have therefore removed the burden previously calculated for its implementation and revised our estimate accordingly.

Section 1.508(a) of the final rule requires an importer to take corrective actions if it determines that one of its foreign suppliers of a food does not produce the food in compliance with processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act. Such corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. As shown in table 5, we estimate that 2,340 importers will need to take a corrective action 1 time annually, and that the corrective action will require 2 hours to complete, resulting in a total annual burden of 4,680 hours.

Section 1.508(b) requires an importer, if it determines by means other than its verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), that one of its foreign suppliers does not produce food using processes and procedures that provide the same level

of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act, to promptly investigate to determine whether the importer's FSVP is adequate and, when appropriate, to modify the FSVP. This provision also requires importers to document any such investigations and FSVP changes. As shown in table 5, we estimate that, on average, 2,340 importers will need to conduct an investigation once a year to determine the adequacy of their FSVP in accordance with § 1.508(b) and that conducting and documenting the investigation will require 5 hours. This results in an estimated annual burden of 11,700 hours.

G. Food Subject to Certain Dietary Supplement CGMP Requirements

Section 1.511 sets forth modified FSVP requirements for food that is subject to certain dietary supplement CGMP requirements. Under § 1.511(a), importers who are required to establish specifications under § 111.70(b) or (d) with respect to a food that is a dietary supplement or dietary supplement component it imports for further manufacturing or processing as a dietary supplement, and are in compliance with the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met, must comply with the requirements under §§ 1.503 and 1.509, but are not required to comply with the requirements in §§ 1.502, § 1.504 through 1.508, or § 1.510. These importers are included in the estimated reporting burden for § 1.509(a).

Under § 1.511(b), if an importer's customer is required to establish specifications under § 111.70(b) or (d) with respect to a food that is a dietary supplement or dietary supplement component it imports for further manufacturing or processing as a dietary supplement, the customer is in compliance with the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that the customer is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.503, 1.509, and 1.510, but is not required to comply with the requirements in §§ 1.502 and §§ 1.504 through 1.508. As shown in table 5, we estimate that 5,574 importers would need to obtain written assurance from

an average of 6 customers in accordance with § 1.511(b) and that documentation of each assurance would take 2.25 hours, resulting in a total annual burden of 75,249 hours. In addition, these importers are included in the estimated annual reporting burden for § 1.509(a).

Under § 1.511(c), importers of other dietary supplements, including "finished" dietary supplements (*i.e.*, packaged and labeled dietary supplements that are not subject to further processing) and dietary supplements imported only for packaging and labeling are subject to different FSVP requirements.

Section 1.511(c)(2)(i) requires importers of finished dietary supplements to establish and follow written procedures to ensure that food is imported only from foreign suppliers that have been approved for use based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities). This burden to importers of "finished" dietary supplements and dietary supplements imported only for packaging and labeling is captured in the burden calculated for § 1.506(a)(1).

Under § 1.511(c)(2)(ii), an importer of a dietary supplement may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.511(c)(2)(i) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer document its review and assessment. This burden is captured in the burden calculated for § 1.506(a)(2).

Section 1.511(c)(3) requires importers of finished dietary supplements to establish and follow procedures for conducting foreign supplier verification activities. This burden is included in the burden calculated for § 1.506(b).

Section 1.511(c)(4)(i) requires importers of finished dietary supplements to determine and document which appropriate verification activities should be conducted, and the frequency with which they should be conducted. The estimated burden for this provision is included in the burden calculated for § 1.506(d)(1) and (2).

Under § 1.511(c)(4)(iii), a dietary supplement importer may rely on a determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier if the importer reviews and assesses whether the entity's determination regarding appropriate activities is

appropriate and documents the review and assessment. This burden is included in the burden calculated for § 1.506(d)(3).

For each dietary supplement imported in accordance with § 1.511(c), the importer would need to conduct one or more of the verification activities listed in § 1.511(c)(5)(i)(A) through (D) before using or distributing the dietary supplement and periodically thereafter. Estimates associated with these activities are included in the burdens presented in table 5 for § 1.506(e)(1)(i) through (e)(1)(iv), respectively.

Section 1.511(c)(5)(iii) requires importers to promptly review and assess the results of the verification activities that they conduct or obtain documentation of under § 1.511(c)(5)(i), or that are conducted by other entities in accordance with § 1.511(c)(5)(ii), and to document the review and assessment of the results. However, importers are not required to retain documentation of supplier verification activities conducted by other entities, provided that the importer can obtain the documentation and make it available to FDA in accordance with § 1.510(b). This burden is included in the burden calculated for § 1.506(e)(3).

Section 1.511(c) also requires importers of finished dietary supplements to conduct evaluations of the foreign supplier, conduct investigations (in certain circumstances) to determine the adequacy of their FSVPs, and ensure that information identifying them as the importer is provided at entry. These importers have been included in the estimated record keeping and reporting burdens for these activities under §§ 1.505, 1.508, and 1.509(a), respectively.

H. Food Imported by Very Small Importers and From Certain Small Foreign Suppliers

Section 1.512 sets forth modified proposed FSVP requirements for very small importers as defined in § 1.500; food from a foreign supplier that is a qualified facility as defined by § 117.3 or § 507.3; produce from a farm that is not a covered farm under the produce safety regulation in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or shell eggs from an egg producer with fewer than 3000 laying hens. Under § 1.512(b)(1), if a very small importer or an importer of food from such a foreign supplier chooses to comply with the requirements in § 1.512, the importer would be required to document, at the end of each calendar year, that it meets the definition of very small importer in § 1.500 or that the foreign supplier

meets the criteria in § 1.512(a)(2)(i), (ii), or (iii), as applicable. As shown in table 5, we estimate that 37,206 very small importers and importers of food from 13,244 certain small suppliers would need to document eligibility each year for themselves and their small suppliers and that such documentation would require 1 hour. The resulting annual burden is 50,450 hours.

Under § 1.512(b)(3), each very small importer or importer of food from foreign suppliers that meet the criteria in § 1.512(a)(2)(i), (ii), or (iii) needs to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in accordance with applicable statutory and regulatory standards. Importers of food from the specified foreign suppliers must obtain written assurance that the supplier is producing food in compliance with applicable requirements or acknowledges that it is subject to applicable standards (as specified in § 1.512(b)(3)(ii) through (iv)). As shown in table 5, we estimate that 50,450 very small importers and importers of food from certain small suppliers would need to obtain an average of 2.8 such written assurances each year and that documentation of each assurance would require 2.25 hours, resulting in a total annual burden of 317,439 hours.

Section 1.512(b)(4) requires very small importers and importers of food from certain small foreign suppliers to take corrective actions. This burden is included in the burden calculated for § 1.508(a).

Section 1.512(c) sets forth requirements that apply to importers of food from the specified types of small foreign suppliers, but not to very small importers. Under § 1.512(c)(1)(i), in approving their foreign suppliers, these importers must consider the applicable FDA food safety regulations and evaluate information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. We include this burden in our calculation of the burden associated with § 1.505(a)(2) in table 5.

Under § 1.512(c)(1)(ii)(A), these importers must promptly reevaluate the concerns associated with the foreign supplier's compliance history when the importer becomes aware of new information about supplier compliance history, and the reevaluation must be documented. Section 1.512(c)(1)(ii)(A) further requires that if the importer

determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. We include these burdens in our calculation of the burdens associated with § 1.505(c) in table 5.

Section 1.512(c)(1)(ii)(A) further requires that if the importer determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. This burden is included in the estimate for § 1.505(c) in table 5.

Under § 1.512(c)(1)(iii), if an entity other than the foreign supplier has, using a qualified individual, performed the evaluation or reevaluation of foreign supplier compliance history, the importer may review and assess the evaluation or reevaluation conducted by that entity, and document its review and assessment. We include this burden in our calculation of the burden associated with § 1.505(d) in table 5.

Under § 1.512(c)(2), the importer of a food from certain small foreign suppliers must approve the foreign suppliers on the basis of the evaluation the importer conducts (or reviews and assesses) and document its approval. We include this burden in our calculation of the burden associated with § 1.505(b).

Under § 1.512(c)(3)(i), importers of food from certain small foreign suppliers must establish and follow written procedures to ensure that they import foods only from approved foreign suppliers (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods are subjected to adequate verification activities before using or distributing). Importers must document their use of these procedures. We include this burden in our calculation of the burden associated with § 1.506(a)(1).

Under § 1.512(c)(3)(ii), an importer may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.512(c)(3)(i) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer documents its review and assessment. We include this burden in our calculation of the burden associated with § 1.506(a)(2).

I. Food Imported From a Country With an Officially Recognized or Equivalent Food Safety System

Section 1.513 establishes modified FSVP requirements for importers of certain food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States. If such importers meet certain conditions or requirements, they will not be required to comply with the requirements in §§ 1.504 through 1.508, but they will be required to comply with §§ 1.503, 1.509, and 1.510.

Section 1.513(b)(1) requires an importer, before importing a food from the foreign supplier and annually thereafter, to document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent and that the food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located.

Section 1.513(b)(2) requires an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier of the food is in good compliance standing, as defined in § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, the importer is then required to take prompt corrective action and to document any such action.

FDA has officially recognized New Zealand as having a food safety system that is comparable to that of the United States; however, we have not recognized any other food safety systems as comparable or determined them to be equivalent. Because we have only recently entered into a systems recognition arrangement with New Zealand recognizing that country's food safety system as being comparable to that of the United States, we are not able to assess the effect of the arrangement on the importation of food from that country. Therefore, we are not including estimates for the recordkeeping burdens associated with § 1.513.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective

date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. We have verified the Web site addresses provided for certain documents, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day One," September 19, 2013, available in Docket No. FDA-2011-N-0143.
2. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day Two," September 20, 2013, available in Docket No. FDA-2011-N-0143.
3. FDA, "Record of Outreach Sessions on FDA Proposed Rules," 2013, available in Docket No. FDA-2011-N-0143.
4. World Trade Organization, "The WTO Agreement on the Application of Sanitary and Phytosanitary Measures" (http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm), 1994.
5. Partnership for Food Protection National Workplan Workgroup, "Model for Local Federal/State Planning and Coordination of Field Operations and Training: A Partnership for Food Protection 'Best

Practice'" (<http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM373333.pdf>), October 2013.

6. Codex Committee on Food Import and Export Inspection and Certification Systems: Guidelines for Food Import Control Systems (CAC/GL 47-2003) (Rev. 1-2006) (http://www.codexalimentarius.net/download/standards/10075/CXG_047e.pdf), 2003.
7. Codex Alimentarius Commission, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application," Annex to CAC/RCP 1-1969 (Rev. 4-2003) (http://www.codexalimentarius.org/download/standards/23/CXP_001e.pdf), 2003.
8. Codex Alimentarius Commission, "General Principles of Food Hygiene," CAC/RCP 1-1969 (Rev. 4-2003) (http://www.codexalimentarius.org/download/standards/23/CXP_001e.pdf), 2003.
9. Codex Alimentarius Commission, "General Standard for the Labelling of Prepackaged Food," CODEX STAN 1-1985 (Rev. 7-2010) (http://codexalimentarius.org/download/standards/32/CXS_001e.pdf), 2010.
10. U.S. Pharmacopeial Convention, "U.S. Pharmacopeial Convention (USP) Food Fraud Database" (<http://www.usp.org/food-ingredients/food-fraud-database>), March 6, 2014.
11. Congressional Research Service, "Food Fraud and 'Economically Motivated Adulteration' of Food and Food Ingredients," (<http://www.fas.org/spp/crs/misc/R43358.pdf>), January 10, 2014.
12. Everstine, K., J. Spink, and S. Kennedy, "Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents," *Journal of Food Protection*, 76:723-735, 2013.
13. Beru, N., and FDA s.v., "Memo on Chemical, Physical and Radiological Hazards Associated with Produce," Memorandum to the Record in Docket No. FDA-2011-N-0921, May 29, 2012.
14. FDA, "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007" (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/RFR/ucm180761.htm>), September 2009.
15. FDA, "FDA's International Food Safety Capacity-Building Plan" (<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341440.pdf>), February 2013.
16. FDA, "Information for Foreign Governments: Frequently Asked Questions on Systems Recognition" (<http://fda.gov/food/internationalinteragencycoordination/ucm367400.htm>), September 5, 2013.
17. Regulation (EC) No 882/2004 of the European Parliament and of the Council, Official Journal of the European Union (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:165:0001:0141:EN:PDF>), April 30, 2004.
18. World Trade Organization, "WTO Ministerial Conference: Implementation-

Related Issues and Concerns," WT/MIN(01)/17 (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm), November 20, 2001.

19. FDA, "Tribal Summary Impact Statement: Final Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals," Docket No. FDA-2011-N-0143.
20. FDA, "Regulatory Impact Analysis For Final Rule On Foreign Supplier Verification Programs (Docket No. FDA-2011-N-0143) Under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)," Docket No. FDA-2011-N-0143.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 11, and 111 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

- 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

- 2. Add subpart L, consisting of §§ 1.500 through 1.514, to read as follows:

Subpart L—Foreign Supplier Verification Programs for Food Importers

Sec.

- 1.500 What definitions apply to this subpart?
- 1.501 To what foods do the regulations in this subpart apply?
- 1.502 What foreign supplier verification program (FSVP) must I have?
- 1.503 Who must develop my FSVP and perform FSVP activities?
- 1.504 What hazard analysis must I conduct?

- 1.505 What evaluation for foreign supplier approval and verification must I conduct?
- 1.506 What foreign supplier verification and related activities must I conduct?
- 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?
- 1.508 What corrective actions must I take under my FSVP?
- 1.509 How must the importer be identified at entry?
- 1.510 How must I maintain records of my FSVP?
- 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?
- 1.512 What FSVP may I have if I am a very small importer or if I am importing certain food from certain small foreign suppliers?
- 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?
- 1.514 What are some consequences of failing to comply with the requirements of this subpart?

Subpart L—Foreign Supplier Verification Programs for Food Importers

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Audit means the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen means a pathogen that is capable of surviving and persisting within the

manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this subpart include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeformers.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm means farm as defined in § 1.227.

Farm mixed-type facility means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Good compliance standing with a foreign food safety authority means that the foreign supplier—

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural

commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise

obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer means:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed,

packed, or held without sale (e.g., imported for a fee).

You means a person who is subject to some or all of the requirements in this subpart.

§ 1.501 To what foods do the regulations in this subpart apply?

(a) *General.* Except as specified otherwise in this section, the requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) *Exemptions for juice and seafood—(1) Importers of certain juice and seafood products.* This subpart does not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

(2) *Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter.* This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) *Exemption for food imported for research or evaluation.* This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public;

(2) Is labeled with the statement "Food for research or evaluation use";

(3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) *Exemption for food imported for personal consumption.* This subpart does not apply to food that is imported

for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(e) *Exemption for alcoholic beverages.* (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i) of this chapter.

(f) *Inapplicability to food that is transshipped or imported for processing and export.* This subpart does not apply to food:

(1) That is transshipped through the United States to another country and is

not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) *Inapplicability to U.S. food returned.* This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

(h) *Inapplicability to certain meat, poultry, and egg products.* This subpart does not apply with respect to:

(1) Meat food products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(2) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(3) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) *General.* Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) *Low-acid canned foods*—(1) *Importers of low-acid canned foods not subject to further manufacturing or processing.* With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that

are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) *Certain importers of raw materials or other ingredients subject to part 113 of this chapter.* With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

(a) *Qualified individual.* A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

(b) *Qualified auditor.* A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical

expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

§ 1.504 What hazard analysis must I conduct?

(a) *Requirement for a hazard analysis.* Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and

(iii) Physical hazards (such as stones, glass, and metal fragments).

(2) Your analysis must include known or reasonably foreseeable hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

(d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) *Hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) *No hazards requiring a control.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and you are not required to conduct foreign supplier verification activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter.

§ 1.505 What evaluation for foreign supplier approval and verification must I conduct?

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

(A) The foreign supplier's procedures, processes, and practices related to the safety of the food;

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) *Reevaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified

in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under § 1.506 or § 1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1).

(d) *Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) *Inapplicability to certain circumstances.* You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under § 1.506 if one of the circumstances described in § 1.507 applies to your importation of a food and you are in compliance with that section.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) *Use of approved foreign suppliers.* (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) *Requirement of supplier verification.* The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) *Determination of appropriate foreign supplier verification activities—*(1)(i) *General.* Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (*e.g.*, when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (e)(1)(i) of this section;

(B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

(2) *Verification activities for certain serious hazards.* When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities listed in paragraph (d)(1)(ii) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with paragraph (c) of this section, based on the determination made under § 1.505.

(3) *Reliance on a determination by another entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) *Performance of foreign supplier verification activities—*(1) *Verification activities.* Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

(i) *Onsite audit of the foreign supplier.* (A) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws

and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(D) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(1) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(2) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(ii) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(iii) *Review of the foreign supplier's relevant food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records

reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* (A) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(2) *Reliance upon performance of activities by other entities.* (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(4) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of

this section, and payment must not be related to the results of the activity.

§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

(a) *Circumstances.* You are not required to conduct an evaluation of a food and foreign supplier under § 1.505 or supplier verification activities under § 1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (*e.g.*, raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard;

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507); or

(2) Obtain a similar written assurance from the entity’s customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) *Written assurances.* Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) *Provision of assurances.* The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 1.508 What corrective actions must I take under my FSVP?

(a) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as

those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risks posed by the food and the foreign supplier’s performance conducted under § 1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(c) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§ 1.509 How must the importer be identified at entry?

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) Before an article of food is imported or offered for import into the

United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer” in § 1.500.

§ 1.510 How must I maintain records of my FSVP?

(a) *General requirements for records.*

(1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(2) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(3) All records must be legible and stored to prevent deterioration or loss.

(b) *Record availability.* (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with § 1.504, § 1.505, or § 1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) *Record retention.* (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after their use is discontinued (e.g., because you no longer import a particular food, you no longer use a particular foreign supplier, you have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic

records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) *Use of existing records.* (1) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

§ 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

(a) *Importers subject to certain dietary supplement current good manufacturing regulations.* If you are required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.503 and 1.509, but you are not required to comply with the requirements in § 1.502, §§ 1.504 through 1.508, or § 1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) *Importers whose customer is subject to certain dietary supplement current good manufacturing practice regulations.* If your customer is required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging

as a dietary supplement, your customer is in compliance with the requirements of §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ 1.503, 1.509, and 1.510, but you are not required to comply with the requirements in § 1.502 or §§ 1.504 through 1.508.

(c) *Other importers of dietary supplements—(1) General.* If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) *Determination of appropriate foreign supplier verification activities—*

(i) *General.* Except as provided in paragraph (c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency

with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;

(B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) *Reliance upon determination by other entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with § 1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) *Performance of foreign supplier verification activities.* (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) *Onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(1) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(2) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may

consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(3) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(4) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(5) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(i) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(ii) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(B) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(C) *Review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed,

the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) *Other appropriate activity.* (1) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(2) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(1) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(ii) *Reliance upon performance of activities by other entities.* (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(iv) *Independence of qualified individuals conducting verification activities.* There must not be any

financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?

(a) *Eligibility.* This section applies only if:

(1) You are a very small importer; or
(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) *Applicable requirements—(1) Documentation of eligibility—(i) Very small importer status.* (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) *Small foreign supplier status.* If you are a importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier

meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(2) *Additional requirements.* If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

(3) *Foreign supplier verification activities.* (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance before importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance before importing the produce and at least every

2 years thereafter that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance before importing the shell eggs and at least every 2 years thereafter that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(4) *Corrective actions.* You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with the assurance provided in accordance with § 1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) *Records*—(i) *General requirements for records.* (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(B) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(C) All records must be legible and stored to prevent deterioration or loss.

(ii) *Availability.* (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation

of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) *Record retention.* (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (e.g., because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer.

(iv) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(v) *Use of existing records.* (A) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(vi) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) *Requirements for importers of food from certain small foreign suppliers.* The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) *Evaluation of foreign supplier compliance history—(i) Initial evaluation.* In approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

(ii) *Reevaluation of foreign supplier compliance history.* (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) *Review of another entity's evaluation or reevaluation of foreign supplier compliance history.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the

requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(2) *Approval of foreign supplier.* You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

(a) *General.* (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(b) *Conditions and requirements.* (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight

of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph (b)(2).

§ 1.514 What are some consequences of failing to comply with the requirements of this subpart?

(a) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(b) *Prohibited act.* The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 4. In § 11.1, add and reserve paragraph (h) and (k) and add paragraph (l) to read as follows:

§ 11.1 Scope.

* * * * *

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

■ 5. The authority citation for 21 CFR part 111 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

■ 6. In § 111.5, add a sentence after the existing sentence to read as follows:

§ 111.5 Do other statutory provisions and regulations apply?

* * * For importers of dietary supplements and dietary supplement components, the regulation on foreign supplier verification programs can be found in subpart L of part 1 of this chapter.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28158 Filed 11-13-15; 8:45 am]

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, and 112
Standards for the Growing, Harvesting, Packing, and Holding of Produce
for Human Consumption; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 11, 16, and 112**

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.

DATES: This rule is effective January 26, 2016. The effective date of §§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13) published September 17, 2015 (80 FR 55908), is January 26, 2016. The effective date of §§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13) published September 17, 2015 (80 FR 56170), is January 26, 2016. See section XXIV of this document for the compliance dates. The incorporation by reference of certain publications listed in this rule is

approved by the Director of the Federal Register as of January 26, 2016.

FOR FURTHER INFORMATION CONTACT:

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Executive Summary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) requires FDA to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities (RACs) for which we have determined such standards minimize the risk of serious adverse health consequences or death. Further, FSMA requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and

practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA published a proposed rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). The comment period for the proposed rule closed on November 22, 2013. In response to information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket for the 2013 proposed rule, information available at that time, and our subsequent analysis of the proposed provisions in light of such information, FDA issued a supplemental notice of proposed rulemaking and reopened the comment period to seek public comment on specific issues and amended and new proposed provisions (79 FR 58434; September 29, 2014). The comment period for the supplemental notice of proposed rulemaking closed on December 15, 2014. We are now finalizing this rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.”

The final rule focuses on biological hazards related to produce growing, harvesting, packing, and holding. We conducted a “Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce” and considered the findings of this assessment in finalizing this rule. While we acknowledge the potential for non-biological (physical or chemical (including radiological)) hazards in produce, we are not addressing such hazards in this rule.

Scope of Coverage of the Rule

The final rule applies to both domestic and imported produce. However, as explained in the remainder of this document, the rule contains several exemptions and limitations:

- The rule does not apply to certain specified produce commodities that are rarely consumed raw.
- The rule also does not apply to produce that is used for personal or on-farm consumption, or that is not a RAC.

■ The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (*e.g. via* a “kill step”) as long as certain disclosures are made and written assurances are received, with appropriate documentation.

■ The rule does not cover farms that have an average annual value of produce sold during the previous 3-year period of \$25,000 or less.

■ The rule provides a qualified exemption and modified requirements for farms that meet two requirements: (1) The farm must have food sales averaging less than \$500,000 per year during the previous 3 years; and (2) the farm’s sales to qualified end-users must exceed sales to others. A qualified end-user is either: (1) The consumer of the food or (2) a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm or not more than 275 miles away. Instead, these farms are required to include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FD&C Act and its implementing regulations) or to display the same information at the point-of-purchase. These farms are also required to establish and keep certain documentation. This exemption may be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce.

The rule also permits States, tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of this rule.

Summary of the Major Provisions of the Rule

The final rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. Based on the findings of the Qualitative Assessment of Risk, we are focusing the provisions of this rule on five major routes of contamination. We are finalizing requirements in the following major areas:

■ Worker Training and Health and Hygiene

○ Establish qualification and training requirements for all personnel who handle (contact) covered produce or

food-contact surfaces and their supervisors (§§ 112.21, 112.22, and 112.23);

○ Require documentation of required training and corrective actions (§ 112.30); and

○ Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (§§ 112.31, 112.32, and 112.33).

■ Agricultural Water

○ Require that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Agricultural water is defined in part as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces (§ 112.3(c));

○ Establish requirements for inspection, maintenance, and certain other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (§§ 112.42 and 112.48);

○ If a farm chooses to treat agricultural water to meet relevant requirements for its intended use, establish requirements related to methods of treatment and monitoring such treatment (§ 112.43);

○ Establish specific requirements for the microbial quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies, under certain specified conditions, and treated water), and requiring certain actions to be taken when such water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality requirements (§§ 112.44, 112.45, 112.46, and 112.47); and provide for the use of alternative requirements for certain provisions under certain conditions (§§ 112.12 and 112.49); and

○ Require certain records, including documentation of inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions (§ 112.50).

■ Biological Soil Amendments

○ Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (§§ 112.51 and 112.52);

○ Prohibit the use of human waste for growing covered produce except in compliance with U.S. Environmental Protection Agency (EPA) regulations for such uses or equivalent regulatory requirements (§ 112.53);

○ Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards (§§ 112.54 and 112.55), including examples of such processes;

○ Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (§ 112.56); and

○ Require certain records, including documentation from suppliers of treated biological soil amendments of animal origin, documentation that process controls were achieved, and corrective actions (§ 112.60).

■ Domesticated and Wild Animals

○ If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, require measures to assess as needed relevant areas during growing and, if significant evidence of potential contamination is found, take measures reasonably necessary to assist later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§§ 112.83 and 112.112).

■ Equipment, Tools, and Buildings

○ Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (§§ 112.121–134); and

○ Require certain records related to the date and method of cleaning or sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities, and corrective actions (§ 112.140).

- Sprouts
 - Establish scope of applicability of sprout provisions (§ 112.141);
 - Establish measures that must be taken related to seeds or beans for sprouting (§ 112.142);
 - Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (§ 112.143);
 - Require testing the growing environment for *Listeria* species (*Listeria* spp.) or *Listeria monocytogenes* (*L. monocytogenes*) and testing each production batch of spent sprout irrigation water or sprouts for *Escherichia coli* (*E. coli*) O157:H7, *Salmonella* species (*Salmonella* spp.) and, under certain conditions, other pathogen(s), and taking appropriate follow-up actions (§§ 112.144–112.148); and

- Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, certain test methods used, and corrective actions (§ 112.150).

The effective date of this rule is 60 days after its publication in the **Federal Register**. As shown in the following table, we are establishing three sets of compliance dates, all of which vary based on size of the farm: (1) For covered activities involving sprouts subject to subpart M, which are also subject to all of part 112 as applicable; (2) for covered activities involving all other produce, which are subject to all of part 112 as applicable except subpart M; and (3) for farms eligible for a qualified exemption and related modified requirements. In the second

set of compliance dates, we are also providing extended compliance dates for certain specified requirements related to agricultural water. In the compliance dates relating to the qualified exemption, the compliance date for the records that a farm is required by § 112.7(b) to maintain to support its eligibility for a qualified exemption is the effective date of this rule, *i.e.*, January 26, 2016. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general compliance date, however. In addition, we are establishing January 1, 2020, as the compliance date for the modified requirement in § 112.6(b)(1).

COMPLIANCE DATES

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of this rule						
Very small business.	3 years	6 years	4 years	Effective date of rule.	January 1, 2020 ...	4 years.
Small business	2 years	5 years	3 years			3 years.
All other businesses.	1 year	4 years	2 years			N/A.

Costs and Benefits

The primary benefits of the provisions in this final rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first ten years after the effective date of the rule at seven percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at 3 percent), valued at \$925 million annually (\$976 million at 3 percent). Similarly, annualized costs, estimated at 7 percent, are expected to be approximately \$366 million annually (\$387 million at 3 percent). Additionally, annualized costs for foreign farms are estimated to be

approximately \$138 million annualized at 7 percent (\$146 million at 3 percent).

I. Background

A. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based,

prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in Table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule or simply "2013 proposed rule".	78 FR 3504, January 16, 2013.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA—Continued

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls rule.	78 FR 3646, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls rule	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification rule	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation rule	79 FR 7006, February 5, 2014.

We also issued supplemental notices of proposed rulemaking for the rules listed in table 2 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice or simply "supplemental notice".	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice	79 FR 58574, September 29, 2014.

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Ref. 1). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in

food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will protect consumers into the future.

B. 2013 Proposed Produce Safety Rule

Eating fruits and vegetables is an important part of a healthy diet. FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables. We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with produce and maintain a high level of consumer confidence in this important food category. Produce is vulnerable to contamination with microorganisms of public health significance (e.g., bacteria and viruses that can cause disease), as well as physical and chemical (including radiological) contaminants. Contamination of produce can occur on-farm during growing (either in an open environment or in a fully- or partially-enclosed building), harvesting, packing, or holding; or elsewhere along the farm-to-table continuum.

Section 105 of FSMA adds section 419 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350h) requiring FDA to adopt a final

regulation to provide for minimum science-based standards for fruits and vegetables that are RACs based on known safety risks, and directing FDA to set forth in the final regulation those procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. On January 16, 2013, FDA issued the produce safety proposed rule to propose such standards, as well as certain exemptions from the standards, consistent with section 419 of the FD&C Act (78 FR 3504; hereafter referred to as "the 2013 proposed produce safety rule" or simply "the 2013 proposed rule"). Specifically, we proposed, among other provisions, to:

- Establish, in 21 Code of Federal Regulations (CFR) proposed part 112, science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms, focusing on the areas of worker training and health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals;

equipment, tools, and buildings; and sprouts;

- Focus the rule on microbiological hazards related to produce growing, harvesting, packing, and holding;
- Apply proposed part 112 to both domestic and imported produce, with several exemptions, including that the rule would not apply to certain specified produce commodities that are rarely consumed raw; produce that is used for personal or on-farm consumption; or produce that is not a RAC;
- Provide an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms (e.g., “kill step”) as long as certain documentation is kept;
- Not cover farms that have an average annual value of food sold during the previous 3-year period of \$25,000 or less;
- Provide a qualified exemption and modified requirements for farms that meet certain requirements, as well as establish circumstances and procedures under which this exemption may be withdrawn; and
- Require compliance within time periods ranging from 2 to 4 years based on the size of farm, with an additional 2 years to comply with some of the proposed water provisions.

We extended the comment period for the 2013 proposed produce safety rule in response to requests that we do so (78 FR 11611, February 19, 2013; and 78 FR 24692, April 26, 2013). We later extended the comment period to allow interested persons an opportunity to consider the interrelationships between the 2013 proposed produce safety rule and the 2013 proposed FSVP and third-party certification rules (78 FR 48637, August 9, 2013). We also issued a notice correcting several typographical, stylistic, and reference numbering errors (78 FR 17155, March 20, 2013). At the time of that correction notice, we also made publicly available, in its entirety, the proposed produce safety rule with all errors corrected. The comment period for the 2013 proposed rule closed on November 22, 2013.

C. Draft Qualitative Assessment of Risk

We conducted a “Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce” (hereafter referred to as “the draft QAR”) to evaluate hazards related to produce production and harvesting. We published the findings of our

assessment, and asked for public comment on our assessment and findings (78 FR 3504, January 16, 2013). The tentative conclusions of this assessment informed our proposed science-based minimum standards for the safe production and harvesting of produce commodities.

D. Produce Safety Supplemental Notice

Taking into account information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket, then-currently available information, and our subsequent analysis of the proposed provisions in light of this information, on September 29, 2014, we proposed certain new provisions and certain amendments to our provisions proposed in the 2013 proposed rule (79 FR 58434; hereafter referred to as “the 2014 supplemental produce safety notice” or simply “the supplemental notice”). Specifically, we proposed among other provisions:

- Amendment to not cover farms that have an average annual value of produce sold during the previous three year period of \$25,000 or less;
- Amendment to the definition of “farm” such that establishments that pack or hold produce that is grown or harvested on another farm would be subject to the produce safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership;
- Amendments to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method; and to incorporate additional flexibility and provide means to achieve this standard, *i.e.*, by applying a time interval between last irrigation and harvest and/or between harvest and end of storage to account for post-application microbial die-off or removal;
- Amendment to provide tiered-approaches for specific testing frequency requirements to test untreated surface water as well as untreated ground water, which would enable testing at a reduced frequency;
- Amendment to remove the 9-month minimum application interval for use of raw manure and other untreated biological soil amendments of animal origin, and defer FDA’s decision on an appropriate time interval until FDA takes certain specified actions;

- New provision to explicitly state that part 112 would not authorize or require covered farms to take actions that would constitute the “taking” of threatened or endangered species in violation of the Endangered Species Act (ESA), or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages; and

- New provisions to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak; and to list the circumstances under which FDA would reinstate a farm’s qualified exemption that is withdrawn.

In the 2014 supplemental produce safety notice, we reopened the comment period only with respect to the specific issues covered in the supplemental notice. In addition, we emphasized that the new and amended proposed provisions we included in the regulatory text were based on a preliminary review of the comments. We also noted the 2013 proposed produce safety rule and the new and amended proposed provisions published in the 2014 supplemental produce safety notice, taken together, constitute the entirety of the proposed rule on “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.” The comment period for the supplemental notice closed on December 15, 2014.

In this document, we use the broad term “proposed produce safety rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed produce safety rule and the new and amended proposed provisions we published in the 2014 supplemental produce safety notice.

E. List of Federal Register Publications Regarding the Proposed Produce Safety Rule

Table 3 lists **Federal Register** publications regarding the proposed produce safety rule. This list does not include the **Federal Register** publications regarding the Environmental Impact Statement (EIS) related to this rule; the EIS and related publications are addressed in section XXVII of this document.

TABLE 3—LIST OF FEDERAL REGISTER PUBLICATIONS REGARDING THE PROPOSED PRODUCE SAFETY RULE

Description	Publication
2013 proposed produce safety rule, requesting comments by May 16, 2013	78 FR 3504, January 16, 2013.
Notice of public meeting (held in Washington D.C. on February 28, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 6762, January 31, 2013.
Notice of public meetings (held in Chicago, IL on March 11, 2013 and in Portland, OR on March 27, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 10107, February 13, 2013.
Notice extending comment period, until May 16, 2013, for the information collection provisions of the 2013 proposed produce safety rule.	78 FR 11611, February 19, 2013.
Notice of correction for the 2013 proposed produce safety rule	78 FR 17155, March 20, 2013.
Notice extending the comment period, until September 16, 2013, for the 2013 proposed produce safety rule and its information collection provisions.	78 FR 24692, April 26, 2013.
Notice extending the comment period, until November 15, 2013, for the 2013 proposed produce safety rule and its information collection provisions.	78 FR 48637, August 9, 2013.
Notice extending the comment period, until November 22, 2013, for the 2013 proposed produce safety rule and its information collection provisions.	78 FR 69605, November 20, 2013.
Produce safety supplemental notice, requesting comments by December 15, 2014	79 FR 58434, September 29, 2014.
Notice of public meeting (held in College Park, MD on November 13, 2014) on the human preventive controls supplemental notice, produce safety supplemental notice, animal preventive controls supplemental notice, and FSVP supplemental notice.	79 FR 63346, October 23, 2014.

F. Public Comments

Since issuing the 2013 proposed rule, we conducted numerous outreach activities. For example, we held four public meetings to solicit oral stakeholder and public comments on the 2013 proposed rule and the supplemental notice, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed rule and the supplemental notice (see Table 3) (Ref. 2) (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6) (Ref. 7). We also traveled across the country and around the world to discuss the 2013 proposed rule, as well as the other foundational FSMA proposed rules listed in section I.A of this document, with persons who would be affected by them (Ref. 8) (Ref. 9) (Ref. 10).

We received a total of about 36,000 submissions (representing approximately 15,000 unique comments) on the proposed produce safety rule by the close of the comment period, each containing one or more comments. We received submissions from diverse members of the public, including produce farms; facilities collocated on a farm; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress; federal, State, local, and tribal government agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments addressed virtually every provision of the proposed produce safety rule, including our requests for comment on various topics.

In sections III through XXIV of this document, we describe these comments, respond to them, and explain any changes we made to the proposed produce safety rule. We discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements. The remainder of this document establishes a final rule (“the final rule,” this final rule,” “the rule,” or “this rule”) based on the proposed produce safety rule.

Some comments address issues that are outside of the scope of this rule. We do not discuss such comments in this document. We also received comments that solely address topics, such as preventive controls applicable to food for humans or animals, traceability, foreign supplier verification programs, and third-party accreditation or certification, which are outside of the scope of this final produce safety rule, and will be appropriately addressed in other relevant FSMA rulemaking documents.

II. Legal Authority

The 2013 proposed rule contained an explanation of its legal basis under authorities in FSMA, the FD&C Act, and the Public Health Service Act (PHS Act). After considering comments received in response to the 2013 proposed rule and supplemental notice, FDA made changes in the final rule. The legal authorities relied on for the final rule are the same as in the 2013 proposed rule unless otherwise described in the paragraphs that follow.

A. Relevant Statutory Authorities Other Than Section 419 of the FD&C Act and Section 105 of FSMA

The final rule requires that, to rely on the exemption in § 112.2(b) for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health concern, a covered farm must disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” (§ 112.2(b)(2)). This requirement is authorized by sections 419 and 701(a) of the FD&C Act (21 U.S.C. 371(a)).

Section 112.2(b) exempts from most requirements in the rule produce that is low risk because it receives commercial processing that will adequately reduce the biological hazards that are the focus of this rule. It is important to ensure that such produce does indeed receive such commercial processing because such processing is the reason the produce is considered sufficiently low risk to be exempt from the other requirements in this rule. A food may pass through multiple entities in the distribution chain before the control is applied. Further, it may not be apparent from visual examination of the food whether a control has been applied. Consequently, without labeling, an entity in the distribution chain might not know whether a control has been applied. Therefore, FDA concludes that information that food has not been processed to adequately reduce the presence of microorganisms of public health significance must be provided in accompanying documentation when a farm is relying on this exemption from the rule. FDA also concludes that such labeling is necessary for the efficient

enforcement of the FD&C Act to help ensure that food receives the required processing. Further, because the relevant hazards can cause communicable disease, FDA concludes that the requirement is necessary to prevent the spread of communicable disease from one State into another State and relies on sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

B. Legal Authority for Records Requirements

We are using our authority under the FD&C Act and the PHS Act to institute certain records requirements. In addition to those requirements we proposed in the 2013 proposed rule and the supplemental notice, we are adding the following new record requirement: For farms eligible for a qualified exemption and modified requirements, adequate records necessary to demonstrate that you satisfy the criteria for a qualified exemption, including a written record reflecting that you performed an annual review and verification of your farm's continued eligibility for the qualified exemption (§ 112.7).

We have also revised some of the records requirements in our 2013 proposed rule and the supplemental notice. We note in particular that the record requirement proposed as § 112.161(b) relating to documentation of corrective actions taken under subparts C, E, F, L, and M is now eliminated and, instead, we added specific provisions in two relevant subparts (E and M), at §§ 112.50(b)(6) and 112.150(b)(6). Moreover, in § 112.50(b)(6), we are also establishing specific requirements for documentation of any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), including the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing.

In addition, we note that the revised records requirements in § 112.2(b) include: (1) For farms relying on the exemption in § 112.2(b), documentation of disclosures required under § 112.2(b)(2) and annual written assurances obtained from customers under § 112.2(b)(3) (§ 112.2(b)(4)); and (2) For entities that provide a written assurance under § 112.2(b)(3), documenting actions taken to satisfy the written assurance (§ 112.2(b)(6)).

As discussed further in the 2013 proposed rule and in sections XI, XIII, XIV, XVII, and XVIII of this document, these records requirements are necessary for regulated industry to ensure their own compliance with these aspects of the rule and for FDA to ensure that industry is complying with the same aspects of the rule. Therefore, these requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both regulated industry and FDA in ensuring that food is not adulterated, and are necessary to prevent the spread of communicable disease because they will aid both regulated industry and FDA in ensuring that food does not become contaminated with human pathogens. In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the underlying requirements are necessary to minimize the likelihood of adulteration and the spread of communicable disease, access to records that demonstrate that regulated industry has followed those requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we conclude that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary, and because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

C. Intrastate Activities

(Comment 1) One comment argues that FDA should not apply this rule to activities that are intrastate in character, citing the lack of an explicit reference to intrastate activities in relevant sections of the FD&C Act, and asserting that the greatest risk of foodborne illness comes from food in interstate distribution networks. This comment argues that the rule as applied to intrastate commerce is beyond the federal government's power under the commerce clause of the Constitution.

(Response) FDA disagrees. We conclude that the rule should be applicable to activities that are intrastate in character. The plain language of section 419 of the FD&C Act directs FDA to establish science-based minimum standards for the safe production and harvesting of fruit and vegetable RACs to minimize the risk of serious adverse health consequences or death. Section 419 does not include a limitation to interstate commerce. In addition, the exemption provided in section 419(f) of the FD&C Act, based in part on the proportion of a farm's sales made to restaurants or retail food establishments intrastate or within 275 miles, suggests that Congress intended the rule issued under section 419 to apply to intrastate commerce because otherwise there would be no need to provide an exemption for farms whose sales are intrastate in character. In addition, section 301(vv) of the FD&C Act provides that "[t]he failure to comply with the requirements under section 419", or the causing thereof, is a prohibited act. Section 301(vv) does not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 419 and 301(vv) of the FD&C Act as not limiting the application of the rule only to those farms with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on their constitutionality. (See *Solid Waste Agency of Northern Cook County v. U.S.*, 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA's responsibilities in implementing those laws, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, see *United States v. Lopez*, 514 U.S. 549, 567 (1995); *U.S. v. Morrison*, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in *Lopez*, supra, the Supreme Court acknowledged the continuing vitality of *Wickard v. Filburn*, 317 U.S. 111 (1942), noting that "although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation

where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.’” (514 U.S. at 556.) See also *Gonzales v. Raich*, 545 U.S. 1, 17–25 (2005). This principle applies to the application of sections 419 and 301(vv) of the FD&C Act, as added by section 105 of FSMA. Accordingly, given the collective impact on commerce of farms that grow, harvest, pack, or hold food that is sold in “intrastate” commerce, FDA concludes that such farms should be subject to the rule unless an exemption from the rule applies (for example, if the farm is eligible for the qualified exemption in § 112.5, or if the farm only grows produce exempt from the regulation under one of the exemptions in § 112.2). This outcome regarding intrastate commerce is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that in any action to enforce the FD&C Act’s requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with FSMA’s risk-based, preventive approach to food safety because the risk presented by unsafe food can be significant, whether or not the food moves from one state to another.

D. Application of Section 112.2(b)(6) to Entities Other Than Covered Farms

As discussed in IX.A.4 of this document, we are specifying in § 112.2(b)(6) that the entities that provide written assurances described in § 112.2(b)(3) must act consistently with the assurances and document the actions taken to satisfy the assurance. Section 112.2(b)(6) applies not just to covered farms, but to other entities that voluntarily agree to provide the written assurances described in § 112.2(b)(3). The application of this requirement to facilities subject to section 418 of the FD&C Act is consistent with section 419(h) of the FD&C Act. Providing, complying with, and documenting compliance with the written assurances described in § 112.2(b)(3) are not activities that are subject to section 418 of the FD&C Act. As discussed in section II.A of this document, in addition to sections 419 and 701(a) of the FD&C Act, this requirement is supported by sections 311, 361, and 368 of the PHS Act.

III. General Comments on the 2013 Proposed Rule

A. General Comments

(Comment 2) Some comments ask us to make the various rules we are

establishing to implement FSMA consistent with each other.

(Response) We have aligned the provisions of the various rules to the extent practicable. For example, we use the same definitions of “farm” and the terms used in the definition of “farm” (*i.e.*, harvesting, packing, holding, and manufacturing/processing) in this rule, the final human preventive controls rule (80 FR 55908; Ref. 11) that established part 117 (the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation; hereafter referred to as “the PCHF regulation”), and the final animal preventive controls rule (80 FR 56170) that established part 507 (the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals regulation; hereafter referred to as “the PCAF regulation”). However, the statutory requirements are not the same for all the rules, and the purposes and contents of the rules differ from each other. For example, section 419(f) of the FD&C Act (which relates to this rule) and section 418(l) of the FD&C Act (which relates to the final human preventive controls rule) both create qualified exemptions with modified requirements for certain entities based in part on business size and/or certain specific sales criteria. However, these two sections provide different criteria for eligibility for exemption from the two rules, and different modified requirements for farms and facilities eligible for the relevant exemptions.

(Comment 3) Several comments ask us to develop guidance to accompany this rule to help covered farms to understand and implement this rule, particularly in the areas of agricultural water, personnel training, domesticated and wild animals, sprout production, and biological soil amendments of animal origin. Some of these comments also ask that drafts of such guidance first be made available for public comment. Comments ask us to take into consideration existing public and private food safety programs as we develop our guidance. Comments also recommend that guidance documents should be easily understood, available in multiple formats (including simple checklists), and issued in a timely manner.

Other comments emphasize the importance of education and outreach and ask us to provide support for ongoing education and outreach, including taking an active role in providing needed instructional examples and lessons learned from

current investigations and foodborne outbreaks.

(Response) We are developing guidance documents, including general guidance on the implementation of this rule, as well as a Small Entity Compliance Guide (SECG) in accordance with section 105(b) of FSMA (21 U.S.C. 350h note) and section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121). A SECG is a guidance that explains the actions a small entity must take to comply with a rule. We also intend to develop guidance specific to commodities, as needed. We agree that we should take into consideration existing public and private food safety programs as we develop our recommendations. We will develop and issue our guidances in accordance with our good guidance practices regulation, 21 CFR 10.115, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate. The public may submit comments on any guidance document at any time (§ 10.115(g)(5)).

We agree with comments that stress the importance of education and outreach. Supporting efforts to help covered farms get the education and technical assistance they need to understand and implement the requirements is a central element of FDA’s strategy to gain compliance with this rule (Ref. 12) (Ref. 13). Within FDA, we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 12). This will allow us to respond in a timely and consistent way to questions from covered farms related to this rule.

We continue to work with other government agencies, academia, and industry groups, as appropriate, to facilitate the successful implementation of this rule. For example, FDA, in collaboration with the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and others, has established the Produce Safety Alliance (PSA). FDA and others also established the Sprouts Safety Alliance (SSA). Both PSA and SSA will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental, on-farm food safety knowledge and equip them to comply with the produce safety regulation. FDA is working to ensure

that the PSA and SSA training materials (which we refer to collectively as “the Alliance courses”) are consistent with the requirements of this rule.

We are also partnering with USDA’s National Institute of Food and Agriculture (NIFA). FDA and NIFA are funding a grant program that will provide funding for food safety training, education and technical assistance to small farm owners and food processors to help them comply with food safety standards to be established under FSMA. The purpose of the grant program is to train owners and operators of small businesses, including small- and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers, and farms that lack access to food safety training and other educational opportunities.

We also plan to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule. FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulation. Such efforts will help ensure widespread compliance.

(Comment 4) Some comments ask us to establish and annually convene a scientific workgroup that includes experts in produce production, public health, and testing and laboratory science to advise us on pathogens that should be addressed in produce safety standards. Some other comments recommend that FDA establish a national advisory committee or a stakeholder advisory committee to provide ongoing input to FDA as FSMA implementation begins, and suggests that such committee include members from States, industry, and other stakeholders, as well as NASDA. These comments recommend that such advisory body should assist FDA in updating regulations or guidance as science evolves and new information becomes available. One commenter also believes such an established advisory body could function in a manner similar to the National Conference on Interstate Milk Shipments or the Interstate Shellfish Sanitation Conference and provide a formal and effective mechanism for dialogue between FDA,

States, NASDA, and the regulated community.

(Response) We disagree with the suggestion to establish an advisory group for the purpose of assisting FDA in updating regulations or guidance as science evolves and new information becomes available. FDA’s rulemaking and guidance development processes allow for future amendments, and also provide ample opportunity for public input when warranted. We will consider the need for such amendments in light of evolving scientific information and, as warranted, take appropriate actions.

(Comment 5) Some comments express the need for FDA to review and update the provisions in the produce safety regulation as new scientific information becomes available. One commenter requests that FDA establish a process for such review and update.

(Response) FDA may, on its own initiative or in response to a petition from an interested person, initiate administrative proceedings to amend existing regulations, including the produce safety regulation. See 21 CFR part 10 for our administrative practices and procedures.

(Comment 6) Some comments assert that the rule should be more concise, and that the average person without a team of experts should be able to understand the rule and manage the application of the rule.

(Response) We agree the rule needs to be understandable. We have incorporated plain language techniques—*e.g.*, by framing the regulation in the form of questions and answers, and using active voice in the requirements. We also have established definitions that enable us to improve readability (*e.g.*, “monitor,” “raw agricultural commodity,” and “you”). We have used examples in the codified, where appropriate, and provided examples throughout the preamble to assist with understanding the requirements. We will be issuing guidance documents that will be helpful in understanding the rule (See Comment 3). We anticipate that these various educational and outreach efforts will involve development of checklists, templates, protocols, and other tools that will facilitate compliance with the produce safety regulation.

(Comment 7) Some comments assert that the rule incorrectly assumes that all bacteria are harmful.

(Response) We have long recognized that some bacteria have a role in food production, such as the lactic-acid producing bacteria that our regulations explicitly acknowledge as being added to yogurt (see *e.g.*, the standards of identity for yogurt, low fat yogurt, and

nonfat yogurt, in 21 CFR 131.200, 131.203, and 131.206, respectively).

This rule defines the term “microorganism,” which explains that the term “undesirable microorganism” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. The produce safety standards established in this rule focus on minimizing the risk of contamination of produce with microorganisms that can cause serious adverse health consequences or death, and are consistent with our “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (the GAPs Guide) (Ref. 14).

(Comment 8) One comment suggests covering school-garden programs under the produce safety regulation. According to this comment, the current requirements for food safety assurance at these farms are variable, and practices such as improper manure or compost use could present a significant risk to high-risk consumers served by such farms.

(Response) We expect most school-garden programs would likely fall below the monetary threshold for coverage in § 112.4 and, therefore, would not be subject to this rule. We have determined the scope and coverage of this rule to establish only those requirements that are reasonably necessary to meet the public health objectives of the regulation. Note, however, that farms that are not subject to this rule are and will continue to be covered under the adulteration and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. We recommend that farms that are not covered under part 112 follow good agricultural practices to ensure that the produce they grow, harvest, pack or hold does not serve as a vehicle for foodborne illness.

(Comment 9) Some comments express concern that current tests for pathogens such as *E. coli* and *Salmonella* are expensive and time-consuming, and could lead to holding up perishable produce in the food chain. Comments also highlight the need for affordable, on-site, and fast test methods, particularly for testing agricultural water.

(Response) We are not requiring final product testing of produce, except as in subpart M under certain circumstances for sprouts, for reasons explained in section III.F of this document. In prescribing certain analytical methods

for testing the quality of agricultural water, for testing the growing environment of sprouts for *Listeria* spp. or *L. monocytogenes*, and for testing spent sprout irrigation water (or sprouts) for certain pathogens (in subpart N of part 112), we also provided flexibility for covered farms to use any other method that is at least equivalent to the prescribed analytical methods in accuracy, precision, and sensitivity in detecting the relevant organism. We are aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems, and that many of these products undergo internal quality control and performance testing, as well as receive additional third-party approvals. In addition, we are aware of programs such as the AOAC International Research Institute's Performance Tested Methods Program that provides an independent third-party review of proprietary test method performance, and that test methods demonstrated to meet acceptable performance criteria are granted Performance Tested Methods (PTM) status. Such methods, including test kit methods, may be acceptable for testing for generic *E. coli* in agricultural water to satisfy the requirements of § 112.46, for testing for *Listeria* spp. or *L. monocytogenes* to satisfy the requirements of § 112.144(a), and for testing for certain pathogens to satisfy the requirements of § 112.144(b) and (c), provided they meet certain conditions in accordance with §§ 112.151(b), 112.152(b), and 112.153(a)(2) and (b), respectively. FDA will consider providing guidance on testing methods, specifically on rapid and low-cost test kits that might be useful for farms.

(Comment 10) Some comments ask us to address model laboratory standards and accreditation to ensure that laboratories are using sound and reliable test methods and practices for detecting and identifying microorganisms of public health significance. These comments argue that if there are no criteria for training and appropriate use of testing devices or interpretation, test results may not be reliable. These comments also suggest posting a list of accredited laboratories on FDA's Web site for use by farms.

(Response) We are currently working on a proposed rule to implement section 202 of FSMA (section 422 of the FD&C Act), which addresses "Laboratory Accreditation for Analyses of Foods." Neither model laboratory standards nor laboratory accreditation are within the scope of the produce safety regulation in part 112.

(Comment 11) In the 2013 proposed rule, we requested comment on whether we should require, in a final rule, any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for *L. monocytogenes* or *Listeria* spp., and any criteria that should be employed to determine which farms should be subjected to such a requirement (78 FR 3504 at 3619). Some comments respond by noting that not all produce operations will be vulnerable to harborage and contamination by pathogens such as *L. monocytogenes*. These comments argue that mandatory environmental monitoring for such operations would not yield a food safety benefit and, instead, would impose a wasteful economic burden. These comments recommend that environmental monitoring or assessment for produce (other than sprouts) should be addressed in guidance and can be a part of food safety plans for operations vulnerable to relevant routes of contamination. On the other hand, some comments, suggest the environmental monitoring requirements we proposed for sprouts should be expanded to other high-risk produce.

(Response) We are not requiring environmental testing for *L. monocytogenes* or *Listeria* spp. for covered produce other than sprouts. See discussion in the 2013 proposed rule (78 FR 3504 at 3619). Farms may consider voluntarily performing environmental testing for *L. monocytogenes* or *Listeria* spp. as appropriate for their operations. See also section VII of this document where we discuss farm-specific food safety plans.

B. Intentional Adulteration

(Comment 12) Several comments address intentional adulteration of produce. One comment contends that small farms are inherently more resilient to terrorism or other forms of intentionally introduced hazards than large farms due to their diversity, independence, and geographic decentralization. According to the comment, if the proposed produce safety rule negatively affects the viability of diverse small farms, in favor of large, centralized farms, then the net result may be an increase in the American food system's vulnerability to terrorism. With regards to economically motivated intentional adulteration, one comment states that this type of adulteration is difficult to prevent and should not be addressed in this rule.

(Response) FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C

Act in a separate rulemaking. As such, neither intentional adulteration nor economically motivated adulteration in the context of fruits and vegetables that are RACs, during activities that occur on produce farms, are within the scope of the produce safety regulation in part 112. On December 24, 2013, FDA published a proposed rule to implement the intentional adulteration provisions for facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (per section 418 of the FD&C Act); for fruits and vegetables that are RACs (per section 419 of the FD&C Act); and for high risk foods, exempting farms except for farms that produce milk (per section 420 of the FD&C Act) (78 FR 78014).

C. Registration

In the 2013 proposed produce safety rule, we requested comment on whether we should require that covered farms, as described in proposed § 112.4(a), register with FDA. We acknowledged that we are not aware of a nationwide database of farms, nor an accumulation of statewide databases, that would enable us to identify the names and locations of all entities subject to the produce safety regulation, which, in turn, would enable us to better provide outreach and technical assistance to covered entities and to allocate our inspection resources. We also requested information about the existence of databases that could help us identify covered farms in the absence of a registration system, and the appropriate data elements that should be collected in a registration system, should we decide to set up such a system.

(Comment 13) Several comments support requiring registration of covered farms with FDA, and state that registration would be most helpful during response activities associated with illness outbreaks and recalls. These comments contend that any registration requirement should be kept simple, occur once annually, and apply to every farm no matter their size, sales volume, or method of trade. According to these comments, registration would provide FDA with key information to monitor each crop industry by knowing the size and scope of the regulated community, with a secondary advantage for that crop's association/board to be able to conduct industry outreach and education to assist with compliance with the final rule. Conversely, several other comments oppose a requirement for farms to register with FDA, stating that such a requirement would be unreasonable and inconsistent with FSMA. These comments argue that

FSMA does not authorize FDA to require farms to register with FDA, and that FDA fails to establish how requiring farms to register would contribute to improved food safety outcomes in produce production. Other comments suggest that FDA has many State and federal partners to assist in reaching out to the produce production community, and that there are existing industry resources, which include lists of producers. Some comments state that local and State agencies or extension agencies, not FDA, should maintain a database of farms. Still other comments argue that registration would be economically burdensome for farmers.

(Response) At this time, we are not establishing a requirement for farms to register with FDA. However, we believe that an inventory of farms would enable us to better provide outreach and technical assistance to covered farms and to allocate our inspection resources, so we intend to pursue other avenues for identifying farms. Historically, when we have needed a list of farms, such as for field assignments involving inspections, or for conducting education and outreach activities, FDA has worked with our district offices, State and local departments of health and agriculture, and local university extension services to identify farm operations. Doing this on an as needed, case-by-case basis can be resource intensive and may, or may not, result in a list of operations sufficient for our needs. FDA has entered into a cooperative agreement with NASDA to help with the implementation of the produce safety regulation, and will explore whether and how an inventory of farms located in the United States may be developed and may enhance these efforts.

D. Consistency With USDA's National Organic Program (NOP)

(Comment 14) Several comments state that the regulation may be interpreted to conflict with the requirements of the NOP. In this context, some comments specifically cited NOP's regulations in 7 CFR 205.200, 205.205, and 205.2.

Another comment expresses concern that the regulation would discourage farms from becoming organic certified.

(Response) We disagree that the final produce safety regulation (or specifically any provisions in subparts E, F, or I) conflicts with, or discourages farms from following NOP standards, including the provisions in NOP's regulations at 7 CFR 205.200, 205.205, and 205.2. The provisions in 7 CFR 205.200 require, in relevant part, that production practices implemented in accordance with the NOP must maintain or improve the natural resources of the

operation, including soil and water quality. The provisions in 7 CFR 205.205 require an organic producer to implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation: (1) Maintain or improve soil organic matter content; (2) provide for pest management in annual and perennial crops; (3) manage deficient or excess plant nutrients; and (4) provide erosion control. The provisions in 7 CFR 205.2 provide definitions of various terms for purposes of the NOP, including "crop rotation," "natural resources of the operation," and "organic production."

Part 112, including subparts E, F, and I, does not establish any specific requirements that conflict with, or discourage compliance with, these or other NOP requirements. As noted in the 2013 proposed rule and the supplemental notice, consistent with sections 419(a)(1)(A), (a)(3)(E), and (a)(3)(D) of the FD&C Act, we consulted with the NOP, USDA's Natural Resources Conservation Service (NRCS), U.S. Fish and Wildlife Service (FWS), and the EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements of this rule. See also sections XIII, XIV, and XV of this document where we discuss the requirements related to water, biological soil amendments of animal origin, and animals, respectively.

E. Consideration of Environmental Standards

(Comment 15) Several comments ask that FDA do more to support on-farm conservation efforts and ensure that farmers can continue to use sustainable practices that enhance conservation and food safety. Some comments request that FDA codify into the regulation specific conservation requirements, including requirements to train farm personnel in conservation practices, not to destroy wild animal habitats, to promote natural barriers, to use sustainable conservation practices, and to use co-management of conservation and food safety. Some comments request that FDA recognize conservation practices intended to protect water quality; train enforcement officials on co-management principles; and/or define the term "co-management" in relation to such requirements.

(Response) As required by section 419 of the FD&C Act, the produce safety regulation establishes science-based minimum standards for the safe

growing, harvesting, packing, and holding of produce for human consumption, and sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. As discussed in the 2013 proposed rule and the supplemental notice, consistent with sections 419(a)(1)(A), (a)(3)(E), and (a)(3)(D) of the FD&C Act, we consulted with the NOP, NRCS, FWS, and EPA to ensure that environmental and conservation standards and policies established by those agencies are appropriately considered in developing the requirements established in this rule.

As discussed in the 2013 proposed rule and reiterated in the supplemental notice, we encourage the application of practices that can enhance food safety and that are also consistent with sustainable conservation. We believe that the provisions of part 112 are consistent with existing conservation and environmental practice standards and policies and are not in conflict with federal or State programs. In addition, by including § 112.84, as proposed in the supplemental notice, we are finalizing a codified statement in the produce safety regulation that the requirements of part 112 do not require or permit the use of practices in violation of the ESA, and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields.

We continue to encourage the co-management of food safety, conservation, and environmental protection. We consider it important to take into account the environmental practice standards and policies of other relevant agencies in the context of food safety. However, the commenters identified no reason that it would be necessary for FDA to go beyond the statements we have included in § 112.84 and create affirmative conservation-related requirements in this rule. Therefore, we are taking no further action in response to these comments.

F. Product Testing as a Strategy To Control Pathogens

(Comment 16) Some comments agree with FDA's tentative conclusion that product testing would be impracticable as a component of this rule, except as proposed in subpart M under certain

circumstances for sprouts. One comment notes that sporadic contamination of produce cannot be detected reliably by product testing. One comment states that maintaining robust records of testing results will allow both farms and FDA to monitor for trends, correct imbalances or inaccuracies, and make adjustments to the system to best protect public health.

(Response) As discussed in section IV.I of the 2013 proposed rule, microbiological product testing for process control purposes presents several challenges that make it impracticable to be included within the framework of mandatory, science-based minimum standards established in part 112, with the exception of certain testing for sprouts described in subpart M (see section XVIII of this document). Among other issues, there are challenges associated with sampling plans, indicator organisms, and pathogen detection such that product testing is not appropriate as a generally applicable strategy to control pathogens across all produce commodities. The final human preventive controls rule also notes that product testing and environmental monitoring are unlikely to be common in facilities complying with that rule that process, pack, or hold produce RACs. We agree that, when testing is conducted (either voluntarily or in compliance with this rule for sprouts), records are important and useful.

G. Aquaponic and Hydroponic Operations

(Comment 17) Several comments request that FDA exempt aquaponic farming (raising produce and fish together in an integrated system) from the produce safety regulation, including specifically from the standards directed to agricultural water in subpart E, the standards directed to biological soil amendments of animal origin and human waste in subpart F, and the standards directed to domesticated and wild animals in subpart I. These comments argue the proposed produce safety rule does not address the nature of aquaponic farming. Some other comments suggest making it clear that the produce safety regulation is not intended to prohibit aquaponic practices.

Some comments requested that the standards related to agricultural water not be applied to aquaponic water containing fish waste fertilizer that is not intended or likely to come into contact with the harvestable portion of the plants; aquaponic water that is drawn from potable sources; or to hydroponics using effluent from

domestic fish or crustaceans that is kept under what commenters describe as closed, hygienic conditions (in accordance with the Aquaponic Association's GAPs). Other comments state that fish waste does not contain *E. coli* and, therefore, the water microbial quality and testing requirements in proposed §§ 112.44 and 112.45 should not apply to water used in aquaponic systems. With respect to subpart F, some comments suggest the water and fish waste used in aquaponic and hydroponic systems should not be considered a biological soil amendment of animal origin. With respect to subpart I, some comments contend fish (including shellfish) are an inherently different reservoir for microorganisms than mammalian or avian species and, while fish may become temporary carriers of human pathogens, they do not act as hosts, and it is unlikely that they will come into contact with the harvestable portions of produce.

(Response) We acknowledge that aquaponic farming systems present a particular set of circumstances that differ in important ways from non-aquaponic farming. However, we do not agree that aquaponic farms should be excluded from the rule. We do not intend to prohibit using aquaponic farming systems to grow covered produce. The routes of contamination we considered for covered produce under this rule are applicable to aquaponic farming and covered produce grown in aquaponic systems is subject to the same potential for contamination from agricultural water, biological soil amendments of animal origin, and animals as covered produce grown using non-aquaponic systems.

With regard to subpart E of this rule, when covered produce is grown in an aquaponic system in which the water is not intended or likely to contact the harvestable portion of the produce, that water is not agricultural water for purposes of this rule. On the other hand, when covered produce is grown in an aquaponic system in which water is intended or likely to contact the harvestable portion of the produce, that water is agricultural water for purposes of this rule and must meet the applicable standards of subpart E, including the relevant microbial quality requirements in § 112.44 and the relevant water testing requirements in § 112.46. Also, as discussed further in Comment 222, the § 112.46(a) exception from water testing requirements applies only when water received from a public water system (as in § 112.46(a)(1)) or a public water supply (as in § 112.46(a)(2)) is not held under your control in a way that meets the

definitions of "ground water" or "surface water" before you use it as agricultural water. For example, where under the circumstances the water used in the aquaponic system is "agricultural water" (because it is intended to, or likely to, contact covered produce), if that water is from a surface water source (or held in a surface water capacity), it must meet the surface water testing requirements in § 112.46. For example, the testing requirements in § 112.46(b) for untreated surface water apply to an aquaponic system that is established in an outdoor stream or pond, if under the circumstances the water meets the definition of "agricultural water." With regard to the comments that asserted that fish do not carry *E. coli*, we note that information submitted or otherwise available to us demonstrates that fish can become carriers of human pathogens, including *E. coli* and *Salmonella*, if they are exposed to contaminated feed (Ref. 15), waters or sediment (Ref. 16) (Ref. 17). Studies show that fish have natural defenses against bacterial colonization of human pathogens, but as the population of the pathogen is elevated the fish become stressed and are no longer able to mitigate harboring the pathogens, becoming more susceptible to carrying human pathogens and becoming infected with other fish pathogens (Ref. 18). Fish are also natural carriers of *Vibrio* spp. (Ref. 19), a zoonotic pathogen.

With regard to subpart F of this rule, we consider growth media to include solid or semi-solid matrices in which plants are grown; we do not consider liquid-only matrices to be growth media. If a liquid matrix in which covered produce is grown is intended to or is likely to contact the harvestable portion of the crop, the water is agricultural water subject to all applicable requirements in subpart E.

Subpart I of this rule applies only in outdoor areas and partially-enclosed buildings. As revised in this final rule, subpart I is not intended to address potential contamination from fish used as part of an aquaculturing system. We conclude that the risks presented by fish used in aquaculture are better suited to regulation via the requirements for agricultural water in subpart E (when the water meets the definition of agricultural water) and the requirements related to harvesting in § 112.112 (for example, if covered produce is reasonably likely to have become contaminated by water containing fish waste that is not managed in compliance with subpart E's requirements for agricultural water). Thus, we are revising § 112.81 to specify

that subpart I does not apply to fish used in aquaculture operations. We note that subpart I does apply to aquaculture operations conducted in outdoor areas or partially-enclosed buildings when, under the circumstances, there is a reasonable probability that animals other than the fish used in the aquaculture operation will contaminate covered produce. We will consider issuing additional guidance related to the application of this rule to aquaculture operations, as appropriate.

(Comment 18) One comment presents various arguments in support of a position that aquaponic or hydroponic farming of produce other than sprouts should not be subject to the proposed requirements in subpart M, including asserting that there are no documented instances of *Salmonella* or *E. coli* transmission via aquaponic or hydroponic produce (other than sprouts), and that the growth conditions in aquaponic or hydroponic systems for produce (other than sprouts) are different and safer than those used to germinate sprouts. This comment also requests that FDA clarify that “water used for growing sprouts” does not cover water used in aquaponic or hydroponic systems for produce (other than sprouts) and, likewise, that the definition of “spent sprout irrigation water,” does not include water used for irrigation in aquaponic or hydroponic systems for produce (other than sprouts).

(Response) We have added new § 112.141 to clarify the scope of subpart M. Therefore, an aquaponic or hydroponic system used to grow covered produce other than sprouts is not subject to the requirements in subpart M. Likewise, “spent sprout irrigation water” is defined as “water that has been used in the growing of sprouts”; thus, the term spent sprout irrigation water, and the requirements for testing spent sprout irrigation water in subpart M, only apply to the water used for growing sprouts, and not to water used in an aquaponic or hydroponic operation growing produce other than sprouts. However, to the extent the specific aquaponic or hydroponic production systems used to grow produce other than sprouts may present risks similar to those associated with sprouts, we encourage aquaponic and hydroponic operations to consider voluntarily implementing the standards in subpart M.

(Comment 19) Some comments ask FDA to consider establishing additional regulations specifically applicable to aquaponics operations, as well as to hydroponic production of crops other than sprouts. According to one

comment, this is especially important for high-risk crops such as leafy greens because the use of growth media in hydroponic production can increase the growth of pathogens.

(Response) At this time, we are not establishing additional standards specifically applicable to aquaponic or hydroponic production of crops other than sprouts. As noted in section V.M of the 2013 proposed rule, sprouts present a special concern with respect to human pathogens compared to other covered produce because of the warm, moist, and nutrient-rich conditions required to produce sprouts, the same conditions that are also ideal for the proliferation of pathogens if present (Ref. 20) (Ref. 21). Sprouts also have been frequently associated with foodborne illness outbreaks and, as a result, we issued our first commodity-specific guidance for sprouts. Likewise, the Codex Alimentarius Commission (or “the Codex”) supplemented the Codex Code of Practice for Fresh Fruits and Vegetables (the Codex Guide) (Ref. 22) with a Sprout Annex (Ref. 23). Therefore, we believe it is necessary to incorporate additional subpart M establishing standards specific to sprouts (including soil- or substrate-grown sprouts harvested with roots). Unlike sprouts, we believe that the production methods and safety considerations associated with aquaponics, generally, as well as with hydroponic production of crops other than sprouts, are sufficiently addressed through the provisions of the rule that are generally applicable to covered produce, including the provisions for water in subpart E, for soil amendments of animal origin in subpart F (which include growth media that serve as the entire substrate during the growth of covered produce), and for harvesting in § 112.112. We will consider issuing guidance on these topics in the future, as appropriate. Aquaponic and/or hydroponic operations growing produce other than sprouts may also voluntarily choose to follow the standards in subpart M.

IV. Comments on the Regulatory Approach

In the 2013 proposed rule, in section IV of that document, we explained in detail our tentative conclusion that we should establish a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. We considered and rejected a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities

or classes of commodities. As discussed in the 2013 proposed rule, foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks. Moreover, as discussed in the QAR, some commodities (e.g., leafy greens) have been consistently associated with outbreaks while others (e.g., grapes, jalapeno peppers) have only rarely been associated with outbreaks. In addition, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness. See also discussion at 78 FR 3504 at 3524–3528. We proposed an integrated approach to prescribe standards for on-farm routes of contamination that we tentatively determined are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. Importantly, this integrated approach does take into account differences in commodities in that it takes into account differences in practices associated with the growing, harvesting, packing, and holding of produce commodities. We believe this integrated approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, provides the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. The requirements of this regulation are based on identified routes of contamination and the associated practices that affect the likelihood that produce becomes contaminated. Agricultural practices that are more likely to contaminate produce require more stringent measures to ensure that the likelihood of contamination is sufficiently minimized. For example, as discussed in section XIII of this document, we are establishing the most stringent microbial quality standard for water that is used in direct contact with the harvestable portion of covered produce during or after harvest activities (when there is little further opportunity for pathogen die-off) and in certain other uses that present significant safety risk for the safety of the produce (such as irrigation of sprouts); less stringent criteria for water that directly contacts the harvestable portion of covered produce (other than sprouts) during growing activities (when

the opportunity for pathogen die-off is greater); and no requirements when water is used during growing, but does not contact the harvestable portion of covered produce (other than sprouts). In addition, we recognized the need for, and proposed, additional standards specifically tailored to the growing, harvesting, packing, and holding of sprouts.

We requested comment on our tentative conclusions related to our proposed regulatory approach. We asked for comment on various issues, as discussed in section IV.C of the 2013 proposed rule.

A. Commodity-Specific Versus Integrated Approach

(Comment 20) Several comments generally support our proposed integrated approach for various reasons, including that: (1) An integrated approach focuses on practices of highest risk and provides a whole farm approach rather than commodity-specific measures, which would be challenging for farms that grow multiple crops; (2) an approach that relies on outbreak data to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA; (3) relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time; (4) relying on pathogen surveillance data would not provide sufficient information to make risk determinations because FDA collects few data on produce and data collected are typically targeted to produce that is already known to be risky, which is not a preventive approach.

In contrast, several other comments request that we develop a commodity-specific approach, arguing that the proposed integrated approach is not sufficiently based on risk or science and does not sufficiently align with the intent of Congress that FDA establish a rule that considers differences in risk among various commodities. Several comments contend that, with the exception of exemptions for produce rarely consumed raw and produce that receives commercial processing, FDA has proposed a generic, one-size-fits-all approach. Some comments maintain that, by focusing on agricultural practices, FDA has ignored relevant commodity-specific factors, such as adhesion and infiltration. Some comments also express concern that FDA did not consider past association with outbreaks a major determinant for

coverage of produce commodities, contending that doing so would result in more cost-effective and targeted risk reduction. Still other comments state that there is a known and significant variation in risk profiles, practices, and regional differences across produce commodities, and ask FDA and USDA to fund research to determine the relative risk of microbial contamination.

Some comments suggest FDA should analyze each commodity separately and develop commodity-specific requirements, and establish a level of regulation commensurate to the level of risk of causing foodborne illness presented by a specific commodity, focusing on commodities presenting the highest risk. Some comments point to commodities such as tree fruits, produce with an inedible peel, and nuts as “low risk,” and argue that such commodities should not be regulated the same way as other commodities that present a greater risk profile. Some comments state that citrus fruit is grown off the ground, the peel is generally not consumed, the fruit is acidic, and irrigation water generally does not touch the fruit and, therefore, citrus fruits should be considered low risk. Other comments suggest FDA should start by regulating only commodities that have been associated with an outbreak and consider expanding to include other commodities only after evaluating the public health benefits of the initial rulemaking. Some comments also ask FDA to consider the crop grouping strategies employed by other organizations, such as the grouping used by Codex Alimentarius (in Codex classification of foods); the USDA (in IR-4 project); and the EPA (in EPA’s Crop Group listings).

(Response) We agree with comments that indicated the integrated approach proposed by FDA is appropriate for a variety of reasons. We recognize the diversity of produce operations and agree with comments that pointed out that multiple, crop-specific standards could be confusing and burdensome both in their implementation and in assessing compliance, especially for diversified operations. As discussed in the 2013 proposed rule and the QAR, we agree that an approach that relies on outbreak data, or certain commodity characteristics, to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA and that relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time. For example, cucumbers are

frequently (although not always) peeled prior to consumption and, until recently, did not have a history of association with outbreaks. In 2009, based on literature indicating the potential for cucumbers to be contaminated with *Salmonella* (Ref. 24) (Ref. 25), we added cucumbers to our routine surveillance sampling assignments and, in fact, detected an outbreak linked to cucumbers that year (Ref. 26) (Ref. 27). Between 2011 and 2014, we have identified cucumbers as the food vehicle in three additional outbreaks (Ref. 28).

FDA based its proposal of a practices-based approach in part on the results of our draft QAR. We received public comment on the QAR and also had it peer reviewed and have now issued a final QAR (or the QAR), which incorporates revisions based on public comments and the peer review (Ref. 29). While we have made some revisions, the conclusions of the QAR are unchanged. We conclude that, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. Commenters did not provide information affecting this conclusion. We also conclude that commodity characteristics, such as an inedible peel or the fact that it is grown off the ground, may be relevant to relative likelihood of contamination during growing, but are not good indicators of an association, or lack thereof, with outbreaks. Commenters also did not provide information affecting this conclusion. The QAR looked at likelihood of contamination during growing, harvest, and postharvest activities for 47 commodities and found that commodity characteristics, including microbial adhesion and infiltration considerations, were not reliably protective against contamination, as evidenced by past association with an outbreak for a range of commodities with variable characteristics. For example, if a pathogen is present on the surface of the peel or rind of a piece of fruit, cutting the fruit with a knife can carry the pathogen into the edible portion of the fruit (Ref. 30). Indeed, produce commodities with a peel or removable outer layer, such as honeydew, cantaloupe, papaya, and mango, have previously been associated with outbreaks of foodborne illness. From 1997 to 2014, there have been a total of 20 outbreaks in the United States

associated with produce commodities sold whole (not fresh-cut) where the commodity has an outer peel that is removed prior to consumption, with a range of pathogens (*Salmonella*, *Shigella*, and *Listeria*) implicated in the outbreak (Ref. 28) (Ref. 29). The public health consequences of these outbreaks have been significant. For example, the 2011 *L. monocytogenes* outbreak in the United States associated with cantaloupe resulted in 147 reported cases of illness, 143 reported hospitalizations, and 33 reported deaths (Ref. 28).

With regard to comments asking that we start by regulating only commodities that have been associated with an outbreak, we note in the QAR that “new” commodities are associated with outbreaks on a regular basis, which means that a history of outbreaks is not appropriate as a basis for determining the regulatory status of various commodities. Many comments asked that we consider factors such as commodity characteristics or past association with an outbreak to define a subset of low risk commodities that would be exempt from the requirements of part 112. However, these comments did not provide data that affected the findings of the QAR, and in finalizing this rulemaking we continue to conclude that the integrated approach is the appropriate regulatory framework to ensure the safety of produce.

In considering options for the regulatory framework for the produce rule, we considered the crop groupings used by Codex Alimentarius, the IR-4 project, and EPA’s crop grouping designations (Ref. 31) (Ref. 32) (Ref. 33), which were suggested by comments. These programs categorize commodities based on commodity characteristics, production practices, or pest pressures. They were not created for the purposes of characterizing relative risk of causing serious adverse health consequences or death, or to determine what procedures, processes, and practices should apply to such commodities to minimize the risk of serious adverse health consequences or death. Thus, we did not find these groupings appropriate for purposes of this regulation. As demonstrated by the QAR, even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In the 2013 proposed rule, we specifically sought comment on various possible strategies for developing a commodity-specific approach, including covering only commodities/commodity groups that had been associated with

outbreaks during a specified time period; covering only commodities/commodity groups that had ever been associated with an outbreak; and combining outbreak-based commodity classification with other information, such as commodity characteristics, or pathogen surveillance data. We noted specific problems with each of these approaches. In summary, commenters did not provide data or information suggesting that the problems we identified could be adequately addressed to allow development of a commodity-specific approach that would be sufficiently protective of public health. As a result, we are finalizing our conclusion that the integrated approach is the most appropriate, risk-based, and scientifically sound approach, and we are adopting such an approach.

We also asked specific questions in the 2013 proposed rule regarding whether we might additionally exclude commodities beyond those we identified as the lowest risk (*i.e.*, those that are rarely consumed raw and those that receive commercial processing that adequately reduces pathogens). We asked if produce, such as bananas and coconuts, that are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity should be covered by the rule or subject to a less stringent set of requirements (78 FR 3504 at 3528). We received several comments indicating that bananas should not be covered because they have an inedible peel, which according to commenters means that it is unlikely that contamination will contact the edible portion. In response to our questions in the preamble, no comments identified any unique characteristics, in addition to the ones we identified, of bananas and coconuts that would justify their exemption. We indicated with our question a characteristic of bananas and coconuts that might put them in a lower risk category than other commodities. However, there is no evidence that bananas and coconuts are lower risk than other low-risk commodities or that the method of peeling or opening these commodities generally precludes transfer of contamination on the exterior to the edible portion. As noted in the QAR, there are limited data on the effect of cutting and peeling on the levels of pathogens across the range of produce commodities (Ref. 29). In addition, in the final QAR, while both bananas and coconuts have low ‘route scores’ in the assessment of potential routes of contamination and likelihood of

contamination on-farm, other commodities have lower scores. As noted previously, we continue to conclude that commodity characteristics, such as an inedible peel or the fact that produce is grown off the ground, may be relevant to relative likelihood of contamination during growing, but are not good indicators of an association, or lack thereof, with outbreaks. Therefore, we conclude that they should be subject to part 112.

We also asked about certain commodities that are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because they have fewer potential routes of contamination and/or lower potential for contamination and have not previously been associated with an outbreak. We asked if commodities that meet both these criteria should be subject to the rule or subject to a less stringent set of requirements (78 FR 3504 at 3528). We specifically mentioned pears, grapefruit, oranges and lemons as examples. As noted earlier, we received a comment arguing that citrus fruits should be considered low risk commodities due to the fact that they are acidic, have a rarely consumed peel, are grown in trees, irrigation water generally does not touch the fruit, and citrus fruits have not been associated with outbreaks. However, the comment did not ask for citrus to be exempt, but to be deemed in compliance with the rule if farms are in compliance with the Citrus industry’s good agricultural practices (the Citrus GAPs) (Ref. 34). However, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. In addition, commodity characteristics, such as an inedible peel or the fact that it is grown off the ground, may be relevant to relative likelihood of contamination during growing, but are not good indicators of an association, or lack thereof, with outbreaks. For these reasons, and because comments provided no other information to suggest that citrus fruits or pears should not be covered by the rule, we conclude that they should be subject to part 112. With regard to compliance with the Citrus GAPs, see Comment 143.

(Comment 21) One comment suggests that, as an alternative to developing a commodity-specific regulatory approach, FDA should provide for a notification process by which industry can voluntarily notify FDA about a particular commodity that should be

characterized as low risk and, therefore, exempt from the produce safety regulation.

(Response) We believe the alternative and variance provisions, in subparts B and P, respectively, provide adequate flexibility to address particular situations, and the rule otherwise provides exemptions for certain types of low-risk produce (§§ 112.2(a)(1) and (b)). We are not establishing an additional process or exemptions.

(Comment 22) We received numerous comments stating that we have adopted a “one-size-fits-all,” rigid and prescriptive approach. These comments argue that our proposed approach is not flexible or scale appropriate.

(Response) Under our regulatory approach, the scope and stringency of the requirements are based on risk, and depend in several cases on the types of practices employed within operations, such that producers of different commodities who use different practices will not necessarily be subject to all of the same requirements. We note that § 112.4(a) requires that “[i]f you are a covered farm subject to this part, you must comply with all *applicable* requirements of this part when you conduct a covered activity on covered produce” (emphasis added). As discussed in the 2013 proposed rule, given various considerations, we proposed an integrated approach that draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. In some cases, our standards are similar to current good manufacturing practices-type provisions, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (e.g., personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). In other cases, our standards require the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (e.g., requirements for visual assessment for working or grazing animals or animal intrusion in § 112.83 and inspection of agricultural water system in § 112.42). In still other cases (e.g., sprouts), our standards require the farm

to develop a written plan, committing itself to specific measures (e.g., sprout environmental testing and spent sprout irrigation water testing). Finally, on a limited basis, we are establishing specific numerical standards against which the effectiveness of a farm’s measures would be compared and actions that would be taken to bring the operation into conformance, as necessary (e.g., microbial quality criteria for agricultural water in subpart E). We rely on the numerical standards approach where our evaluation of current scientific information to determine reasonable measures allows us to establish numerical criteria that are broadly applicable across a wide range of conditions, while acknowledging that such criteria may be tailored, as appropriate, when applied specifically to a commodity (or group of commodities) or under a set of farm practices.

We incorporated flexibility into the standards, where appropriate, so covered farms are able to comply with the requirements while taking into account their specific commodities and conditions in their operations, and risk profile associated with them. For example, we define “agricultural water,” in relevant part, to mean water that is intended to, or likely to, contact the harvestable portion of the crop or food-contact surfaces, thus allowing consideration of commodity-specific characteristics and/or practices. For example, if irrigation water does not contact the produce (e.g., drip or furrow irrigation of tree fruit), the microbial quality criteria for agricultural water applied during growing using a direct water application method (for produce other than sprouts) do not apply because the water is not “agricultural water” as we have defined that term. We also incorporated additional flexibility to accommodate future changes in science and technology and the particularities of local growing conditions and commodities. Under § 112.12, we list the specific numerical standards established in this rule for which we allow alternatives to be established and used in appropriate circumstances. This provision provides significant flexibility by allowing individual farms to develop alternative standards suitable to their operations with appropriate scientific support (for example, under §§ 112.12(a) and 112.49(a), alternatives are permitted to the microbial quality criteria in § 112.44(b) related to agricultural water used in a direct application method during growing of produce (other than sprouts)). In addition, in subpart P, we

provide for a mechanism by which a State, tribe, or a foreign country from which food is imported into the United States may request a variance from one or more requirements of part 112, where such variance, among other conditions, is demonstrated to provide the same level of public health protection as the relevant requirement(s) of part 112.

Taking into account comments in response to the 2013 proposed rule and as proposed in the supplemental notice, we incorporated further flexibility in certain key areas such as the standards for agricultural water. For example, § 112.45(b)(1) provides additional means by which to satisfy the microbial quality criteria for agricultural water that is used in a direct application method during the growing of produce (other than sprouts). Allowing for microbial die-off between last irrigation and harvest and/or microbial reduction or removal resulting from postharvest practices provides covered farms viable options to meet the microbial quality criteria without needing to, for example, treat water or switch to a ground water source. This additional flexibility recognizes the diversity of commodities and production practices. It may also be useful for other postharvest activities, for example, commercial washing and controlled atmosphere storage of apples, with adequate supporting data and documentation.

We believe the coverage threshold, qualified exemption, and extended compliance periods adequately address concerns related to scale-appropriate regulation of farms. We have provided as much flexibility as is appropriate while maintaining the overall public health goal of this produce safety regulation. This regulation does not apply to those businesses with \$25,000 or less in sales of produce, as described in § 112.4(a), because such farms do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated. In addition, for farms that fit our criteria for very small business or small business, we are providing extended compliance periods ranging from two to three years for covered activities involving sprouts; and ranging from three to four years for most provisions coupled with more time for certain water-related requirements for covered activities involving all other covered produce (see section XXIV of this document), so they are given sufficient time to make any necessary adjustments to their current practices. There are also provisions for qualified exemption for certain farms based on monetary value and direct-to-consumer sales, and associated modified

requirements, as described in §§ 112.5, 112.6, and 112.7.

In addition, the provisions in subpart A provide risk-based exemptions for certain types of produce based on our determination that the manner in which the produce is consumed does not require that produce to be subject to the requirements in part 112. We are exempting produce commodities that are rarely consumed raw (§ 112.2(a)(1)). Produce that receives commercial processing that adequately reduces the presence of pathogens is also eligible for exemption under certain conditions (§ 112.2(b)).

(Comment 23) One comment asks whether covering all commodities in the rule is compliant with the provisions of the WTO–SPS agreement about the appropriate level of protection. This commenter expresses concern specifically with respect to covering under this rule those fruits and vegetables that have an inedible peel and that are peeled before consumption.

(Response) We believe that the regulatory framework underlying the science-based minimum standards established in part 112 is supported by currently available scientific information, as explained throughout the 2013 proposed rule and in this rule and, as such, satisfies our obligations under the WTO–SPS agreement. We also note that not all produce commodities are subject to the rule. Section 112.2(a)(1) specifies certain commodities that are not covered based on our conclusion that they are rarely consumed raw. See Comment 20 for our consideration of produce with inedible peel.

B. Use of Quantitative Metrics

(Comment 24) Several comments express concern with the use of quantitative metrics in the rule. For example, one comment indicates the proposed requirements in subpart I to “monitor . . . for evidence of animal intrusion” and “evaluate whether the covered produce can be harvested”, allows for regional and commodity diversity and provides sufficient flexibility to be applicable to any operation, whereas the quantitative metrics, such as in proposed §§ 112.44, 112.45, 112.55 and 112.56, are too prescriptive and inflexible to be codified in the regulation. Several comments argue the current status of produce safety research is inadequate to establish the quantitative metrics as applicable to all commodities and regions and all situations. Another comment asks us to limit the metrics to those for which sufficient scientific evidence exists that such standards will

protect public health and reduce risk. Some comments argue that guidance would be a more appropriate vehicle to convey quantitative metrics, as recommendations rather than requirements, because there is such variation in region, operations, and commodities, and because guidance is easier to amend than a regulation.

(Response) The standards that FDA is issuing in part 112 are based in science. Taking into account comments received in response to the 2013 proposed rule we proposed revisions to some provisions in the supplemental notice and explained our rationale, including scientific support for those new and amended proposed provisions. Among proposed §§ 112.44, 112.45, 112.55, and 112.56, which included quantitative criteria, there was one, the minimum application interval for an untreated biological soil amendment of animal origin in proposed § 112.56, for which we indicated that we would conduct further research and a risk assessment. FDA has committed to pursuing this work before revisiting the interval. We conclude we have an adequate basis on which to finalize the metrics in this rule, including in final §§ 112.44, 112.45, 112.46, and 112.55. For a discussion of the final provisions, and comments received in response to the supplemental notice, we refer you to sections XIII and XIV of this document. We disagree with comments that suggest eliminating all quantitative metrics from this rule in favor of recommending such numerical criteria in guidance. We believe it is clearer to regulated industry to establish these metrics in the rule, and important for public health that these metrics be binding requirements rather than recommendations.

C. Scientific Support for the Rule

(Comment 25) Some comments state the record of proven on-farm causation of outbreaks is thin. One comment acknowledges our estimates of produce-related reported outbreaks, outbreak-related illnesses, hospitalizations, and deaths, and argues that, although these adverse impacts are regrettable, the number of deaths pale in comparison to the 2.5 million total deaths in the country, including about 35,000 caused by motor vehicle accidents.

(Response) In the 2013 proposed rule, FDA outlined the history of contamination associated with produce, predominantly during growing, harvesting, packing, and holding (78 FR 3504 at 3507), from 1996 to 2010. On-farm contamination of produce is well documented. We also developed and finalized the QAR which evaluates likely routes of contamination for 47

produce commodities, including pre-harvest and postharvest activities on farms. We have updated our outbreak data since the 2013 proposed rule issued, and between January 2011 and 2014, there were 44 outbreaks, 3120 illnesses, 735 hospitalizations, and 42 deaths associated with produce (including sprouts) (Ref. 28). We continue to conclude that there is an ample history of microbiological contamination of produce on farms to justify establishing the provisions of part 112 to help prevent contamination and illness. This rule is also consistent with our statutory mandate to develop standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death.

(Comment 26) One comment questions FDA’s interpretation of the term “scientifically valid,” which, according to the commenter, relies too much on peer review for validation.

(Response) We use the term “scientifically valid” to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Use of peer-reviewed literature is just one component of what we mean by the term “scientifically valid;” however, we continue to believe that peer-reviewed literature may be an important source of validation of, for example, a procedure, process, or practice allowed as an alternative to a specific requirement of this rule under § 112.12.

(Comment 27) Some comments suggest we should revise the regulation to align with what the commenters identify as the modern microbial ecology paradigm, stating that achieving public health goals is more complex than eliminating pathogens and that exposure to diverse microbes may be necessary for health.

(Response) We do not expect or intend for this rule to bring about a “microbe-free” food production system. We acknowledge that eliminating all pathogens would not be a realistic expectation, especially in an open field environment. However, foodborne illness associated with consumption of contaminated produce can carry high public health and financial costs. Many produce contamination events are preventable, and we will work with industry and other stakeholders to achieve successful implementation of this rule and, ultimately, protect public health. This rule is also consistent with our statutory mandate to develop standards for the safe production and harvesting of produce to minimize the

risk of serious adverse health consequences or death.

D. Market Channels

(Comment 28) We received several comments in response to our question about whether and how we could use market channels as a factor in the rule beyond inclusion of the qualified exemption that already takes market channels into account. One commenter states that local food is less risky because there is less time between harvest and consumption (and, therefore, less time for pathogen growth and multiplication) as well as less centralized processing with potential for cross contamination. This comment argues that FDA's analysis confuses data on hazards that occur on-farm, with hazards that occur off-farm, including hazards that occur later in the chain of production. In addition, one comment suggests that FDA should support research and data collection to compare the risks of different types of supply chains, including direct-to-consumer and multiple "touch-points" supply chains. One comment recommends establishing a three-tiered structure for the regulation of produce safety, reflecting current produce production and marketing systems. As recommended, the three tiers would be: (1) "Farm-direct," which would include farm stands, farmers' markets, community supported agriculture (CSA) programs (e.g. subscription farms) and other strategies where the relationship between individual farmers and consumers is "immediate and understood;" (2) "identity-preserved," which would include distribution on a regional scale where the farmer and consumer do not necessarily meet, but the identity of the farm is displayed or otherwise preserved on products all the way through the system; and (3) "commodity-stream," which would include other distribution systems besides "farm-direct" and "identity-preserved."

(Response) FDA disagrees with the commenter who argues that we are using off-farm food safety data to justify control of farming practices. We recognize that contamination can happen at any point in the supply chain. In a review of outbreaks in the United States attributed to fresh leafy vegetables between 1973 and 2012, Herman and colleagues noted that most (85 percent) fresh leafy vegetable outbreaks during the study period were attributed to food prepared in a restaurant or catering facility (Ref. 35). According to Herman et al., the large number of fresh leafy vegetable outbreaks in which the food was

prepared in a restaurant and contaminated with norovirus, often by an ill food worker, underscores the need to enforce safe handling practices for food workers for these types of foods. The authors also noted, however, that contamination of leafy vegetables early in production by bacterial pathogens such as Shiga-toxin producing *E. coli* (STEC) and *Salmonella* caused nearly all multistate outbreaks associated with those commodities, including some of the largest leafy vegetable outbreaks: *Shigella* and fresh parsley in 1998, Hepatitis A and green onions in 2003, *E. coli* O157:H7 and spinach in 2006. Furthermore, leafy green vegetables used in ready-to-eat pre-packaged salads retain much of their indigenous microflora after minimal processing, including pathogens, if present (Ref. 36).

The focus of the produce rule on contamination on-farm, the earliest point in the supply chain, is consistent with FSMA's focus on prevention of food safety problems. On-farm routes of contamination have been well documented. However, this does not mean that FDA is singling out farms as the only source of contamination for produce; other efforts are directed to potential contamination at later stages of manufacturing and processing. For example, the PCHF regulation addresses manufacturing/processing operations for food, including produce commodities; the FDA Model Food Code (Ref. 37) addresses practices at the retail level; and educational campaigns, such as consumer advice for safe handling of raw produce and juice (Ref. 38) (Ref. 39), are designed to enhance safe handling practices by consumers.

We decline to establish the three-tiered system advocated for by a comment. The comment described potential categorizations that relate to traceability of produce. Tracing may be easier when only selling through the types of arrangements described in the commenter's "farm-direct" category, or in a manner described in the commenter's "identity-preserved" category; however, the goal of this regulation is the prevention of foodborne illness. The commenter did not provide data or information from which we can conclude that the "farm-direct" or "identity-preserved" market channels described represent lower risk of foodborne illness, only that such market channels may better facilitate traceback after illness occurs.

As discussed in the 2013 proposed rule, we acknowledge that the number of opportunities for contamination during packing and holding may be greater for produce in market channels involving greater numbers of handlers

and touch points. At the same time, we concluded that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, and we indicated that we were not aware of any data that would allow us to compare the likelihood of contamination for produce in more or less direct market channels. This rule includes the statutory qualified exemption which addresses market channels (see section 419(f) of the FD&C Act, and § 112.5). We identified no data that would allow us to otherwise use market channels as a basis of risk categorization under this rule. Nor did commenters provide any data or factual information that would allow us to do so. We believe that the commenter who advocated the three tiered system described previously is arguing that it is most important from a public health standpoint to focus our efforts on large farms that sell produce through attenuated supply chains. We agree that we should prioritize our enforcement and compliance efforts in an efficient way that is based on risk. See our discussion in section XXII of this document. We also note that the proposed revised definition of "retail food establishment" (80 FR 19160; April 9, 2015) may affect the number of farms that are subject to the requirements of part 112.

E. Guidance in Lieu of the Produce Safety Regulation

(Comment 29) Several comments recommend that FDA consider issuing guidance, or otherwise providing information and advice to farms, in lieu of establishing the produce safety regulation. These comments note there is a tremendous amount of research being done to address known produce safety issues and enhance produce safety, and use of guidance rather than a regulation would allow FDA to readily and easily incorporate new science and preventive controls as they become available. Some comments state FDA has not explained why we determined not to adopt a voluntary approach and request that any guidance documents consider industry-developed recommendations. Some commenters ask FDA to consider the number of other regulations with which farms must currently comply, suggesting that further regulation is unnecessary.

(Response) Under section 419 of the FD&C Act (created by section 105 of FSMA), Congress explicitly requires the issuance of regulations establishing science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of

fruits and vegetables, that are RACs for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. Adopting a voluntary approach, in lieu of regulatory requirements, does not fulfill this statutory mandate nor does it achieve the public health objectives intended by the produce safety regulation. Rather, this rule implements the statutory mandate described in section 419 of the FD&C Act. We also recognize that there are many requirements with which produce farms must comply, including environmental and worker safety regulations. However, such regulations do not minimize the risk of severe adverse health consequences or death from produce for consumers, which is the goal of part 112.

FDA recognizes that there are many growing situations across the country and abroad, each of which is unique to a particular growing region and site location, and that there may be different measures a farmer can take to prevent and/or minimize food safety risks in compliance with the regulation. In this regard, we note that part 112 gives farm operators sufficient flexibility to tailor their practices as appropriate to achieve compliance with the applicable produce safety standards. Moreover, guidance will play an important role in providing recommendations to assist farms in tailoring their activities to the conditions, practices and commodities specific to their farm. As discussed throughout this document, we intend to issue guidance to help covered farms comply with the requirements of this rule, including a SECG specifically intended for small and very small businesses.

F. Existing Industry Guidelines and Certification Programs

(Comment 30) Several comments request FDA approve or recognize existing industry voluntary programs, and accept participation in such programs as a means to meet the requirements of the produce safety rule. Some comments believe such programs are as protective, or more protective, of public health than the proposed produce safety rule. Some comments note that many farms currently use and understand voluntary auditing and other food safety programs such as the USDA Good Agricultural Practices (GAP) and Good Handling Practices (GHP) programs, the Global Food Safety Initiative's (GFSI) food safety program, the California Leafy Greens Marketing Agreement (CA LGMA) (Ref. 40), the California Cantaloupe Marketing Order, the Arizona Leafy Greens Products

Shipper Marketing Agreement (AZ LGMA) (Ref. 41), the Florida Tomato Good Agricultural and Best Management Practices programs, the Citrus GAPs, and the Massachusetts GAP and Commonwealth Quality programs. Some comments argue that it would not be efficient to create a separate inspection framework under the produce safety regulation without taking steps to provide integration with such existing programs, and integrating inspections would allow FDA to focus its resources on operations that are not part of an existing system. Some comments state that the internal and external audit components of these programs would serve as an additional check to ensure food safety practices are being implemented effectively at farms. Some comments suggest that FDA should grant an exemption or an alternative or variance for GAP-certified farms, those participating in the CA LGMA or AZ LGMA, or those complying with other certification programs.

(Response) FDA appreciates the efforts of commodity groups and industry segments that have proactively developed food safety programs. We also appreciate that farms currently implementing these programs may have developed an understanding and comfort level with the provisions in these programs. Such farms will likely be well-positioned to comply with this rule.

To the extent that certification schemes or food safety programs are consistent with the produce safety regulation, then compliance with those schemes or programs could be relevant to compliance with the requirements of part 112. We reviewed widely used food safety schemes and programs in developing this rule and note that there are consistencies with several of the provisions of this rule. We understand that, as of the publication of this document, many of the widely used food safety schemes and programs will be considering whether and how to revise their provisions in light of the requirements of FDA regulations, including this produce safety regulation and our other new FSMA regulations. Over time, we expect that certification programs and food safety programs will develop tools to demonstrate the alignment of their provisions with FDA requirements. FDA believes there is value in such efforts and will consider the possible implications for FDA's work if and when such information on alignment is available. With respect to the comment about alternatives or variances, see our response to Comment 143.

G. Reducing Burden on Small Farms

(Comment 31) Some comments request a range of options designed for small and mid-sized agricultural operations, and express concern about the burden of the rule on small farms and their ability to stay in business. Some comments state the rule should be established in a manner that does not create a burden on new farm startup enterprises. Comments also request the rule minimize burden on smaller operations by streamlining and reducing unnecessary paperwork. Several comments agree problems with food safety need to be addressed, but request FDA's emphasis should be on "industrial agriculture," which they contend is the primary source of food safety problems, rather than on small farms. One comment suggests costs of compliance will be more burdensome to small farms than to large farms because certain costs, such as those associated with water testing, paperwork, and documentation, remain relatively constant regardless of the size of the operation.

(Response) FDA appreciates that this rule will establish, for the first time, regulatory requirements for on-farm growing, harvesting, packing, and holding of produce. We also appreciate that implementing the requirements of this rule will come with a cost, both in time and resources. As discussed in section IX of this document, we have incorporated a coverage threshold (§ 112.4(a)) and a qualified exemption and corresponding modified requirements (§§ 112.5, 112.6, and 112.7), as well as extended compliance periods (see section XXIV of this document) each based, in part, on the size of the farm. We conclude that these provisions adequately address the concerns of small farms and are in compliance with our statutory mandate under section 419 of the FD&C Act. This rule also provides sufficient flexibility to allow individual operations to tailor their practices as appropriate. Our recordkeeping requirements established in subpart O of part 112 allow farms to use existing records, and do not require duplication provided such records satisfy all of the applicable requirements of part 112. FDA agrees that education, training, and technical assistance to farmers is important. As mentioned throughout this document, FDA will be issuing guidance, including SECG, specifically aimed at assisting small and very small farms to comply with the requirements of this rule. See also Comment 3 and sections XI and XXII of this document.

(Comment 32) Some comments assert the rule will disproportionately affect New England farmers, with negative impacts on New England's food supply because New England farms are small and production costs are higher compared to elsewhere in the country. Other comments assert this rule will force small farmers out of business, forcing the United States to rely on foreign suppliers who these commenters assert are under very little FDA oversight. These comments argue the requirements of this rule should be reduced in various ways as a means of supporting small, local farmers. Other comments express concern that this rule will discourage farmers from supplying the "Farm to School" market.

(Response) We believe that the "farm" definition that we have established in the PCHF regulation, and which we are adopting into part 112 through this rule, reduces the impact of the FSMA rulemakings on farms of all sizes, because several types of operations that were required to register as food facilities under the section 415 registration regulations as established in 2003 (68 FR 58894, October 10, 2003) will no longer be required to do so by virtue of the changes we are making to the definition of "farm." (See the discussion of the changes to the "farm" definition in section IV of the final human preventive controls rule (80 FR 55908).) In addition, a farm that has annual sales of produce below the monetary threshold in § 112.4(a) is not covered under this rule. Moreover, under § 112.5, a farm is eligible for a qualified exemption (and subject to certain modified requirements) if it satisfies certain criteria. We are also establishing delayed compliance dates for small and very small businesses as discussed in section XXIV of this document. All of these factors will reduce the burden of this rule on small farms.

H. Estimated Produce Outbreaks and Associated Illnesses

(Comment 33) Several comments question our analysis and estimates of produce-related outbreak illnesses. According to these comments, the number of outbreaks and health consequences should be reduced by removing known foreign-sourced outbreaks. Some comments point out limitations of the CDC dataset, including that the data do not differentiate between illnesses caused by contamination in the production of produce and contamination due to improper handling by the consumer, and that the data do not include illnesses caused by "unspecified

agents". Finally, some comments contend that FDA should limit its consideration of past outbreak data on which it relies in the proposed regulation; for example, if previous outbreaks are related to activities that would be covered by the proposed Preventive Controls for Human Food rule, then these comments argue that FDA should not consider those outbreaks when determining the risk of activities covered by the produce safety regulation.

(Response) FDA acknowledges that there are a number of limitations associated with available outbreak data. For example, the data do not include illnesses that were not reported, sporadic cases of illness, or illnesses transmitted person-to-person (secondary transmission). The data also do not include a large number of reported illnesses/outbreaks where the contaminated food vehicle cannot be determined. The data do not include illnesses/outbreaks where the point of contamination is determined to be the home, retail, or institutional setting. We thus conclude that, if anything, our dataset likely undercounts the number of outbreaks associated with the production of produce. We disagree with comments that suggest illnesses and outbreaks attributed to foreign sources should be excluded from data considered in support of this rule. Our goal is to minimize illnesses and deaths associated with the consumption of contaminated produce. Imported produce, like domestically-grown produce, contributes to the risk of foodborne illness from contaminated produce and is therefore relevant to this rulemaking.

Finally, while we are not counting these illnesses for purposes of the Regulatory Impact Analysis (RIA) for this rule, we are otherwise considering them in our assessment in the QAR and in establishing this rule. We have determined that it is most appropriate to attribute the benefits of avoiding fresh-cut produce related illnesses to the PCHF regulation for purpose of economic analysis to avoid double counting such benefits; however, we note that it appears that in several cases, the most likely point of original contamination for the fresh-cut-related outbreaks occurred on the farm rather than at the fresh-cut facility. Both farms and fresh-cut manufacturing/processing operations provide routes of contamination that may contribute to adulteration of fresh-cut produce, and the integrated system of preventive controls we are establishing under FSMA is intended to address these risks at multiple stages in the farm-to-table

continuum. Thus, illnesses attributable to fresh-cut produce are relevant to both this rule and the PCHF regulation even though the economic benefits of avoiding illnesses attributable to such products are being estimated only in the RIA for the PCHF regulation.

I. Impact on Traditional Farming Methods

(Comment 34) Several comments express concern that the proposed produce safety rule would impose undue restrictions on traditional farming methods. Comments indicate concern with our proposed approach as applied to diversified livestock-crop farms, the use of working animals, and the use of biological soil amendments of animal origin. These comments urge FDA to remove restrictions applicable to these methods of farming, absent data showing an actual, verified increased rate of foodborne illness associated with use of such. In addition, these comments argue that FDA is inappropriately placing the burden on farmers to prove that their methods are safe.

(Response) We disagree the produce safety regulation would impose undue restrictions on traditional farming methods, such as diversified livestock-crop farms, the use of working animals, or the use of biological soil amendments. These issues are further discussed in sections XIV (standards directed to biological soil amendments) and XV (standards directed to animals) of this document. We have made changes in those subparts that we expect will address at least some of these commenters' concerns. See also section III.E of this document. Farms have a responsibility to produce food that complies with the FD&C Act, and FDA disagrees that we are inappropriately placing burden on farmers to prove that their methods are safe. We are establishing requirements in this rule that will minimize the risk of serious adverse health consequences or death from produce. We are also establishing a rule with significant flexibility for farms to tailor their practices to their operations while remaining in compliance with the rule. We intend to commit significant resources to education, training, and technical assistance to help farms comply with the rule—see section XXII of this document. Also, as discussed in section X of this document, although we expect farms that establish and use an alternative approach (where permitted) to have the necessary scientific data or other information in support of that alternative, such data or information may be developed by you, available in

the scientific literature, or available to you through a third party. We anticipate that the necessary scientific support for an alternative could be developed with broad efforts across the produce community, involving academia, extension services, industry associations, and federal, State, tribal, and local government agencies. FDA is collaborating with partners on research that may provide scientific support for specific alternatives, and we intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

J. Other Comments

(Comment 35) Comments strongly encourage FDA to interact with the retail community to promote the adoption of the final produce rule as a uniform public/private standard. Citing concerns that farms are suffering from “audit fatigue” due to the multitude of requirements already in place from handlers, retailers, and state authorities, these comments urge FDA to facilitate standardization of produce safety requirements and third-party audits.

(Response) FDA is aware of the multitude of audit programs with varying requirements and the associated burden that this places on farms. The produce safety regulation represents science-based minimum standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death. We understand that, as of the publication of this document, many of the widely used food safety schemes and programs will be considering whether and how to revise their provisions in light of the requirements of FDA regulations, including this produce safety regulation and our other new FSMA regulations. We expect to continue to work in collaboration with stakeholders, including the buyer community, as we move forward in implementing this rule.

(Comment 36) One comment requests FDA to provide a safe harbor exemption for contracts and from torts when produce is not delivered due to demonstrated food safety concerns.

(Response) We are not establishing requirements of the type suggested by this commenter. We do not believe it would be appropriate for FDA to dictate, or to invalidate, the specific aspects of contract terms between private parties that the commenter asks us to regulate in this rule. We do not discourage

private parties from including “safe harbor” provisions such as those described by the commenter in their agreements, but we decline to require or otherwise establish them. In addition, we note that section 301(a) of the FD&C Act already prohibits the introduction or delivery for introduction of adulterated food into interstate commerce. Tort law duties are outside the scope of this rulemaking.

V. Final Qualitative Assessment of Risk

In the 2013 proposed produce safety rule, we discussed the findings of a draft qualitative assessment of risk (“the draft QAR”) of hazards related to produce production and harvesting that we conducted to inform the development of our proposed regulatory approach. The draft QAR addressed various questions related to produce safety, including: (1) What are the biological hazards of concern in produce that can lead to serious adverse health consequences or death? (2) How does produce become contaminated (*i.e.*, routes of contamination) during on-farm growth, harvesting, and postharvest operations? (3) Does the likelihood of contamination vary among produce commodity types? (4) Does the likelihood of illness attributable to produce consumption vary among produce commodity types? (5) What is the impact of postharvest practices on the level of contamination at consumption? (6) What on-farm interventions are available to reduce the likelihood of contamination?

As indicated in the 2013 proposed produce safety rule, the draft QAR was peer reviewed in April, 2013. We considered peer reviewers’ comments as well as public comments received in response to the proposed produce safety rule, and finalized the QAR. We consider changes made from the draft QAR to the final QAR, such as adding a sensitivity analysis regarding the scoring system used in the draft QAR and updating the datasets for outbreaks and farm investigations to include data through 2014, to have improved the robustness of the QAR. We provide a brief summary of conclusions of the QAR in the paragraphs that follow. For the complete QAR and our responses to comments received, see (Ref. 29) (Ref. 42), respectively. Key conclusions from this assessment are: (1) Produce can be contaminated with biological hazards, and the vast majority of produce-related illnesses are associated with biological hazards; (2) the known routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed (for sprouts), water, soil amendments, animals, worker health and hygiene,

and buildings/equipment; (3) although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of these potential routes of contamination; (4) the specific growing, harvesting, and on-farm postharvest conditions and practices associated with a produce commodity influence the potential routes of contamination and the likelihood that the given route could lead to contamination and illness. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low; and (5) postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and, thus, may decrease the likelihood of exposure of consumers to contamination.

Hazards of concern in produce—The scientific evidence from outbreaks, surveys and published literature establishes that human pathogens (*e.g.*, *Salmonella*, pathogenic *E.coli*, *Shigella*, and *Cyclospora*) constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

Potential routes of contamination—Based on our observations during inspections, investigations, and surveillance activities and other available information, we have grouped the possible routes of contamination into five major pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings. Seed is an additional route of contamination for sprouts.

Likelihood of contamination—All produce commodities can be contaminated before, during, and/or after harvest through one or more of the potential routes of contamination. Although the likelihood of contamination varies by commodity, it appears to be dependent on the practices employed and, to a lesser extent, on the characteristics of the commodity. There appears to be greater variability in the likelihood of contamination among commodities during growing than during harvest or after harvest.

Likelihood of exposure—Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood that consumers will be exposed to contamination (see also section IX.A.3 of this document).

Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of exposure if indeed the produce is contaminated.

Risk of illness—Contaminated produce has the potential to cause illness. However, there are differences among commodities in the risk of illness, primarily based on the routes of contamination associated with the commodity.

Produce commodities that are ranked as “higher” risk of illness and those ranked as “lower” risk of illness share some of the same characteristics. Both categories include:

- Crops where the harvestable portion grows in the ground;
- Row crops where the harvestable portion grows on or near the ground;
- Crops where the harvestable portion grows above the ground;
- Crops where the harvestable portion grows on trees, high above the ground; and
- Crops that are generally grown without soil.

Such diversity suggests that sorting commodities for risk based only on the manner in which commodities grow would be inappropriate. This diversity also characterizes commodities associated with outbreaks. Even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In summary, some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

The QAR also identifies certain data gaps and research needs that would reduce our uncertainty in understanding how produce becomes contaminated and how that contamination contributes to risk during growing, harvesting, and postharvest activities. Areas for research needs identified in the QAR are origins of pathogens in the farm environment;

survival and distribution of pathogens in the farm environment, specifically in animals, soils, water; transfer of pathogens to produce; survival and growth of pathogens on produce; and prevalence and levels of pathogens in produce that cause illness.

We conclude the QAR advances our ability to describe, in a systematic manner, the current state of our knowledge about the likelihood of illness associated with produce and the likely routes of contamination from on-farm activities. It provides a framework for integrating and evaluating the scientific knowledge related to public health and can be used in support of regulatory decisions in the implementation of section 419 of the FD&C Act.

In the 2013 proposed rule, we also provided our tentative conclusions of a quantitative risk assessment to estimate the predicted effectiveness of our proposed requirements related to irrigation water with respect to one example commodity, *i.e.*, fresh-cut lettuce, and one example pathogen, *i.e.*, enterohemorrhagic *E. coli* (EHEC) (Ref. 43). We noted that the quantitative risk assessment document was being peer-reviewed, and we would consider peer reviewers’ and public comments in finalizing the quantitative risk assessment and the 2013 proposed rule.

However, taking into account public comments received in response to the 2013 proposed rule, in the supplemental notice, we proposed revised requirements for agricultural water, including those for irrigation water. To inform our revised proposed requirements, we conducted two new separate analyses: (1) An analysis of existing recommendations and standards related to water quality to determine whether and how they may be used to develop appropriate microbial quality criteria for water used during growing of produce (other than sprouts) using a direct water application method (Ref. 44); and (2) an evaluation of decay rates of microorganisms on produce to determine whether a decay rate between irrigation and harvest could be identified and, if so, identify an appropriate decay rate (Ref. 45). We relied on the conclusions derived from these new analyses to support our revised proposed requirements for agricultural water quality in proposed § 112.44. In this rule, we are finalizing those proposed requirements, with revisions, consistent with our updated supporting analyses (see section XIII of this document).

Because the quantitative risk assessment of fresh-cut lettuce cited in the 2013 proposed rule pre-dates our

revised proposed requirements in the supplemental notice, and because we continue to rely on the new analyses to finalize our proposed requirements, we are not taking further action to finalize the quantitative risk assessment of fresh-cut lettuce cited in the 2013 proposed rule.

VI. Comments on Non-Biological Hazards

In the 2013 proposed rule, FDA tentatively concluded that the produce safety regulation should be limited in scope to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (78 FR 3504 at 3524). FDA noted that the frequency and nature of non-biological hazards in produce are such that promulgation of a new regulatory regime for their control does not, at this time, appear to be reasonably necessary to prevent their introduction into produce or to provide reasonable assurances that produce will not be adulterated under section 402 of the Act. We requested comment on this approach, and specifically, on whether there are procedures, practices or processes that are reasonably necessary to prevent the introduction of known or reasonably foreseeable non-biological hazards into produce or otherwise to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. After considering comments, we are finalizing this rule, as proposed, with its scope limited to biological hazards.

Although in the 2013 proposed rule, we referred to radiological hazards separately from chemical hazards, we believe that radiological hazards have been considered in the past as chemical hazards and, therefore, we use the phrase “chemical (including radiological)” throughout this rule. This reference to radiological hazards as a subset of chemical hazards is consistent with how these hazards are considered in the PCHF regulation (see definition of “hazard” in § 117.3).

(Comment 37) Several comments generally agree with our proposed approach to focus on biological hazards, and state that food safety resources should be allocated where public health is best served by limiting the scope of the rule to biological hazards. These comments agree with FDA that there are already sufficient regulatory controls on the use of agricultural chemicals in the United States, as evidenced by FDA’s own historical data. One comment states that farms are already regulated at both the State and federal levels in their use of agricultural chemicals, and this

should not be duplicated. Comments also maintain that most produce farms have already implemented sufficient controls to minimize the likelihood of physical hazards reaching consumers; *e.g.*, washing, visual sorting, and mechanical separation devices (such as gaps in rollers) to remove potentially harmful objects from produce. In addition, comments note that physical hazards rarely, if ever, present a risk of severe adverse health consequences or death.

(Response) FDA is finalizing the produce safety regulation with the scope limited, as proposed, to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards. As we noted in the 2013 proposed rule, although the potential for physical or chemical (including radiological) contamination of produce exists, we do not believe that a new regulatory regime is necessary to address those hazards. In a reference memorandum that accompanied the 2013 proposed rule (Ref. 46), FDA provided an overview of the non-biological agents that are reasonably likely to occur in produce at the farm and capable of causing adverse health effects. FDA identified the hazards using relevant sources, such as scientific literature and recall data. Our analysis led us to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. This is because physical or chemical (including radiological) hazards in produce either: (1) Occur only rarely at levels that can pose a risk of serious adverse health consequences or death (*e.g.*, radiological contamination as a result of a nuclear power plant accident); (2) occur with greater frequency, but rarely at levels that can pose a risk of serious adverse health consequences or death (*e.g.*, pesticide or mycotoxin residues); or, (3) occur infrequently and usually do not pose a risk of serious adverse health consequences or death (*e.g.*, physical hazards). We have also updated our analysis to consider hazards from food allergens associated with produce (Ref. 47). No comments included data or information suggesting that we should adjust these conclusions about hazard severity and frequency.

FDA continues to routinely monitor chemical and pesticide residues through its regulatory monitoring programs, with an emphasis on RACs and foods consumed by infants and children (Ref. 48). We continue to believe that current

programs, such as FDA monitoring, EPA registration of pesticides, and State and industry efforts are sufficient to keep these hazards under control. In addition, our focus on biological hazards is consistent with the recommendations in the Codex Guide, which pay particular attention to minimizing microbial hazards and address physical and chemical hazards only in so far as these hazards relate to good agricultural and manufacturing practices (Ref. 22).

It is also important to note that potential contamination of produce from physical or chemical (including radiological) hazards will continue to be covered under the applicable provisions of the FD&C Act and implementing regulations. Under section 402(a)(1) of the FD&C Act, a food is adulterated if it bears or contains any added poisonous or deleterious substance which may render it injurious to health, and such substances may include or otherwise result from physical and chemical (including radiological) contamination.

(Comment 38) One comment notes that food allergens, which are chemical hazards, are rarely introduced in the growing and handling of intact produce, except when the produce itself is a food allergen (*i.e.*, tree nuts and peanuts). Another comment refers to the practice among some small farms of using milk to manage downy mildew, and expresses concern with the introduction of food allergens into produce. This commenter requests that FDA forbid the use of allergens in contact with produce, regardless of the size of the farm or the type of crop.

(Response) The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108–282) addresses, among other issues, the labeling of foods that contain major food allergens. Raw agricultural commodities such as fruits and vegetables in their natural state are not within the scope of FALCPA. However, allergen hazards associated with the growing, harvesting, packing, or holding of produce rarely occur. A review of our recall data from 2004 to 2014 shows that there were no recalls associated with allergens and produce commodities in their RAC form (Ref. 47). As with other chemical hazards associated with produce, we do not believe that the incidence of food allergens as a hazard associated with growing, harvesting, packing, or holding of produce warrants adoption of a new regulatory scheme.

(Comment 39) Some comments argue that the language of FSMA means that the produce safety rule should cover

physical and chemical (including radiological) hazards.

(Response) We disagree. Focusing the produce safety regulation on biological hazards is consistent with section 419(c)(1)(A) of the FD&C Act, which requires FDA to “set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards . . . and to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act].” This language provides FDA with discretion to determine what procedures, processes, and practices are “reasonably necessary” for the purposes identified in the statute with respect to the identified types of hazards.

As discussed previously, we carefully considered different types of hazards, and determined that available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. There is also no pre-existing federal regulatory requirement directed at minimizing the risks presented by biological hazards in produce. Thus, we conclude it is reasonably necessary to set forth controls to prevent the introduction of biological hazards into produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of biological hazards.

On the other hand, FDA’s analysis of the potential for physical and chemical (including radiological) hazards to contaminate produce and cause serious adverse health consequences or death, as well as the adequacy of existing regulatory programs to address such potential, did not demonstrate that additional regulation was reasonably necessary. We conclude that it is not reasonably necessary to establish controls for physical or chemical (including radiological) hazards in this rulemaking in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards.

(Comment 40) Several comments argue for an approach that includes a broader range of hazards, in light of local, regional or country-wide

differences. A number of comments maintain that the rule should apply the principles of the Hazard Analysis and Critical Control Point (HACCP) to identify risks. One comment argues that the general requirement in § 112.11 should apply to all known or reasonably foreseeable hazards. Several comments provide example scenarios where they believe biological, chemical, or physical hazards could represent a significant food safety hazard on a farm. For example, one comment argues that water is a potential source of chemical contaminants so the requirements for water should cover these hazards. Other comments maintain that if a covered farm's land was previously used for another activity that may have contaminated the soil with chemical hazards, the covered farm should be required to take measures (such as collecting and analyzing soil samples for residues) to prevent the introduction of the chemical hazards into or onto produce. Other comments express concern about the use of sewage sludge that can carry a high load of heavy metals and other chemicals (such as drug residues).

(Response) While FDA recognizes that specific scenarios are likely to arise in which physical or chemical (including radiological) hazards present risks of contaminating produce on farms, we conclude that it is not reasonably necessary to establish required controls for such hazards in this rulemaking, in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards. FDA agrees that it is desirable for individual operations to consider their particular circumstances and address relevant hazards. As discussed in section VII of this document, we believe that one way to do this is through the voluntary use of farm-specific operational assessments and food safety plans. Although we are not requiring that covered farms conduct operational assessments or develop food safety plans, we continue to believe that such assessment can help farms identify and take measures that may be prudent for their individual operations to prevent the introduction of known or reasonably foreseeable hazards, including any non-biological hazards. Implementation of food safety plans that are developed based on operational assessments can help farms to be more proactive and effective in protecting the safety of their produce. We also acknowledge that existing guidances on produce safety, including the GAPs Guide, the Codex Guide, and Industry Harmonized GAPs (Ref. 49)

(Ref. 50), all recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation.

Even on a voluntary basis, FDA believes that a full-fledged HACCP approach would not necessarily be appropriate at the farm level because, although there are practices to reduce contamination of produce on the farm, there are typically few critical control points. However, many of the principles of HACCP can still be applied, such as an assessment of risk and the development of a food safety plan based on that assessment.

As discussed previously, we continue to believe that current programs are sufficient to keep these hazards under control. We also emphasize that contamination of produce with physical or chemical (including radiological) hazards will continue to be covered under applicable provisions of the FD&C Act and implementing regulations, and adulterated food may be subject to enforcement action by FDA, as appropriate.

(Comment 41) Citing the increased importance of urban agriculture and urban farming, one comment maintains that FDA failed to consider the contamination of urban properties in the United States with chemical (including radiological) hazards, as well as similar contamination of agricultural lands in other countries used for growing produce, and suggests addressing this issue, at a minimum in guidance.

(Response) We have and will continue to consider agency action, as appropriate, to address the issues associated with risks presented to produce by urban farming, heavy metals, and other non-biological hazards. For example, the GAPs Guide addresses previous land use including animal grazing, chemical application, and toxic spills. In addition, at the request of some foreign audiences, the JIFSAN International GAPs Train-the-Trainer program (Ref. 51) has been updated to include information about the importance of previous land use due to the potential for contamination with both biological and non-biological hazards and a section on EPA requirements for pesticide use.

(Comment 42) One comment notes that while other regulatory and non-regulatory control programs may indirectly control physical and chemical food safety hazards, the fact that those programs are not necessarily intended to deliver food safety outcomes means there may be gaps which a food safety focused regulation may need to address. Another comment states that even though pesticide use does not cause

immediate adverse health consequences or death, food safety is still a concern. This comment urges FDA to consider certain research on the public health risk associated with widespread use of commercial pesticides and herbicides built up in our environment, watershed, and food supply. The comment mentions the 2010 report by the President's Cancer Panel and other bodies, which the commenter believes documents growing evidence on the negative impacts of agricultural chemical use on public health. Other comments express concern over other chemical hazards, such as those used in fields, and state that these chemicals can have harmful effects on both health and the environment.

(Response) That physical or chemical (including radiological) hazards are not addressed in this regulation does not mean that these hazards do not exist or that there is no potential for contamination of produce from these hazards. It also does not mean that these hazards are not included in a comprehensive food safety regulatory strategy. Rather, we believe the frequency and nature of physical and chemical (including radiological) hazards occurring in produce and the existing regulatory programs are such that promulgation of a new regulatory regime is not reasonably necessary to minimize the risk of serious adverse health consequences or death associated with these hazards.

There are effective governmental control programs in place in the United States to assure generally that unlawful pesticide residues are unlikely to occur. For pesticides, these controls include pesticide registration, applicator licensure, and government sampling and enforcement programs. For example, the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136–136y) (FIFRA) authorizes EPA to regulate the use and sale of pesticide to protect human health and to preserve the environment. As part of this evaluation, EPA must ensure with a reasonable certainty that no harm will result from the legal uses of the pesticide. EPA's evaluation considers, among other things, the combined risk from that pesticide from all non-occupational sources (including uses on food), and whether there is an increased sensitivity from exposure of the pesticide to infants and children (Ref. 52). Pesticide tolerances set by EPA are enforced by FDA for most foods and by USDA's Food Safety and Inspection Service (FSIS) for meat, poultry, and some egg products. As mentioned previously, FDA also routinely monitors for chemicals, pesticide residues, metals

and radionuclides through its regulatory monitoring programs, with an emphasis on RACs and foods consumed by infants and children (Ref. 48). Other federal and state programs, too, monitor chemical hazards in food directed at food safety. For example, AMS operates the Pesticide Data Program, which collects and analyzes samples for pesticide residues in food, and data from this program is utilized by USDA, FDA, EPA, and other groups (Ref. 53). Individual States also have programs to routinely monitor for non-microbiological hazards in foods.

With respect to the 2008–2009 President’s Cancer Panel “Reducing Environmental Cancer Risk” (Ref. 54), we note that, among other conclusions, the Panel recommends that consumers can reduce exposure to pesticides in food by selecting food grown without pesticides or chemical fertilizers and washing conventionally grown produce to remove residues. This recommendation is consistent with FDA and the Partnership for Food Safety Education advice to consumers that produce should be washed immediately before preparation and consumption (Ref. 38) (Ref. 55).

(Comment 43) One comment points out that a recent United States Government Accountability Office (GAO) report criticized FDA for its lack of pesticide residue testing on food. This commenter asks FDA to adopt better chemical safety standards for produce.

(Response) In October, 2014, the GAO released a report entitled “Food Safety—FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations” (GAO–15–38). In that report, GAO discusses its review of federal oversight of the foods regulated by FDA, FSIS, and AMS, and makes a number of recommendations to further enhance the pesticide monitoring programs of the two agencies. As noted in that report, FDA has already undertaken certain actions to enhance its program. For example, FDA has increased its monitoring of pesticide residues by taking actions consistent with the GAO recommendations and increased the scope of its testing program. FDA uses AMS’s Pesticide Data Program, which generates national statistically-valid data, to target commodities for testing. FDA also has an ongoing effort as part of its pesticide residue monitoring program to evaluate the effectiveness of regulatory actions in preventing violations.

(Comment 44) Some comments maintain certain biological soil

amendments contain chemical hazards that FDA should address in this rule.

For example, one comment states that animal manure from animal production facilities can contain heavy metals, such as arsenic, zinc, and copper; and animal drug residues, including antibiotics that raise human health concerns. Some comments point out that industry commodity-specific food safety guidelines and the NOP prohibit the use of both raw human waste and biosolids, as these materials present a risk of introducing pharmaceuticals and heavy metals. Some comments also state that research on the risks presented by pharmaceuticals present in produce-growing soils that have been treated with biosolids, and any subsequent uptake into plants, is in its infancy.

(Response) As discussed previously, FDA’s analysis of the potential for chemical hazards (including heavy metals and drug residues) to contaminate produce and cause serious adverse health consequences or death, as well as the adequacy of existing regulatory programs to address such potential, did not demonstrate that additional regulation was reasonably necessary. We conclude that it is not reasonably necessary to establish controls for physical or chemical (including radiological) hazards in this rulemaking in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards. Therefore, we are limiting the scope of this rulemaking to biological hazards.

VII. Comments on Farm-Specific Food Safety Plans

We discussed farm-specific operational assessments and food safety plans in section IV.F of the 2013 proposed produce safety rule. We tentatively decided not to require farms to conduct operational assessments or to develop food safety plans. However, we explained that operational assessments and food safety plans have a prominent place in ensuring produce safety and recommended that farms do so, because this could help farms be more effective in protecting the safety of their produce. We requested comment on whether we should require that some or all covered farms perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement. After considering comments, we are finalizing this rule as proposed, with no requirement for a covered farm to conduct an operational assessment or to develop a farm-specific food safety plan,

although we recommend that farms do so.

(Comment 45) Several comments recommend that FDA require all covered farms to perform operational assessments and/or develop a written food safety plan. These comments state that conducting an assessment of likely hazards that could occur on the farm can help farmers identify potential situations which could lead to contaminated food, helping allocate resources efficiently. Some comments indicate that this requirement is appropriate regardless of the size of an operation or volume of sales and note that many farms already operate using well-developed, monitored, and maintained food safety plans. Some comments also state that operational assessments would also provide inspectors—whether State or federal—with a mechanism for understanding the particular hazards the farm believes it is mitigating. In addition, some comments maintain that many farms currently develop and use food safety plans under certain industry programs. One comment supports a requirement for a food safety plan, but indicates that the food safety plan should be used as a tool to advance food safety practices rather than as an enforcement tool to determine if a farm is non-compliant.

Conversely, many comments oppose any FDA requirement for farms to develop food safety plans. Although acknowledging that some farms may perform operational assessments or develop food safety plans and farms may benefit from food safety plans, these comments argue that FSMA does not authorize FDA to require farms to perform operational assessments or develop food safety plans. These comments believe that such a requirement established in regulation would be unreasonable; overly burdensome, particularly for small farmers; would decrease the flexibility of the produce safety rule; and may affect current State requirements or industry recommendations. Other comments find a requirement for a farm-specific food safety plan unnecessary because, according to these commenters, FDA has already performed a hazard analysis for most operations by identifying in the produce safety proposed rule the hazards reasonably likely to occur, and communicated that future guidance will include additional information on control measures that operations can use to minimize the likelihood of those hazards affecting produce.

(Response) In our guidances to industry, FDA has previously recommended the use of farm-specific

food safety plans. For example, in the GAPs Guide, we stated that the recommendations in that guide would be most effective if farms took them and tailored them to their individual operations (Ref. 14). Since publication of the GAPs Guide, the principle of tailoring practices to an individual operation has evolved into using an operational assessment and developing an on-farm food safety plan that is specific to that operation, based on the assessment. Food safety plans have become an important component in a number of existing programs and guidances and, as several commenters noted, tools are currently available to fit a variety of operations. FDA's draft commodity-specific guidances, too, include draft recommendations to develop and maintain written food safety plans and standard operating procedures for areas such as handling and storage practices; field, building, and vehicle cleaning and sanitation; and employee training programs (Ref. 56) (Ref. 57) (Ref. 58).

FDA agrees that all farms, irrespective of the size of the operation, the commodities they grow, the practices they follow, or their status with respect to coverage under the produce safety rule, could benefit from performing an operational assessment and having a food safety plan, and we encourage all farms to do so. A site-specific assessment can help a farm tailor practices to their specific operation. We agree that assessments and plans should be commensurate with the size and scope of an operation and that different assessment tools may be best suited for different operations, *e.g.*, by commodity, size, or region.

We continue to believe, however, that requiring covered farms to conduct an operational assessment and develop a food safety plan, particularly at the level required for hazard analysis and development of a food safety plan in our juice HACCP regulation (*i.e.*, the Hazard Analysis and Critical Control Point Systems regulation in 21 CFR part 120) and our seafood HACCP regulation (*i.e.*, the Fish and Fishery Products regulation in 21 CFR part 123), or prescribed by section 418 of FSMA for food facilities, is not warranted as a mandatory requirement for the safe production of covered produce. The statutory direction in section 419 is for FDA to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated. As discussed in the 2013 proposed rule, relevant documents on

produce safety, such as the GAPs Guide, industry commodity-specific guidelines for melons, tomatoes, leafy greens, and green onions (Ref. 40) (Ref. 59) (Ref. 60) (Ref. 61), the CA LGMA, the AZ LGMA, the Association of Food and Drug Officials' (AFDO) Model Code of Practice for the Production of Fresh Fruits and Vegetables (the AFDO Model Code) (Ref. 62), the Codex Guide, and Industry Harmonized GAPs, all recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation. We believe the most appropriate approach for the produce safety regulation is to establish the standards that are described in part 112. While operational assessments and food safety plans are valuable tools, we believe they may be more than a minimum standard and more than what is reasonably necessary for us to require to achieve the statutory purposes. Therefore, we are not establishing a requirement for farms to conduct operational assessments or to develop food safety plans.

FDA agrees that, in issuing the produce safety regulation, FDA has essentially performed a hazard analysis and established what could be characterized as a baseline or minimum food safety plan for covered farms. We also agree the process of conducting an operational assessment and developing a plan could be a useful exercise to help many farms, whether they are subject to the rule or not, to more closely examine their operations and identify potential risks along with ways those risks might best be reduced. Therefore, we encourage farms to develop a food safety plan.

In response to comments urging education and outreach efforts, FDA notes that the PSA working groups identified operational assessments and food safety plans as being valuable components of an on-farm food safety system and have developed a food safety plan training module as part of their training curriculum. The PSA is also planning an optional 2-day workshop that can be added to their basic training on the assessment and food safety plan development process. We also acknowledge the efforts of other non-governmental organizations, farm groups, and private businesses that are currently working with farmers on development of food safety plans.

Finally, in response to the comment suggesting that food safety plans should not be used in enforcement, we note that we are recommending, but not requiring, that farms have a food safety plan.

(Comment 46) Some comments suggest that FDA should provide in guidance documents model food safety plans for use by farms that are not covered by the rule or that are eligible for the qualified exemption. Some comments state that they expect the produce safety regulation to lead consumers and commercial buyers to demand that all produce farms are following practices that reduce food safety risks, such that farms that are not required to comply with the rule would be at a disadvantage in the market.

(Response) As discussed previously, FDA continues to recommend operational assessments and food safety plans for all farms, including those not required to comply with the rule, and we intend to address this further in guidance.

(Comment 47) Some comments suggest that FDA should stipulate that farms eligible for the qualified exemption that have food safety plans would have protection from having that exemption revoked. According to these commenters, if these farms receive additional incentives to develop food safety plans, it would help prevent them from creating conditions that could cause their exemption to be revoked, and assist them in defending themselves, should the FDA determine that a food borne illness was caused by material conduct or conditions linked to their operation. Another comment states that FDA guidance and model food safety plans should encourage farms to record information that would be useful in the event of a challenge to their exemption.

(Response) We encourage the use of food safety plans by all farms, including those that are not covered by the produce safety regulation as well as those that are eligible for a qualified exemption and subject to certain modified requirements. We also refer you to the discussion in section XXIII.A of this document where we discuss the circumstances under which FDA may withdraw a qualified exemption, in accordance with § 112.201. As established in § 112.201(b)(1), before FDA issues an order to withdraw your qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction. Although we are not providing any categorical limitation on withdrawal of qualified exemptions based on existence of a food safety plan, we believe that food safety problems are less likely to happen in an operation that has

thoughtfully assessed its risks, identified potential hazards, and taken steps to mitigate the hazards identified.

(Comment 48) One comment suggests that the produce safety rule could be structured to allow farms to comply either by following the requirements as proposed or by developing, documenting, implementing, monitoring, and maintaining a food safety plan based on a comprehensive hazard analysis that utilizes the same principles as HACCP in the proposed human preventive controls rule. The commenter explains that, instead of following the prescribed standards, a covered farm would have the option to demonstrate and document the identification of its risks through its unique hazard analysis, and maintain adequate scientific data or information to support its resultant approach and conclusion that its food safety plan would provide the same level of public health protection as following the set of prescribed rules, similar to the alternative provisions permitted under proposed § 112.12.

(Response) As noted in response to Comment 45, we do not believe requiring covered farms to conduct an operational assessment and develop a farm-specific food safety plan, particularly at the level required for hazard analysis and development of a food safety plan in our juice and seafood HACCP regulations, or prescribed by section 418 of FSMA for food facilities, is warranted to meet the statutory direction in section 419 to establish “minimum science-based standards” for produce safety and “procedures, processes, and practices that the Secretary determines to be reasonably necessary” to meet the statutory goals of preventing introduction of known or reasonably foreseeable hazards and providing reasonable assurances produce is not adulterated.

We agree that an operational assessment and written food safety plan could be useful to a farm to identify whether and how an alternative approach to an FDA-established requirement (as permitted under § 112.12) could be applied to the specific operations at the farm. Note, however, section § 112.12 provides for the use of alternatives for only certain specified requirements of part 112, and not for all of the requirements of part 112. FDA does not agree with the commenter’s suggestion that we should allow covered farms to choose between complying with the requirements of part 112 and conducting an operational assessment and developing a food safety plan based on such assessment. Such an approach would be akin to permitting

the use of an alternative to every one of the provisions of part 112, which FDA has determined is not an appropriate approach (we refer you to the discussion in section X.C of this document). The provisions FDA is establishing in this rule are those that FDA has determined are appropriate to require of all covered farms when they are applicable to the farms’ operations. Where FDA believes that alternative approaches may reasonably provide the same level of public health protection, we have provided an option to use an alternative in § 112.12.

(Comment 49) One comment suggests that national and regional crop associations should have the flexibility to add commodity-specific and risk-based standards to FDA-prescribed standards to fit their own crop(s), as necessary. This comment maintains that such an approach would allow farms to continue using commonly accepted food safety practices that they have determined to be the best approach for their crop(s). This comment refers to mandatory food safety and recall plans within a food safety program as examples.

(Response) Part 112 does not prohibit or otherwise preclude covered farms from developing and implementing farm-specific food safety plans, including continued use of food safety plans that may be currently in place, as long as the farms also comply with the provisions of part 112. The provisions for use of alternatives (in accordance with § 112.12) and use of variances (in accordance with subpart P of part 112) provide flexibility for the use of measures that are tailored to specific commodities and conditions, either in addition to the FDA-established science-based minimum standards in part 112, or in lieu of them where allowed under the rule. FDA anticipates that its guidance may also contain additional commodity-, region- and practice-specific, risk-based recommendations, as needed and appropriate, to assist covered farms in following best practices appropriate to their crop(s), region and practices. In developing such guidance, we intend to take existing guidance and produce safety programs into consideration, similar to our development of draft commodity-specific guidances for melons, tomatoes, and leafy greens.

VIII. Comments Related to Foreign Farms

In the 2013 proposed produce safety rule, we noted that proposed part 112 would apply to foreign farms that meet the criteria to be covered farms and that grow, harvest, pack, or hold covered

produce for import into the United States. We also noted our intention to provide equal treatment for foreign and domestic farms and to identify areas for outreach and technical cooperation to help foreign farms understand the rule’s applicability to them.

We received a number of comments regarding foreign farms from both domestic and foreign stakeholders that addressed various aspects of the produce safety regulation. For example, comments addressed issues related to coverage of farms (subpart A), personnel training (subpart C), variances (subpart P), and compliance and enforcement (subpart Q), which we considered in the sections of this document where the relevant subparts of part 112 are discussed. In this section, we summarize and respond to comments that address general and cross-cutting issues related to foreign farms.

(Comment 50) Several comments recognize the need to apply the rule equally to domestic and foreign farms that sell produce in the United States market, but believe that the rule may place domestic farmers at an economic disadvantage. These comments argue that enforcement of the regulation will inevitably be more stringent on United States farms than on foreign farms, citing limitations of FDA resources and FDA jurisdiction over foreign farms.

(Response) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage United States farms as compared to foreign farms.

With respect to enforcement, FDA intends to use the resources at its disposal to ensure that both domestic and foreign producers are following the requirements of the rule. As discussed in section XXII of this document, our strategy to ensure the safety of produce, both domestically-produced and originating from foreign farms, will focus on education, training, and guidance to achieve compliance. This will include outreach to foreign governments. We will also work to provide education and assistance in local languages to reach farmers exporting covered produce into the United States, including by working with organizations and other sources of information that are familiar and accessible to the produce farming community (such as alliances, international organizations, universities, trade associations, foreign partners, JIFSAN, and federal agencies (such as USAID and USDA), among others).

Inspections will also play a key role. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed, such as to prevent significant hazards from entering the food supply or in response to produce safety problems. While FDA is not in a position to inspect every foreign farm that produces food for consumption in the United States, the inspections FDA is able to conduct will be bolstered by other efforts, such as the final FSVP rule establishing subpart L of 21 CFR part 1 (hereafter referred to as “the FSVP regulation”) (published elsewhere in this issue of the **Federal Register**). The FSVP regulation establishes requirements for importers to verify that imported food (including produce) is produced in compliance with FDA food safety regulations (including the produce safety regulation) or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required in the United States.

(Comment 51) Several comments stress the importance of publishing the Produce Safety rule concurrently with the import-related FSMA rules, such as the FSVP and third-party certification rules, in order to ensure consistent regulation of domestic and imported produce.

(Response) In finalizing this rule, FDA has considered issues related to the FSVP and third-party certification rules. Section 301 of FSMA directs us to establish foreign supplier verification programs for importers of food. In addition, section 307 of FSMA directs us to establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet certain requirements. In the rulemakings establishing the FSVP regulation and the third-party certification regulation, published elsewhere in this issue of the **Federal Register**, FDA explained how the supplier verification requirements and third-party certification requirements in those rules relate to farms that are subject to the produce safety regulation and those that are not subject to the produce safety regulation.

(Comment 52) Several comments argue that the requirements of the rule will disadvantage foreign farms as compared to domestic farms. Some of these comments argue that the rule is too prescriptive and suggest that greater flexibility could be achieved by allowing foreign farms to make their own choices about what methods and tools are necessary to ensure food safety. These comments also note that foreign authorities have a role in enforcing their

own requirements regarding food safety practices. One comment recommends that FDA not establish any requirements related to foreign farms’ production practices. Instead, the comment asserts that FDA should only verify whether articles of produce themselves comply with the FD&C Act, and should only check the compliance of produce from farms with a history of non-compliance.

(Response) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage foreign farms as compared to domestic farms. The risks from imported and domestic produce arise from the same or similar pathogens and routes of contamination. Therefore, the requirements that we are establishing in part 112 apply equally to these concerns wherever they arise.

We also disagree with comments that suggest that the rule is too prescriptive. We have incorporated significant flexibility into our requirements, wherever appropriate, by relying on an integrated approach that employs various mechanisms (for example, current good manufacturing practices, numerical criteria, and monitoring) as appropriate to the hazards. This provides sufficient flexibility to allow all covered farms, both foreign and domestic, to determine the methods and tools necessary to produce safe food as appropriate, taking into account the specific practices, procedures, and processes in their individual farm operations. We have also provided additional flexibility by permitting a foreign government to request from FDA a variance from any one or more of the requirements in part 112, under certain conditions as described in subpart P of part 112.

Neither FDA, generally, nor this rule, specifically, imposes any restrictions on foreign governments from establishing or enforcing their own requirements within their sovereign nations. This rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown domestically for export to foreign countries. To the extent a foreign covered farm exports covered produce to the United States, such farm must ensure that its production of such produce complies with all applicable requirements of part 112. Conversely, the requirements of part 112 do not apply to produce that is grown, harvested, packed, or held on a foreign

farm that is not exported to the United States.

Finally, with respect to the comment about focusing on the produce commodity, itself, rather than on production practices, we refer you to the discussion in section IV.I of the 2013 proposed rule and section III.F of this document, where we explain our conclusion that product testing requirements (except under certain circumstances for sprouts) would be impracticable. We also refer you to the discussion on commodity-specific approaches in section IV.A of this document.

(Comment 53) Several comments argue that requiring foreign farms to adhere to the rule will cause them to incur considerable costs and restrict farms from engaging in trade with the United States. Some of these comments specifically state that the rule should not impose requirements that would act as barriers to trade in conflict with United States trade obligations.

(Response) This rule is fully consistent with United States trade obligations. In developing the produce safety standards in part 112, and in formulating our implementation strategy (as described under subpart Q of part 112), we considered United States trade obligations to ensure that the final rule is based on risk and on science, and we are applying the same standards to imported and domestic food to ensure the safety of the United States food supply.

(Comment 54) Some comments argue that imported produce should be more closely monitored than domestically-grown produce. Some of these commenters believe that applying additional oversight to imported produce may decrease the number of contamination events and illnesses occurring in the United States.

(Response) This rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown domestically for export to foreign countries. We are not aware of evidence indicating that imported produce contributes a disproportionately higher risk of illness to United States consumers compared to domestically-grown produce. We expect that compliance with the standards in part 112 will reduce the risk of foodborne illness associated with the consumption of contaminated produce, whether domestic or imported.

(Comment 55) One comment asks FDA to clarify the applicability of the rule to a foreign farm that harvests produce and ships it to the United States in non-consumer containers, where the produce is subsequently packaged in retail containers sold to the public.

(Response) In this example, neither the foreign location of the farm nor the packaging/repackaging that occurs in the United States affects the status of the foreign farm or its produce under this rule. Assuming that the foreign farm is a covered farm, and the produce is covered produce, the farm and its produce are subject to this rule.

(Comment 56) Many comments express the need for FDA to engage foreign governments to help them understand what is expected of foreign farms under this rule. One comment states that FDA should provide training and capacity building programs for foreign governments. Another comment requests that FDA provide translations of the regulation as well as accompanying guidance documents in order to facilitate understanding by both foreign governments and foreign farms, and compliance by foreign farms.

(Response) As noted previously, education, training, and guidance will be key components of our strategy to achieve compliance with the produce safety regulation, both for domestic and imported produce. Specifically, we recognize that some foreign farms may have difficulty understanding the applicability of the rule to them, and we will work with new and existing partners to identify areas for international outreach and technical cooperation to achieve greater understanding. Moreover, section 305 of FSMA directs FDA to develop a plan to build the capacity of foreign governments with respect to food safety. Leveraging and partnerships are important in everything FDA does, and even more so with capacity building. FDA recognizes the importance of establishing strong relationships and mutual support among all stakeholders from farm to table. We will also work to provide education and assistance in local languages to reach farmers exporting covered produce into the United States, and will work with organizations and other sources of information that are familiar and accessible to the produce farming

community (such the Alliances, international organizations, universities, trade associations, foreign partners, JIFSAN, and federal agencies (such as USAID and USDA), among others). We will work with partners to provide technical assistance to the farming community, especially small and very small farms, regarding compliance with this rule. We also intend to disseminate guidance documents in multiple languages.

IX. Subpart A—Comments on Definitions and General Provisions

In proposed subpart A of part 112, we proposed to establish provisions that establish the scope of, and definitions applicable to, this regulation, and which identify who and what is subject to the requirements of this part. As proposed, this subpart also described the criteria for eligibility for qualified exemptions, and modified requirements for those eligible for a qualified exemption from this rule. We asked for comment on all provisions in subpart A.

We are finalizing these provisions with revisions (see Table 4). We discuss these changes in this section.

TABLE 4—DESCRIPTION OF REVISIONS TO SUBPART A

Final provision	Description of revisions
§ 112.1(b)(1)	—Revisions to the list of examples of fruits and vegetables.
§ 112.2(a)(1)—exhaustive list of rarely consumed raw produce.	—Revisions to the list of exempt commodities based on our updated robust analysis using more recent data and information, and considering public comments.
§ 112.2(b)—produce that receives commercial processing.	—Addition of wine and beer as examples in § 112.2(b)(1). —New provisions § 112.2(b)(2), (3), and (4) to require certain disclosure and documentation, and annually obtain certain written assurances. —New provision § 112.2(b)(6) related to entities that provide the written assurances described in § 112.2(b)(3)(i) or (ii).
§ 112.3(b)—Definition of “small business” and “very small business”.	—Revision to acknowledge that such businesses may be subject to only some requirements of part 112 if the farm is also eligible for qualified exemption.
§ 112.3(c)—Definition of “agricultural tea”	—Revision to add “Agricultural teas are soil amendments for purposes of this rule”. —Revision to replace “humus” with “stabilized compost”. —Revision to specify that agricultural teas are soil amendments for the purposes of this rule.
§ 112.3(c)—Definition of “biological soil amendment”.	—Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “biological soil amendment of animal origin”.	—Revision to add animal mortalities as an example.
§ 112.3(c)—Definition of “composting”	—Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “covered activity”	—Revision to reflect new § 112.2(b)(6) by adding “Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in section 112.2(b) of this part are also covered activities.”
§ 112.3(c)—Definition of “curing”	—Revision to replace “maturation” with “final”. —Revision to add “Curing may or may not involve insulation, depending on environmental conditions.”
§ 112.3(c)—Definition of “farm”	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “ground water”	—New definition of “ground water” added, with corresponding changes to definition of “surface water”.
§ 112.3(c)—Definition of “growth media”	—Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “harvesting”	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “hazard”	—Revision to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard” by replacing “is reasonably likely to” with “has the potential to”.
§ 112.3(c)—Definition of “holding”	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “known or reasonably foreseeable hazard”.	—Replacing the term “reasonably foreseeable hazard” with “known or reasonably foreseeable hazard”. —Revision to more clearly distinguish this term from “hazard”. —Revision to specify that for the purposes of this rule, such hazards are biological.

TABLE 4—DESCRIPTION OF REVISIONS TO SUBPART A—Continued

Final provision	Description of revisions
§ 112.3(c)—Definition of “manufacturing/processing”.	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “mixed-type facility”	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “monitor”	—Revision to replace the phrase “when applicable” with “when required”.
§ 112.3(c)—Definition of “non-fecal animal by-product”.	—Revision to replace “other than excreta” with “other than manure”.
§ 112.3(c)—Definition of “packaging” (when used as a verb).	—Deleted consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “packing”	—Revision consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “produce”	—Revision to add “primarily” before “grown and processed for use as meal, flour, baked goods, cereals and oils” in description of grains. —Revision to replace “fresh consumption” in description of grains with “direct consumption as small, hard fruits or seeds”. —Revision to include “oilseeds” as an example of grains, and to include flax seed, rapeseed, and sunflower seed as more specific examples. —Revision to add commas.
§ 112.3(c)—Definition of “qualified end-user”	—Revision to add “or the same Indian reservation”. —Revision to move “The term ‘consumer’ does not include a business” from under (ii) into a parenthetical phrase within the definition.
§ 112.3(c)—Definition of “sanitize”	—Revision to refer to adequately treating “surfaces” rather than “food-contact surfaces,” consistent with changes made in PCHF regulation.
§ 112.3(c)—Definition of “stabilized compost” ...	—Revision to use the term “stabilized compost” rather than proposed term “humus” to better reflect the finished product of composting.
§ 112.3(c)—Definition of “soil amendment”	—Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “static composting”	—Revision to replace “covered with at least 6 inches of insulating material” with “that may or may not be covered with insulating material”. —Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “surface water”	—Revision corresponding to new definition of “ground water,” to clarify the differences between the two sources.
§ 112.3(c)—Definition of “turned composting” ...	—Revision to replace “humus” with “stabilized compost”.
§ 112.3(c)—Definition of “visitor”	—New definition of “visitor” added, with corresponding deletion of proposed definition that previously appeared in § 112.33(a) (content of final definition is unchanged).
§ 112.3(c)—Definition of “you”	—Revision to clarify that “you” as used in this part “means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112”. —Revision to adjust the monetary threshold for inflation.
§ 112.4	—Revision to reflect revised definition of “you”.
§ 112.5	—Revision to reflect revised definition of “you”.
§ 112.6	—Revision to add subpart O (Records) to the list of subparts applicable to farms eligible for the qualified exemption, corresponding to addition of new records provision in § 112.7. —Revision to clarify which other subparts of part 112 are applicable to farms eligible for the qualified exemption.
§ 112.7	—Revision to reflect revised definition of “you”.
§ 112.7	—New provision to establish certain recordkeeping requirements in relation to qualified exemption.

A. Food That Is Covered and That Is Not Covered (§§ 112.1 and 112.2, and Definition of “Produce” in § 112.3(c))

1. Definition of “Produce” (§ 112.3(c)) and Food That Is Covered (§ 112.1)

We are finalizing our definition of “produce” with certain changes discussed in the paragraphs that follow, and editorial changes (adding commas). We note that the definitions of “produce,” “fruit,” and “vegetable” in this rule are applicable for the purposes of this rule. FDA has used different definitions of “fruit” and “vegetable” in certain other contexts and continues to do so. For example, see 65 FR 54686 at 54687 (September 8, 2000) (“Although seeds are clearly part of the plant kingdom, they are not ordinarily thought of as vegetables. Therefore, FDA is concerned that the term ‘vegetable oil

sterol esters’ may not be understood to cover esterified sterols from sources like canola oil”); see also discussion of “vegetable” in Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice (“the agency considers the term “vegetable” in the context of the juice definition to refer more narrowly to edible plant parts that consumers are accustomed to eating as vegetables in their diet”) (Ref. 63).

(Comment 57) Some comments state that we should not consider peanuts or tree nuts to be “produce” for the purposes of this regulation. In support of this argument, one comment states that there are controls in place to limit the level of aflatoxin in nuts.

(Response) These comments did not provide us with information from which to conclude that we should change our view of whether peanuts or tree nuts are

“produce” within the definition in the rule. As explained in the 2013 proposed rule, the dictionary definitions of “peanut” and “nut” are consistent with our definition of “produce,” the industry appears to recognize peanuts and tree nuts as produce, and the biological hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of peanuts and tree nuts are generally similar to those for other produce, including the shared hazard of pathogens. Aflatoxin, a mycotoxin, is a chemical hazard rather than a biological hazard. In section VI of this document, we discuss this rule’s focus on biological hazards. Because this rule focuses only on biological hazards and controls relevant to biological hazards, mycotoxin risk is not relevant to

determining whether peanuts or tree nuts should be considered to be “produce” for the purposes of this rule. Determining that peanuts and tree nuts are “produce” is only the first step in determining whether a particular type of nut, or a particular lot of nuts, is subject to the rule. Some types of nuts are not covered by the rule because they are rarely consumed raw. Cashews, hazelnuts, peanuts, and pecans are listed in § 112.2(a)(1) and are therefore not covered by this rule. We also expect that some nuts will be exempt from this rule (with appropriate documentation) because they receive commercial processing that adequately reduces the presence of microorganisms of public health significance under § 112.2(b).

(Comment 58) Some comments ask whether “produce” includes food grains, algae, dry legumes, and food crops used in the production of spices, dietary ingredients, or food additives. Some comments express diverse views and disagree on whether oilseeds (such as sunflower seeds) should be considered “covered produce”.

(Response) As explained in the 2013 proposed rule, for the purposes of part 112, the definition of “produce” does not include food grains. We explicitly excluded grains from our proposed definition of produce, which stated, “Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.” We are aware that there are some commodities, such as sunflower and flax seeds, soybeans, black-eyed peas, and chickpeas, that are both processed for use in other forms (such as oil or flour) and consumed directly as small hard fruits or seeds. For example, sunflower seeds can be processed into oil or consumed directly as sunflower seeds. When used for direct consumption as hard fruits or seeds, these commodities typically receive some commercial processing that adequately reduces pathogens, such as roasting, before they are consumed and, therefore, these commodities are not likely to present the hazards or the level of risk that warrants applying the standards of this rule even though they may have some uses other than as grains. We are revising the grains definition to clarify that such

commodities are grains if they are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption. In response to comments, and to provide clarity, we are revising the definition of “produce” to include “oilseeds” generally as an example, and to provide flaxseed, rapeseed, and sunflower seed as additional examples of grains. We are also replacing the term “fresh consumption” in this portion of the definition with “direct consumption as small, hard fruits or seeds” for clarity. As revised, this part of the definition states, “Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).”

As defined, the term “produce” includes fruits (the harvestable or harvested part of a plant developed from a flower) and vegetables (harvested part of any plant or fungus), which by definition does not include algae. Algae are organisms that were at one time classified as plants due to having chlorophyll and other pigments, but now, with the exception of blue-green algae (which are considered to be bacteria, of the kingdom Monera), are regarded as belonging in the kingdom Protista for possessing cellular features not found among plants and animals and for their lack of true stems, roots, and leaves (Ref. 64). Algae do not form a distinct phylogenetic group, but include widely varying green, brown, and red organisms that grow mostly in water, and can range in size from single cells to large spreading masses. Algae are a major component of marine plankton and can also be seen as pond scum or as blooms in tidal pools (Ref. 65). In addition, algae are not all closely related, and do not form a single evolutionary lineage devoid of other organisms, which makes classification challenging. As an example, the blue-green algae, also known as cyanobacteria, are generally considered to be bacteria (Ref. 66), but because blue-greens are aquatic and possess photosynthetic pigments like seaweeds, they are still called algae (Ref. 67). We

do not consider algae to be “produce” within the scope of this rule. However, algae that are used as “food” will continue to be covered under the FD&C Act and applicable implementing regulations. As appropriate, we may consider issuing guidance on the topic of algae production for human food use in the future.

Legumes are a group of commodities rather than a single commodity. For example, peanuts, beans (such as lima beans, white pea beans, and great Northern beans) and lentils (such as green lentils, yellow lentils, and brown lentils) are all legumes. Many legumes fall within our definition of “produce” but also meet the criteria for produce that is rarely consumed raw, and are therefore not subject to this rule under § 112.2(a)(1).

For example, as discussed in the 2013 proposed rule, we consider that peanuts fit within the definition of produce (78 FR 3504 at 3536). However, peanuts are rarely consumed raw and are therefore not subject to this rule under § 112.2(a)(1).

As another example, we consider beans to fit within the definition of produce. Beans are typically sold in both a “fresh” and a dried form and the drying in these cases creates a distinct commodity. The fresh beans are produce RACs (rather than processed foods) and are subject to this rule except where an exemption applies. Some types of fresh beans are not subject to this rule because they fit the criteria for produce that is rarely consumed raw, and are therefore exempt under § 112.2(a)(1) (e.g., black beans, great Northern beans, and kidney beans are exempt). Other types of fresh beans (for example, broad beans, cowpea beans, and pink beans) do not meet the criteria for rarely consumed raw and therefore are covered produce except where another exemption applies. We understand that many beans receive commercial processing that adequately reduces the presence of microorganisms of public health significance, such that in many cases, beans that are not exempt from this rule as rarely consumed raw may be eligible for the exemption in § 112.2(b). In addition, dried beans are distinct commodities from fresh beans and are therefore processed foods. Processed foods are not subject to this rule (see § 112.2(a)(3)), such that once beans subject to this rule are dried/dehydrated, they are no longer subject to this rule.

We also consider that lentils fit within the definition of produce. Lentils are the edible part of an herbaceous plant grown for an edible part, and are the harvestable or harvested part of the

plant. Lentils are “small, hard fruits or seeds of arable crops” (the first part of the definition of grains), but because they are not primarily grown and processed for use as “meal, flour, baked goods, cereals and oils” rather than for direct consumption (Ref. 68), they are not “grains” as we have defined that term, and therefore they are produce. However, lentils are rarely consumed raw and are therefore not subject to this rule under § 112.2(a)(1).

The definition of “produce” in § 112.3 and the provisions for produce that is not covered under this rule in § 112.2(a) apply regardless of whether that produce is used in other finished foods. Produce that is covered under this rule is eligible for exemption if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance (§ 112.2(b)). Produce that is used in the production of spices, ingredients of dietary supplements, or food additives, to the extent it is covered produce (*i.e.*, it is not excluded under § 112.2(a)), may be eligible for exemption under § 112.2(b) if it meets the criteria set forth in that section. Such produce is not exempt by virtue of its use in spices, dietary supplements, or food additives; such produce may be exempt only if it meets the criteria in § 112.2(b) (*i.e.*, it receives commercial processing that adequately reduces the presence of microorganisms of public health significance and the covered farm takes the required steps set forth in that section). As discussed previously, processed foods are not subject to this rule (see § 112.2(a)(3)), such that once produce RACs subject to this rule are made into processed foods, those processed foods are not subject to this rule.

(Comment 59) Some comments ask whether edible flowers that are consumed raw are considered “covered produce.”

(Response) Within the definition of produce, we define a “vegetable” as the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Edible flowers fit within our definition of “produce” and when reasonably expected to be directed to a food use, unless otherwise exempt under other provisions of subpart A,

they are covered produce subject to the requirements of this rule.

(Comment 60) One comment questions whether FDA intends to apply the rule to farms that export their produce to foreign countries.

(Response) Section 112.1(a) explains that the rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown domestically for export to foreign countries.

2. Produce That Is Covered and Not Covered (§ 112.2)

(Comment 61) One comment states that the proposed produce safety rule should apply to all fruit and vegetable commodities, and opposes all of the exemptions we proposed in § 112.2. This comment argues that people are consuming more fruits and vegetables to maintain a healthier diet, and thus all fruit and vegetables should be subject to the same preventive safety requirements.

(Response) We disagree. FSMA mandates that FDA set risk-based standards to ensure the safety of produce. In §§ 112.2(a)(1) and 112.2(b), we exempt, or make eligible for exemption, produce that pose little to no risk of foodborne illness, either because it is rarely consumed raw (§ 112.2(a)(1)) (see section IX.A.3 of this document) or because it receives commercial processing that adequately reduces the presence of pathogens (§ 112.2(b)). We conclude that it is not reasonably necessary to apply the requirements of the rule to such produce to minimize the risk of serious adverse health consequences or death or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. In addition, we exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management (§ 112.2(a)(2)), and produce that is not a raw agricultural commodity (§ 112.2(a)(3)). These exemptions are consistent with sections 419(g) and 419(a)(1)(A), respectively, of the FD&C Act. We note, however, that produce exempt from this rule under § 112.2 is and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether it is included within the scope of the produce safety regulation.

3. Produce That Is Exempt Because It Is Rarely Consumed Raw (§ 112.2(a)(1))

(Comment 62) Some comments oppose exempting produce commodities based on the produce being rarely consumed raw. One such comment argues that the public has an expectation that FDA will oversee and regulate all fruits and vegetables. This comment suggests that an appropriate approach would be to provide regulatory oversight combined with guidance documents addressing specific variability applicable to different fruits and vegetables, which in the view of this comment, would be similar to the seafood HACCP regulation. Other comments point out that rarely consumed raw produce may still cause food safety problems. One commenter explains that food safety begins with agricultural growing practices and continues through the supply chain to the consumer, and believes that exemption of produce rarely consumed raw would ignore the issue of potential cross-contamination at retail and during food preparation by consumers. Another commenter suggests that any produce exempt as rarely consumed raw should be required to undergo a processing step that adequately reduces the presence of microorganisms of public health concern.

(Response) As discussed in section IV.A.2.a of the 2013 proposed rule, we are exempting produce that is “rarely consumed raw” from the requirements of part 112 because such fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that can be expected to adequately reduce the presence of microorganisms of public health significance in most cases. Studies have shown that the numbers of microorganisms of public health significance (such as *L. monocytogenes*, *Salmonella*, STEC) are significantly reduced in produce by a variety of relatively moderate heat treatments (Ref. 69) (Ref. 70) (Ref. 71) (Ref. 72). Therefore, cooking that produce receives before it is consumed, whether commercially or by the consumer, can be expected to reduce the risk of serious adverse health consequences or death associated with commodities that are rarely consumed raw. As a result, FDA concludes it is not reasonably necessary to subject such commodities to requirements under this rule, or in the alternative to require such commodities to undergo a processing step to adequately reduce pathogens.

We are not aware of any information or scientific data suggesting that cross-contamination at retail or during food preparation in the home represent a

significant concern for any of the commodities that we are identifying as “rarely consumed raw” produce. The 2013 FDA Model Food Code includes provisions (e.g., 3–302.11) designed to protect food against cross-contamination in retail settings.

We also note that rarely consumed raw produce commodities that are exempt from this rule under § 112.2(a)(1) are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule.

(Comment 63) One commenter suggests revising the rarely consumed raw exemption so that it would be invalidated for a specific farm if that farm’s otherwise rarely consumed raw produce were marketed for fresh consumption.

(Response) We are not adopting this approach. The § 112.2(a)(1) exemption from the requirements of part 112 is based on our finding that commodities that are almost always consumed only after being cooked constitute very low to no risk with respect to biological hazards (see Ref. 29) and, therefore, it is not reasonably necessary to apply the standards established in part 112 to these commodities. This determination applies without regard to the manner in which such commodities may be marketed. Such commodities are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. Manufacturers and producers of food, including produce, for human consumption have the responsibility to ensure the safety of their food.

(Comment 64) Some comments, while not opposed to exempting certain produce commodities rarely consumed raw, disagree with FDA establishing an exhaustive list of such exempted produce. Multiple comments express a preference for guidance documents to indicate to industry which foods FDA considers to be rarely consumed raw and therefore exempt from the rule. These commenters argue that such an approach would be preferable because it would allow the exemption to reflect new data and changes in dietary habits without requiring FDA to conduct rulemaking to update an exhaustive list.

(Response) We considered and rejected the possibility of providing a list of rarely consumed raw commodities in guidance without establishing any specific criteria for

what “rarely consumed raw” means in the regulation, because such an approach would present significant challenges for compliance and enforcement. For example, such an approach would require covered farms to implement the standards in part 112 without FDA clearly identifying in the rule itself whether and which of the farm’s commodities would be subject to those standards. We also considered providing a list of rarely consumed raw commodities in guidance with accompanying underlying quantitative criteria listed in the regulation. We rejected this approach because it, too, would not be adequate for the purposes of clarity of coverage and could present challenges for compliance and enforcement. The complexity of the analysis (see Ref. 73) necessary to obtain consumption patterns that consistently and adequately represent consumption among consumers across the United States does not make this a viable approach. Therefore, we are adopting the proposed approach, in which we explicitly provide an exhaustive list of rarely consumed raw commodities within § 112.2(a)(1). However, we are revising our proposed list based on an analysis of more recent data and taking into account comments received. Moreover, we intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available.

Section 112.2(a)(1) provides an exhaustive list of produce that is rarely consumed raw and is, therefore, exempt from coverage under this rule. We conclude these commodities are predominantly eaten cooked by most consumers across the United States at this time. The identification of a commodity on this list does not mean that the produce is never eaten raw or that it is not eaten raw, typically or occasionally, in specific regions of the United States (or among specific ethnic communities in the United States). This list also does not reflect the form in which these commodities are consumed by populations in other countries, where the produce may be grown and/or from which the produce may be imported into the United States. Furthermore, our analysis underlying the development of this list reflects dietary intake information that consumers across the United States reported in a national survey. The most recent of these data that are currently available show consumption that was reported only as recently as 2010, but not consumption as it occurs today. Therefore, this list may not necessarily

reflect or fully reflect current or emerging patterns of forms in which produce is consumed or new dietary trends toward consumption of raw foods.

As revised, § 112.2(a)(1) lists the following produce as rarely consumed raw among United States consumers: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

For this final rule, we conducted an updated analysis of dietary consumption of produce in the United States to identify those produce RACs that we consider to be rarely consumed raw. We evaluated food consumption data available in the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) database, specifically the datasets available from the 2003–2010 NHANES/WWEIA surveys (Ref. 74). By comparison, in the 2013 proposed rule, we were using the datasets available from the 1999–2006 NHANES/WWEIA surveys (Ref. 75). In addition, in both this final rule and the 2013 proposed rule, we used the Food Commodity Intake Database (FCID) (Ref. 76), developed by the EPA’s Office of Pesticide Programs, to identify proportions of produce (as that terms is defined for purposes of this rule) present as ingredients in foods/food categories listed in the NHANES/WWEIA datasets. Moreover, where NHANES/WWEIA datasets provide the necessary data, we made additional modifications to our analysis compared to the analysis described in the 2013 proposed rule to provide a more robust evaluation of consumption in the United States. For example, in our updated analysis, we evaluated all produce commodities included in FCID as applied to the NHANES/WWEIA surveys rather than just a subset of the FCID commodities. In our updated analysis, we characterized each eating occasion based on meals and snacks reported by survey respondents (e.g., breakfast, brunch, lunch, dinner, supper, snacks) such that each snack is considered a separate eating occasion. In our updated analysis, we also considered consumption based on both one-day dietary intakes and 2-day dietary intakes reported by survey

respondents in the NHANES/WWEIA datasets.

In addition, we added a third element to the set of criteria we applied to determine whether a commodity is rarely consumed raw. In the 2013 proposed rule, we applied two criteria, *i.e.*, the commodity is consumed uncooked by less than 0.1 percent of population and it is consumed uncooked on less than 0.1 percent of eating occasions. As mentioned above, we considered these two criteria together, and for the final analysis we considered that these two criteria were satisfied for a commodity if either the 1-day dietary intake data, the 2-day dietary intake data, or both met both criteria. For the final analysis, we also added a third criterion, *i.e.*, we identified those commodities for which consumption (in any form—raw, processed, or other) was reported by at least 1 percent of weighted number of survey respondents. We added this threshold in response to comments and anecdotal evidence suggesting that our proposed criteria were not sufficiently robust because they resulted in exemptions for several commodities that seem likely to be consumed raw with significant frequency. For example, kale, which we proposed to exempt, was identified by many commenters as being regularly consumed raw. This is reflected in the inclusion of raw kale in popular restaurant dishes (Ref. 77) (Ref. 78) (Ref. 79); recipes from nationally-recognized chefs (Ref. 80) (Ref. 81); and reports in public media (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85) (Ref. 86) (Ref. 87). To improve the robustness of our analysis and to ensure that our conclusions that commodities are rarely consumed raw are sufficiently reliable to justify removing those commodities from the rule’s coverage, we concluded that we should add another criterion to the analysis. We concluded that where fewer than 1 percent of the weighted number of survey respondents reported consuming the commodity in any form, we did not have sufficient data to

provide a reasonable representation of how the commodity is consumed in the U.S. for the purposes of exempting commodities from the coverage of this rule. Thus, in addition to meeting the criteria we originally proposed, at least 1 percent of the weighted number of survey respondents over the eight year timespan of the NHANES/WWEIA surveys must have reported consuming the commodity (all forms, taken together, excluding juice/juice drinks) for us to conclude that the commodity is rarely consumed raw and should therefore be exempt from this rule. Accordingly, for all commodities meeting the first two criteria, we also analyzed whether the commodity’s 2-day consumption number “N” was equal to or greater than 2,938,915 ($293,891,529 \times 0.01$), whether its 1-day consumption number “N” was equal to or greater than 2,938,517 ($293,851,741 \times 0.01$), or both. Our analysis is described in greater detail in an accompanying memo to the record (Ref. 73).

Based on our analysis of the NHANES/WWEIA datasets, we identified a list of produce commodities that we consider to be rarely consumed raw, applying the revised criteria. First, there are the commodities for which quantitative data about uncooked consumption is available and that meet three numerical thresholds either in the one-day reported intakes, 2-day reported intakes, or both, based on FCID analyses of NHANES/WWEIA datasets, *i.e.*, at least 1 percent of weighted number of survey respondents having reported consuming the commodity in any form; commodities consumed uncooked by less than 0.1 percent of the United States population; and commodities consumed uncooked on less than 0.1 percent of eating occasions. See column 1 of Table 5.

Second, there are commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the NHANES/WWEIA surveys do not include an “uncooked” food form. We conclude that such commodities may also be reasonably

considered to fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions because lack of an “uncooked” reported food form indicates that they were not consumed uncooked in any measurable quantity. To such commodities, we applied the new numerical threshold, *i.e.*, at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers. See column 2 of Table 5.

Third, the consumption of certain produce RACs is reported in the NHANES/WWEIA not as RACs, but only in the form of certain processed foods. For example, coffee beans are only reported consumed in beverage form as coffee; and cocoa beans are only reported consumed as cocoa beverage, chocolate beverage, chocolate, or related products. We conclude that these commodities are rarely consumed raw when the only forms in which they are reported in the NHANES/WWEIA surveys indicates they were cooked as part of the process of being made into the identified processed foods, and therefore we infer that they fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions because they were not consumed uncooked in any measurable quantity. To such commodities, we applied the new numerical threshold, *i.e.*, at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers. We are therefore adding them to the list of rarely consumed raw produce in § 112.2(a)(1). See column 3 of Table 5.

TABLE 5—LIST OF PRODUCE THAT ARE RARELY CONSUMED RAW IN THE UNITED STATES

[Based on an analysis of the National Health and Nutrition Examination Survey/What We Eat in America Survey Datasets Using the Food Commodity Intake Database]

“Complete data” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; less than 0.1% of population consumed uncooked; AND on less than 0.1% of eating occasions, using either 1-day or 2-day survey	“No uncooked code” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and no uncooked code reported in NHANES, using either 1-day or 2-day survey	“Processed food” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and reported consumed only in processed food form with cook step using either 1-day or 2-day survey
Asparagus	Beans, black	Coffee beans.
Beans, lima	Beans, great Northern	Cocoa beans.
Beets, garden (roots and tops)	Beans, kidney	
Beets, sugar	Beans, navy	

TABLE 5—LIST OF PRODUCE THAT ARE RARELY CONSUMED RAW IN THE UNITED STATES—Continued

[Based on an analysis of the National Health and Nutrition Examination Survey/What We Eat in America Survey Datasets Using the Food Commodity Intake Database]

“Complete data” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; less than 0.1% of population consumed uncooked; AND on less than 0.1% of eating occasions, using either 1-day or 2-day survey	“No uncooked code” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and no uncooked code reported in NHANES, using either 1-day or 2-day survey	“Processed food” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and reported consumed only in processed food form with cook step using either 1-day or 2-day survey
Cherries, sour Chickpeas Collards Corn, sweet Cranberries Dates Dill (seeds and weed) Eggplants Figs Ginger..... Horseradish..... Pecans..... Potatoes..... Pumpkins..... Water chestnuts.....	Beans, pinto Cashews Hazelnuts Lentils Okra Peanuts Peppermint Squash, winter Sweet potatoes	

Table 6 shows a comparison of proposed to final rarely consumed raw commodities.

TABLE 6—COMPARISON OF PROPOSED TO FINAL LIST OF RARELY CONSUMED RAW COMMODITIES IDENTIFIED IN § 112.2(A)(1)

[All analyses combined, alphabetical by commodity]

Proposed	Final
Arrowhead ¹ ; Arrowroot ¹ ; Artichokes ¹ ; Asparagus; Beets; Black-eyed peas ¹ ; Brussels sprouts ¹ ; Bok choy ¹ ; Chick-peas; Collards; Crabapples ¹ ; Cranberries; Eggplant; Figs; Ginger root; Kale ¹ ; Kidney beans; Lentils; Lima beans; Okra; Parsnips ¹ ; Peanuts; Pinto beans; Plantains ¹ ; Potatoes; Pumpkin; Rhubarb ¹ ; Rutabaga ¹ ; Sugarbeet; Sweet corn; Sweet potatoes; Taro ¹ ; Turnips ¹ ; Water chestnut; Winter squash; Yams ¹ .	Asparagus; Beans, black ² ; Beans, great Northern ² ; Beans, kidney; Beans, lima; Beans, navy ² ; Beans, pinto; Beets, garden (roots and tops); Beets, sugar; Cashews ² ; Cherries, sour ² ; Chickpeas; Cocoa beans ² ; Coffee beans ² ; Collards; Corn, sweet; Cranberries; Dates ² ; Dill (seeds and weed) ² ; Eggplants; Figs; Ginger; Hazelnuts ² ; Horseradish ² ; Lentils; Okra; Peanuts; Pecans ² ; Peppermint ² ; Potatoes; Pumpkins; Squash, winter; Sweet potatoes; Water chestnuts.

¹ Removed from list in final rule.
² Added to list in final rule.

Table 7 shows changes in the nomenclature for rarely consumed raw commodities in proposed § 112.2(a)(1) to final § 112.2(a)(1).

TABLE 7—CHANGES IN COMMODITY NOMENCLATURE FROM PROPOSED TO FINAL LIST OF “RARELY CONSUMED RAW” COMMODITIES

Commodity name in proposed list	Commodity name in final list
Beets	Beets, garden (roots and tops).
Chick-peas	Chickpeas.
Ginger root	Ginger.
Kidney beans	Beans, kidney.
Lima beans	Beans, lima.
Pinto beans	Beans, pinto.
Sugarbeet	Beets, sugar.
Sweet corn	Corn, sweet.
Winter squash	Squash, winter.

We acknowledge there are certain limitations to this analysis. Although the NHANES/WWEIA datasets are the most comprehensive and robust,

nationally-representative datasets currently available on dietary intakes in the United States, we recognize that they do not cover all commodities and

that the data are incomplete or limited in certain cases, as discussed previously. In addition, we agree with several commenters who point out that

dietary consumption patterns can change over time such that produce not currently consumed raw may be consumed raw (and reported as “uncooked” based on FCID analyses of NHANES/WWEIA datasets) in the future, or vice versa. Nevertheless, we can only analyze consumption patterns using data that necessarily lags behind changes in consumption. While the data source we have has certain limitations, it is the best we could identify for this purpose. Moreover, we believe it is consistent with providing standards that minimize the risk of serious adverse health consequences or death to exempt from such standards as “rarely consumed raw” only those commodities for which we have robust, quantitative data from nationally representative data sources (such as NHANES/WWEIA and FCID) supporting a conclusion that the commodity is rarely consumed raw. We recognize that our current list of produce that is rarely consumed raw may need to be updated as new information becomes available.

As discussed previously, we also understand that the overall consumption rates of some produce in the United States are too low for the NHANES/WWEIA data to be useful to evaluate whether the produce is rarely consumed raw or even whether it is consumed in any form. In this final rule we are establishing a factor of weighted number of respondents of at least 1 percent of the total respondents to the eight year span of 2003–2010 NHANES/WWEIA surveys to apply as a threshold that provides a reasonable representation of the frequency with which a commodity is consumed by U.S. consumers. For foods that are reported consumed (in any form) by fewer than a weighted number of 2,938,915 respondents (for 2-day intakes) or 2,938,517 (for 1-day intakes), we consider the overall reported rate to be too low to justify relying on these data as a reasonable representation of consumption among U.S. consumers for purposes of this rule. Therefore, we consider that such commodities should be covered by the rule. For example, certain tropical fruits (such as guava, kumquat, and lychee) meet two of the three criteria (*i.e.*, consumed uncooked by less than 0.1 percent of the United States population *and* consumed uncooked on less than 0.1 percent of eating occasions) based on the NHANES/WWEIA datasets. However, these commodities are reported consumed by fewer than 1 percent weighted number of respondents, and we conclude that this is insufficient to provide a reasonable representation of

consumption across U.S. consumers for purposes of excluding such commodities from the coverage of this rule as rarely consumed raw. As another example, certain regional or ethnic foods that are not widely consumed by the United States population are not covered in the NHANES/WWEIA datasets and, therefore, we have no robust, nationally-representative data from which to determine whether or not such foods are typically consumed cooked among United States consumers. As a result, we are not exempting such commodities, but we intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available. We encourage stakeholders who have information about produce commodities not currently reported in NHANES/WWEIA datasets or included in FCID recipes, or reported consumed in any form by fewer than 1 percent weighted number of respondents in the NHANES/WWEIA surveys to identify relevant data for FDA’s review and evaluation. To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities across the United States to allow us to draw scientifically-valid conclusions.

(Comment 65) Some comments seek clarification regarding the meaning of “raw” and “uncooked” as those terms apply to proposed § 112.2(a)(1). One comment states that their interpretation of “raw” extends beyond cooking at the consumer level, and that although both consumer-level cooking and commercial processing can reduce pathogen populations, these are treated differently in the proposed regulation. The comment urges FDA to recognize the broad range of commercial practices that could similarly justify designating a food as rarely consumed raw. Other comments suggest that commodities treated with propylene oxide (PPO) to reduce levels of *Salmonella* and other vegetative pathogens should be exempt as rarely consumed raw. These comments state that, although such PPO-treated products are likely to be seen as “raw” by consumers, they undergo an appropriate pathogen reduction control step.

(Response) We are exempting produce that is “rarely consumed raw” from the requirements of part 112 in § 112.2(a)(1) because such fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that can be expected to adequately reduce the presence of microorganisms of public health significance in most cases. Our use of “produce that is rarely consumed raw”, therefore, is intended

to mean that such produce commodities are almost always eaten only after being cooked (*i.e.*, heat treated in some form). We do not distinguish between cooking conducted by a consumer or a food manufacturer.

The exemption provided for rarely consumed raw produce (in § 112.2(a)(1)) is separate and distinct from the eligibility for exemption provided for produce that receives commercial processing (in § 112.2(b)). Produce commodities exempt under § 112.2(a)(1) are almost always eaten only after being cooked and, therefore, the exemption applies generally for that commodity regardless of the method of preparation prior to consumption. For example, we consider that potatoes meet the criteria for rarely consumed raw and, although they may be consumed in different forms, they are almost always cooked prior to consumption. We also recognize that foods that are rarely consumed raw may be cooked in a home setting by the consumer or in a commercial setting by a food manufacturer/processor. In contrast, produce may be exempt, if eligible, under § 112.2(b), even if the commodity involved is not always consumed only after cooking. For example, tomatoes are frequently consumed raw, without any cooking, but also can be consumed after they receive commercial processing that adequately reduces pathogens, such as treating with a validated process (*e.g.*, as processing to produce tomato paste or shelf-stable tomatoes) to eliminate spoilage organisms and destroy vegetative pathogens (such as *Salmonella*, *L. monocytogenes*, and *E. coli* O157:H7). Tomatoes are eligible for exemption under § 112.2(b) only in the latter case (where the farm is required to take certain actions (see section IX.A.4 of this document), including establishing and keeping certain documentation), but not in the former case where the tomatoes do not receive such a commercial processing step. Therefore, it would not be appropriate to combine the exemptions in § 112.2(a)(1) and (b) into a single general exemption. We note that produce that receives a PPO treatment may be eligible for the exemption in § 112.2(b) if all relevant conditions are met, including that the treatment adequately reduces the presence of microorganisms of public health significance.

We recognize, however, that a produce commodity that is generally exempt from this part because it is rarely consumed raw may, in some cases, also receive commercial processing that adequately reduces the presence of microorganisms of public health significance. However, because

such commodity is already exempt under § 112.2(a)(1), we would not consider the commodity under the provision in § 112.2(b)(1) or expect the farm to take the steps required under § 112.2(b)(2).

4. Produce That Is Eligible for Exemption Based on Receipt of Commercial Processing That Adequately Reduces Pathogens (§ 112.2(b))

(Comment 66) Some comments that are generally supportive of the exemption for produce that undergoes commercial processing that adequately reduces pathogens state that it is essential to ensure that such produce does not then re-enter the fresh produce supply chain if it does not eventually receive the required processing. One comment expresses concern about the exemption and states that diversion of “processing grown” cannery, Roma, or plum tomatoes is a common practice. This comment states that there are numerous instances where tomatoes grown for commercial processing that would adequately reduce pathogens were shipped to Mexico, relabeled for sale as RACs in the fresh produce market, and then shipped back into the United States as RACs. One comment states the documentation requirements described under proposed § 112.2(b) would not be practicable for some farms. According to this comment, for example, wine grapes delivered to a winery are generally made into wine, but the farm will usually not be privy to the specific production processes that the crop undergoes nor who performs them. The comment further notes that wine grapes delivered to a winery may be crushed and converted to grape must at the first facility, and then transferred to another winery for fermentation and additional processing, without any knowledge by the farm.

(Response) The exemption in § 112.2(b) applies to produce that receives commercial processing that adequately reduces the presence of pathogens. Thus, the exemption is only available to produce that is actually processed in a manner that adequately reduces pathogens. The failure to comply with the requirements of part 112 is a prohibited act under section 301(vv) of the FD&C Act, as set forth in § 112.192, for which FDA may take appropriate action. Therefore, it is important that covered farms that rely on the exemption in § 112.2(b) ensure that the relevant produce meets the exemption criteria and take the steps required in revised § 112.2(b).

We are adding certain examples to this paragraph to make clear that such commercial processing includes

processing produce into products in which the nature of the product or its production process as a whole, rather than a single “kill step,” adequately reduces the presence of pathogens. We are adding as examples of commercial processing that adequately reduces the presence of microorganisms of public health concern “otherwise manufacturing/processing produce into products such as . . . wine, beer, or similar products.” Winemaking and brewing beer adequately reduce the presence of microorganisms of public health significance (Ref. 88).

Fresh-cut processing does not qualify as commercial processing that adequately reduces the presence of pathogens for the purposes of the exemption in § 112.2(b). As described in FDA’s Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (Ref. 89), processing produce into fresh-cut products can increase the risk of bacterial growth and contamination. Adding antimicrobial substances to produce wash water at a fresh-cut manufacturing/processing facility can reduce the likelihood of produce contamination, including for example to help prevent the cross-contamination of surrounding produce with any pathogens that may be introduced into the wash water from a single fruit or vegetable. However, washing does not adequately reduce the presence of pathogens (see also our response to Comment 334). FDA’s Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (Ref. 89) clearly identifies the need for use of both good agricultural practices and good manufacturing practices to prevent or minimize microbial hazards in fresh-cut produce.

In light of the comments about farms’ limited knowledge of the specific production processes that their crop undergoes at later stages of the supply chain and the entities performing such processes; and in light of our approach to similar issues in the PCHF regulation, we have revised the conditions of this exemption. The revised requirements are more practicable for farms with respect to their limited knowledge of the entities and processes involved in the distribution chain subsequent to the farm’s own customer. The revised requirements are also consistent with similar requirements in §§ 117.136 and 117.137 of the PCHF regulation, and in § 1.507 of the FSVP regulation, which allow facilities and importers, respectively, to rely on customers and subsequent entities in the distribution chain to control hazards under certain circumstances.

Under the first of the new provisions (§ 112.2(b)(2)), you must disclose in documents accompanying the produce that the food is not processed to adequately reduce the presence of microorganisms of public health significance. The documents that accompany the produce could be bills of lading or other papers that accompany the produce, or the containers may be labeled with this information. Under the next of the new provisions, (§ 112.2(b)(3)), you must annually obtain certain written assurances from your customer with respect to the produce for which you rely on this exemption. This may be an assurance from the customer that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance (§ 112.2(b)(3)(i)), or it may be an assurance from the customer that an entity after the customer in the distribution chain will perform such processing (§ 112.2(b)(3)(ii)). In the latter case, the customer’s written assurance must also affirm that the customer will disclose in documents accompanying the food that the food is not processed to adequately reduce the presence of microorganisms of public health significance and that the customer will only sell to another entity that agrees, in writing, that it will either: (1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance or (2) obtain a similar written assurance from its customer that the produce will receive the required commercial processing and that there will be disclosure in documents accompanying the food that it is not processed to adequately reduce microorganisms of public health significance. Under § 112.2(b)(4), we are requiring you to keep documentation of the disclosures required under § 112.2(b)(2), and the annual written assurances obtained from customers required under § 112.2(b)(3). This replaces the requirement in the 2013 proposed rule that you keep documentation of the identity of the recipient of the produce that performs the commercial processing, as we recognize that a farm may not have knowledge of the identity of the entity performing such processing. We are finalizing the requirement in § 112.2(b)(5) (proposed as § 112.2(b)(3)) that the requirements of this subpart and subpart Q apply to produce exempt under this section, without change.

In addition, while we are not requiring specific language for the

written assurances described in § 112.2(b)(3), we are specifying in § 112.2(b)(6) that the entities that provide them must act consistently with the assurances and document the actions taken to satisfy the assurance. Section 112.2(b)(6) applies not just to covered farms, but to other entities that voluntarily agree to provide the written assurances described in § 112.2(b)(3). The application of this requirement to facilities subject to the section 418 of the FD&C Act is consistent with section 419(h) of the FD&C Act. Providing, complying with, and documenting compliance with the written assurances described in § 112.2(b)(3) are not activities that are subject to section 418 of the FD&C Act. We believe the combination of the written assurance, the disclosure in accompanying documents that the food is not processed to adequately reduce microorganisms of public health significance, and the requirements to act consistently with the written assurance will provide a reasonable level of protection to ensure that produce that is exempt from the requirements of part § 112 under this section actually receives the required commercial processing and will not be diverted to the fresh produce market.

(Comment 67) One comment recommends that frozen vegetables should be eligible for exemption under § 112.2(b) because, according to this commenter, most commercially frozen vegetables are blanched before freezing and are subsequently not intended to be eaten raw. This commenter also states that blanching involves temperatures from 140 °F to 180 °F for one or more minutes, and effectively eliminates harmful bacteria. In addition, the commenter believes that a frozen or previously frozen, thawed vegetable is typically not desirable for raw consumption and is rarely consumed raw.

(Response) Produce, including vegetables, that receive commercial processing that adequately reduces the presence of pathogens is eligible for exemption under § 112.2(b) if all of the conditions in that section are met. Blanching and/or freezing processes may qualify if they are validated to ensure that the specific procedures followed adequately reduce pathogens in the food. Whether frozen or thawed vegetables are typically consumed raw is not relevant to the analysis.

5. Specific Produce Commodities and §§ 112.2(a) and 112.2(b)

(Comment 68) Several comments request that we consider or reconsider our treatment of certain commodities as

covered produce or rarely consumed raw (and therefore not covered produce), where such commodities are those for which data about uncooked consumption is available. Some comments request removing the following commodities from the list of rarely consumed raw produce so that they would be covered produce, stating that such commodities are regularly consumed raw: asparagus, beets (including, specifically, beet greens), bok choy, Brussels sprouts, collard greens, figs, ginger root, rhubarb, sweet corn, turnips (roots and greens), and water chestnuts. Some comments specifically asked FDA to finalize its tentative conclusion that bean sprouts are covered produce and are not exempt as rarely consumed raw produce. On the other hand, some comments request exempting the following commodities as rarely consumed raw that were not in FDA's proposed list: almonds, burdock roots, olives, pecans, pistachios, soybean beans, sunflower seeds, walnuts, and yuca.

(Response) NHANES/WWEIA data are available with respect to uncooked consumption of each of these commodities. Based on the analysis described previously (see our response to Comment 64), asparagus, beets (garden (roots and tops)), beet (sugar), collards, figs, ginger, sweet corn, and water chestnuts are reported consumed (all forms, taken together) by more than 1 percent weighted number of survey respondents, and consumed uncooked by less than 0.1 percent of the United States population, and consumed uncooked on less than 0.1 percent of eating occasions (Ref. 73). Therefore, despite commenters' suggestions that these commodities might not meet the criteria for rarely consumed raw, they are in fact rarely consumed raw per our established criteria (see column 1 of Table 5) and they are therefore included in the list in § 112.2(a)(1).

On the other hand, bok choy, Brussels sprouts, rhubarb, and turnip, all of which we had proposed as rarely consumed raw commodities are now shown, using the more recent NHANES/WWEIA data and applying our revised criteria for rarely consumed raw, not to satisfy our criteria for rarely consumed raw produce (Ref. 73).

Bok choy does not meet our revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form. Therefore, we are removing bok choy from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, bok choy is covered produce subject to

the requirements of part 112 as applicable.

For Brussels sprouts, in the 2013 proposed rule, we based our tentative conclusion that they are rarely consumed raw on the lack of an uncooked code reported in the 1999–2006 NHANES/WWEIA dataset. (We note that we incorrectly described our categorization of this commodity in the 2013 proposed rule in a way that did not affect the ultimate result, but did affect the reason given for that result (Ref. 73)). In contrast, the current NHANES/WWEIA datasets provide quantitative information about uncooked consumption of Brussels sprouts, which shows that they do not meet the revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form. Therefore, we are removing Brussels sprouts from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, Brussels sprouts are covered produce subject to the requirements of part 112 as applicable.

We did not propose to exempt sprouts as rarely consumed raw and we are not changing this conclusion. Alfalfa sprouts do not meet the first two criteria for rarely consumed raw. Mung bean sprouts also do not meet the first two criteria for rarely consumed raw. Soybean sprouts meet the first two criteria for rarely consumed raw but do not meet the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Sprouts are covered produce subject to the requirements of part 112 as applicable, including those in subpart M.

With respect to requests to add new commodities for which uncooked consumption data are available to the rarely consumed raw list, we analyzed the data and agree that pecans meet the revised criteria for rarely consumed raw (see Table 5) (Ref. 73). Therefore, we have added pecans to the list in § 112.2(a)(1).

On the other hand, almonds, olives, pistachios, walnuts, and yuca (cassava) do not meet the first two criteria for rarely consumed raw (Ref. 73). Burdock meets the first two criteria for rarely consumed raw but does not meet the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Therefore, these commodities are not included in the list of rarely consumed raw commodities in § 112.2(a)(1) and, instead, are covered produce subject to

the requirements of part 112 as applicable. (Note that we consider oilseeds, such as soybeans and sunflower seeds, to be grains and therefore not “produce” (see our response to Comment 58).

Note that our analysis of beets (garden), dasheen (or taro), turnips, and chicory accounts for both roots and greens, collectively, of each commodity. Similarly, our analysis for dill accounts for both seeds (dill seed) and greens (dillweed) (Ref. 73). Although for each of these commodities, NHANES/WWEIA includes separate reported entries for “roots” and “tops” (and for dill, NHANES/WWEIA includes separate entries for “dill seed” and “dillweed”), for purposes of determining coverage under this rule, we find it appropriate to analyze consumption collectively to account for the entire harvested or harvestable portion of the plant. Based on our analysis using the combined data for roots and tops for each of these commodities, we conclude that beets (garden (roots and tops)) and dill (seeds and weed) are rarely consumed raw (see column 1 of Table 5). Therefore, beets (garden) and dill listed under § 112.2(a)(1) specify “root and tops” and “seeds and weed”, respectively. Conversely, dasheen (corm and leaves), chicory (roots and tops), and turnip (roots and tops) do not meet our criteria for rarely consumed raw. Regarding dasheen (or taro), we had proposed to exempt “taro” as rarely consumed raw in the 2013 proposed rule. However, based on the current NHANES/WWEIA datasets, dasheen (corm and leaves) does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion. Similarly, we had proposed to exempt turnip as rarely consumed raw in the 2013 proposed rule. However, based on the current NHANES/WWEIA datasets, turnip (roots and greens) does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion. Therefore, we are removing “taro” and “turnip” from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, both dasheen (corm and leaves) and turnip (roots and greens) are covered produce subject to the requirements of part 112 as applicable.

In addition, two other commodities (*i.e.*, artichokes and plantains) that we had proposed to exempt as rarely consumed raw produce (based on previously available uncooked consumption data) are now not on our final list in § 112.2(a)(1) because less

than 1 percent weighted number of survey respondents report consumption of these commodities in any form and therefore they do not meet our revised criteria for rarely consumed raw (Ref. 73). Artichoke is reported in the current NHANES/WWEIA datasets under two separate entries: Artichoke, Jerusalem, for which there is quantitative information on uncooked consumption, and Artichoke, globe for which there is no “uncooked” consumption code. Neither Artichoke, Jerusalem nor Artichoke, globe meets our revised criteria for rarely consumed raw in that although both meet the first two criteria, they do not meet the third criterion. Likewise, plantain, for which there is quantitative information on uncooked consumption, does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion (Ref. 73). (See also Comment 69 for other commodities for which there is no reported “uncooked” consumption code that we proposed to exempt as rarely consumed raw but that are not on our final rarely consumed raw list).

(Comment 69) Several comments request that we consider or reconsider our treatment of certain commodities as covered produce or rarely consumed raw (and therefore not covered produce), where such commodities are those reported in NHANES/WWEIA data but for which there is no “uncooked” consumption category reported. Several comments argue that kale, which was on the proposed list of rarely consumed raw produce, has greatly grown in popularity and is often consumed raw. These comments provide various types of evidence that kale is frequently consumed raw by United States consumers, and recommend removing kale from the list of rarely consumed raw produce such that it would be “covered produce” subject to the requirements of part 112. Some comments also suggested removing parsnips from the list of rarely consumed raw produce for similar reasons. On the other hand, some comments request exempting brazil nuts, breadfruit, cashews, chestnuts, hazelnuts, macadamia nuts, palm heart leaves (palm heart, palmito, chonta, or jebato), peppermint (mint), pigeon peas, and pine nuts as rarely consumed raw. Finally, some comments ask that FDA finalize its conclusion that peanuts are rarely consumed raw without change.

(Response) As discussed previously (under Comment 64), we have concluded that commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the NHANES/WWEIA

surveys do not include “uncooked” can be reasonably considered to fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population *and* consumed uncooked on less than 0.1 percent of eating occasions because lack of an “uncooked” reported food form indicates that they were not consumed uncooked in any measurable quantity by most consumers across the United States. To such commodities, we applied the new numerical threshold of weighted number of survey respondents of at least 1 percent of the total number of survey respondents having reported consumption of the commodity in any form.

Brazil nuts, breadfruit, cashews, chestnuts, hazelnuts, kale, macadamia nuts, palm heart leaves, parsnips, peanuts, peppermint, pigeon peas, and pine nuts are all commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the NHANES/WWEIA surveys do not include “uncooked.” We find brazil nuts, breadfruit, chestnut, kale, macadamia nuts, palm heart leaves, parsnips, pigeon peas, and pine nuts do not meet our revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). In contrast, cashews, hazelnuts, peanuts, and peppermint meet the revised criteria for rarely consumed raw in that more than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73).

Therefore, we conclude that brazil nuts, breadfruit, chestnuts, kale, macadamia nuts, palm heart leaves, parsnips, pigeon peas, and pine nuts do not meet the criteria for rarely consumed raw and we do not include them in the list in § 112.2(a)(1). Instead, these commodities are covered produce subject to the requirements of part 112 as applicable. We also conclude that cashews, hazelnuts, peanuts, and peppermint are rarely consumed raw and, therefore, we include them in the list in § 112.2(a)(1). See column 2 of Table 5. (We note that hazelnuts have been associated with one outbreak in 2010–2011 (Ref. 28); however, hazelnuts meet our criteria for rarely consumed raw, which are based on consumption of produce commodities by U.S. consumers as indicated by NHANES/WWEIA surveys, as described in response to Comment 64. While hazelnuts are exempt from this rule under § 112.2(a)(1), we note that the FD&C Act still applies to the production of hazelnuts.)

In addition, five other commodities that we proposed to exempt as rarely consumed raw based on lack of uncooked code reported in the previous NHANES/WWEIA dataset are now not on our final list in § 112.2(a)(1). Black-eyed pea (or cowpea bean) does not meet the revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Crabapple is not a survey item in the current NHANES/WWEIA datasets, so we have no current data to which the revised criteria for rarely consumed raw may be applied for this commodity. Rhubarb, rutabaga, and yam also do not meet our revised criteria for rarely consumed raw in that less than less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). Therefore, we are removing black-eyed pea, crabapple, rhubarb, rutabaga, and yam from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, these commodities are covered produce subject to the requirements of part 112 as applicable. We intend to review the status of these commodities upon availability of updated dietary consumption information, including data obtained from NHANES/WWEIA 2015–2016 surveys. We encourage stakeholders who may have data or information relevant to this analysis to consult with us. (See also Comment 68 for other commodities for which there is quantitative information on uncooked consumption that we proposed to exempt as rarely consumed raw but that are not on our final rarely consumed raw list).

(Comment 70) Some comments requested exemption of coffee beans and hops as rarely consumed raw because they are typically consumed in beverage form as coffee and beer, respectively.

(Response) As discussed previously (under Comment 64), we are adding coffee beans to the list of exempt commodities in § 112.2(a)(1). The consumption of coffee beans is reported in the NHANES/WWEIA only in roasted form as the beverage, coffee. Similarly, the consumption of cocoa beans is only reported as cocoa beverage, chocolate beverage, chocolate, or related products. We conclude that these commodities are rarely consumed raw because the only forms in which they are reported in the NHANES/WWEIA surveys indicates they were cooked as part of the process of being made into the identified processed foods (such that we infer that they were not consumed uncooked in any measurable quantity), and they satisfy the new numerical threshold

(i.e., at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers). We are therefore adding them to the list of rarely consumed raw produce in § 112.2(a)(1) (see column 3 of Table 5). On the other hand, while the consumption of hops is reported in the NHANES/WWEIA only in beverage form as beer, we cannot conclude that this indicates that hops were cooked as part of the process of being made into beer. We are aware that hops are regularly added to beer after all cook steps are completed in a process known as “dry hopping” (Ref. 90). Therefore it would not be reasonable to infer on this basis that hops were not consumed uncooked in any measurable quantity by most consumers across the United States, and we are not adding hops to the list of rarely consumed raw produce. Instead, hops are covered produce subject to the requirements of part 112 as applicable. However, we note that hops used in the making of beer will be eligible for exemption from the requirements of part 112 under the provisions of § 112.2(b)(1), provided the covered farm establishes and maintains documentation in accordance with § 112.2(b)(2). Brewing beer adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (Ref. 88). We are adding this to our list of examples of products of commercial processing in § 112.2(b)(1).

(Comment 71) Some comments request exempting the following commodities that are not covered in the NHANES/WWEIA datasets as rarely consumed raw: ackee, aronia, atemoya, butterbur, chipilin, dragon fruit, fiddleheads, ginkgo nut, komatsuna, longan, loroco, pomelo, ramp, tamarillo, ti plant, and ulluko (melloco). We also received comments asking about the status of lotus root and swamp cabbage.

(Response) As discussed previously (under Comment 64), where a commodity is not included in the NHANES/WWEIA data at all, we have no robust, nationally-representative data from which to determine whether or not such foods are typically consumed cooked among United States consumers, and commenters did not provide any such information. As a result, we are not exempting ackee, aronia, atemoya, butterbur, chipilin, dragon fruit, fiddleheads, ginkgo nut, komatsuna, longan, loroco, pomelo, ramp, tamarillo, ti plant, or ulluko (melloco) (Ref. 73). Instead, they are covered produce

subject to the requirements of part 112 as applicable.

While lotus root and swamp cabbage are reported in NHANES, they are reported only in cooked forms, and there are no data from which their raw consumption may be analyzed. However, neither commodity satisfies the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73).

Two other commodities that we proposed, in the 2013 proposed rule, to exempt as rarely consumed raw based on non-NHANES data and other references are arrowhead and arrowroot. Neither of these commodities is reported in the current NHANES/WWEIA datasets, and we have no data to which the revised criteria for rarely consumed raw may be applied for these commodities. Therefore, we are removing arrowhead and arrowroot from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, arrowhead and arrowroot are covered produce subject to the requirements of part 112 as applicable.

We intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available. We encourage stakeholders who have information relevant to consumption of these produce commodities to identify relevant data for FDA’s review and evaluation. To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities by consumers across the United States to allow us to draw scientifically valid conclusions.

(Comment 72) One comment argues that, although tree fruits and berries are frequently consumed raw, they should nevertheless be added to the list of “rarely consumed raw” as being “low-risk” because, according to the comment, as long as ground irrigation is used there is no scientific evidence that *E. coli* or other bacterial contamination can be carried through the roots to the fruit, which the comment contrasts with lettuce and other leafy green vegetables. The comment adds that all consumers should be aware of the need to wash produce before consumption to prevent foodborne illnesses.

(Response) Our criteria for determining which produce commodities are rarely consumed raw relate only to the frequency with which produce commodities are consumed uncooked and not to commodity characteristics, agricultural practices, or other consumer practices (such as washing) as suggested by the comment.

We do not agree that either tree fruits generally or berries generally should be considered to be exempt as rarely consumed raw for the reasons suggested by the comment. In section IV of this document, we address our integrated approach and how it reflects relevant differences across commodities, such as the use of agricultural practices presenting varying levels of risk.

(Comment 73) Several comments urge FDA to exempt wine grapes as rarely consumed raw. These comments state that wine grapes are not grown or selected for raw consumption, but rather are selected for properties that make good wine. According to these comments, winemakers select specific grape varieties based on skin, color, and texture, among other things, and virtually all wine grapes are grown, harvested, and then delivered for processing at a winery rather than sold into the fresh market. These comments state that wine grapes are substantially different from grape cultivars selected for fresh consumption in that wine grapes usually have seeds, and have thick skins and high sugar content. These comments also cite wine's inherent anti-microbial properties and a lack of evidence of microbial illness resulting from either wine grapes or wine, to argue that wine grapes should be exempt from the standards established under this rule under proposed § 112.2(b) for produce that receives commercial processing that adequately reduces pathogens.

(Response) Based on the data available to us, we do not agree that wine grapes meet the criteria for rarely consumed raw. Uncooked consumption data are available for “grapes, wine and sherry” in the 2003–2010 NHANES/WWEIA datasets, and our analysis shows that “grapes, wine and sherry” do not meet the first two criteria for rarely consumed raw (Ref. 73). Although this category (“grapes, wine and sherry”) includes grapes used in the making of both wine and sherry, we consider the NHANES/WWEIA data to be the best data available for this purpose, and using this data it appears that “wine grapes” do not meet the criteria for rarely consumed raw. We do not have information on the specific grape cultivars or varieties that are solely and exclusively grown for use in winemaking that would allow us to establish a category covering only “wine grapes” and evaluate their eligibility using currently available dietary consumption data. In addition, according to the National Grape Registry (Ref. 91), many *Vitis vinifera* cultivars are multi-purpose in use. For example, the Malvasia Bianca grape cultivar can

be used as a wine grape or a table grape, and the Muscat of Alexandria grape cultivar can be used to make wine or raisins, or as a table grape. For these reasons, FDA concludes that “wine grapes” are not rarely consumed raw, and we do not include them in § 112.2(a)(1). Instead, wine grapes are covered produce subject to the requirements of part 112 as applicable.

However, we note that grapes used in the making of wine are eligible for exemption from the requirements of part 112 under the provisions of § 112.2(b)(1), provided the covered farm takes the required steps in accordance with § 112.2(b). Winemaking adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (Ref. 88). We are adding this to our list of examples of products of commercial processing in § 112.2(b)(1).

B. Definitions Other Than Small Business, Very Small Business, and Produce (§ 112.3(c))

In the 2013 proposed rule, under proposed § 112.3(c), we proposed to establish the various definitions that would apply for the purposes of part 112 (78 FR 3504 at 3539–3549). In addition, in the supplemental notice, taking into account public comment, we proposed to amend our originally proposed definitions of “covered activity,” “farm,” “harvesting,” “holding,” and “packing” in proposed § 112.3(c) (79 FR 58434 at 58438–58440). In both the 2013 proposed rule and in the supplemental notice, we asked for public comment on our proposed definitions.

In this section of this document we discuss comments that we received on the definitions proposed in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the amended proposed definitions in the supplemental notice.

Several comments received in response to the amended proposed definitions of “farm,” “harvesting,” “packing,” and “holding” in the supplemental notice are also the same comments we received in response to those amended proposed definitions in the supplemental human preventive controls notice. Because we already considered and discussed these comments in the final human preventive controls rule that established revised definitions for “farm,” “manufacturing/processing,” “harvesting,” “packing,” and “holding” in § 1.227 (Ref. 11), and because we are adopting definitions of these terms in

this rule that are the same as the definitions established in the final human preventive controls rule, in this section of this document, we focus on comments related to these definitions that are specific to part 112 that were not otherwise addressed in the final human preventive controls rule.

1. Definitions of Farm and Related Terms (Manufacturing/Processing, Harvesting, Holding, and Packing)

We revised the proposed definitions of farm, manufacturing/processing, harvesting, holding, and packing in the final human preventive controls rule (see 80 FR 55908 at 55925–55936), and established the revised definitions in §§ 1.227 and 117. We are adopting the same definitions of farm, manufacturing/processing, harvesting, holding, and packing established in § 1.227 for purposes of the PCHF regulation, now in § 112.3(c) for purposes of the Produce Safety regulation.

Definition of “farm.” In the supplemental notice, taking into account public comment on our proposed definition of “farm” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “farm” as it applies to proposed part 117, we proposed to amend the definition of “farm” in proposed § 112.3(c) such that establishments that pack or hold produce that is grown or harvested on another farm would be subject to the produce safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership.

We proposed to amend the originally proposed definition of farm to mean “an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” as proposed in the supplemental notices would include establishments that, in addition to these activities: (1) Pack or hold RACs; (2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of the “farm” definition; and (3) Manufacture/process food, provided that:

- All food used in such activities is consumed on that farm or another farm under the same ownership; or
- Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
 - Drying/dehydrating RACs to create a distinct commodity, and packaging

and labeling such commodities, without additional manufacturing/processing; and

○ Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing.

Even after the revisions we proposed in the supplemental notice and the supplemental human preventive controls notice, some comments asserted that the overall “farm” definition still presented an unrealistic and incomplete understanding of how most farms in the United States are structured with regard to their physical location(s) and business models. Most of the comments suggested alternative or additional regulatory text or asked us to clarify how we will interpret the provisions. After considering these comments, we revised our proposed definition of “farm” (as well as the definitions of “manufacturing/processing,” “harvesting,” “packing,” and “holding”) and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definitions of “farm” (and of “manufacturing/processing,” “harvesting,” “packing,” and “holding”). See also relevant discussion in section V of the final human preventive controls rule, where we respond to comments on the organizing principles for how the status of a food as a RAC or as a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act.

Consistent with the definition of “farm” in § 1.227, we are defining “farm” in § 112.3(c) to indicate that there are two types of farms: (1) A Primary Production Farm and (2) a Secondary Activities Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. In addition to these activities, the term “farm” includes operations that (1) pack or hold raw agricultural commodities; (2) pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food as described below, and (3) manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same management; or any

manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of the following: drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing); treating to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation). A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm.

(Comment 74) Some comments ask us to use the phrase “jointly controlled farm business operation” within the farm definition and to define it “as a business that supplies raw agricultural commodities and is majority controlled by two or more farm operators.”

(Response) We do not see the need to define “jointly controlled farm business operation” or to use it in the farm definition, given the revisions to the farm definition explained in the final human preventive controls rule, and “farm” as defined does not refer to farm operators.

(Comment 75) Some comments request the revised proposed farm definition should not result in foreign farms being considered to be a part of a domestic farm under the same ownership.

(Response) There are two relevant considerations in the revised “farm” definition. First, in the revised “farm” definition established in § 1.227, we replaced the phrase “under one ownership” in the proposed “farm” definition with the phrase “under one management.” Although the original

phrase “under one ownership” was not referring to a single owner, we agreed that the “farm” definition should reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple farms, food aggregators, and food hubs) and use language that the modern farming community understands (80 FR 55908 at 55925–55932). Second, a “farm” is defined to be in “one general physical (but not necessarily contiguous) location.” While a domestic farm and foreign farm might be under the same management for purposes of the business model, they would not likely be in the same general location, unless the farm straddled an international border. So, we believe it is unlikely that a domestic and foreign farm with the same owner would be considered a single farm under the revised definition.

(Comment 76) Some comments point to the inconsistency in treatment of packing and holding of produce that occurs on a farm versus at an off-farm location using the same practices even though there is no difference in risk. Some comments suggest adding a new paragraph to § 112.4 that extends the produce safety rule to registered establishments that perform holding and packing activities of covered produce consistent with covered activities performed by a farm, but not growing or harvesting activities. Other comments suggest, alternatively, providing an exemption from part 117 for those off-farm activities that adhere to the produce safety standards in part 112, if appropriate documentation is maintained.

(Response) Under the revised definition of “farm” we established in § 1.227, an operation devoted only to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition, provided that the farms that grow or raise the majority of the RACs harvested, packed, and/or held by the operation own, or jointly own, a majority interest in the operation. See “secondary activities farm” within the farm definition. Under this definition, off-site packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) can be within the “farm” definition provided that the ownership criteria are met. We are adopting this definition of farm in § 112.3(c).

(Comment 77) Another comment asks to clarify that “produce” does not include wild-harvested produce where produce is not cultivated but harvested wild, such as some blueberries.

(Response) Under the revised definition of “farm” we established in § 1.227, an operation that is devoted only to the harvesting of covered produce grown in the wild is within the “farm” definition. We are adopting this definition of farm in § 112.3(c). Because, in this circumstance, the farm is not engaged in the growing of the covered produce, the standards in part 112 relating to growing activities do not apply to such a farm (see § 112.4(a), providing that covered farms subject to part 112 must comply with all applicable requirements when conducting a covered activity on covered produce). However, the harvesting activity and any other covered activities conducted by the farm on covered produce are required to comply with those requirements in part 112 that are applicable. We also expect that a large proportion of such operations (*i.e.*, those that harvest covered produce grown in the wild) may not be covered under this rule (see § 112.4(a)) or may be eligible for a qualified exemption (see § 112.5) based on their size.

(Comment 78) In the supplemental notice, we requested comment on whether to include in the final rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment (79 FR 58434 at 58440). Several comments express concern that the proposed definition of “farm” would negatively impact the ability to trace produce, and ask FDA to ensure it has access to necessary records to fulfill its public health goals. One commenter supports requiring records that identify the immediate previous source and subsequent recipient of the produce to allow timely and effective recalls, when needed. Another commenter argues that FSMA does not authorize FDA to require traceability records for all covered farms, and states that, if we decide to require farms that pack and hold RACs from other farms to maintain records for traceability purposes, the record requirements: (1) Should not exceed a one-up-one-down record of the transaction; (2) should be limited to those documents generated in the ordinary course of business; (3) should not include records retention for more than one year; and (4) should allow written records, and not require electronic records.

(Response) At this time, we are not requiring documentation when a covered farm packs or holds covered produce from a farm under a different

management. We recognize that many small or very small farms may routinely pack or hold produce grown and harvested at a neighbor’s farm or at a farm that is not under their management, as a course of business or when necessary to fulfill a specific volume of produce to be delivered to their supplier. We encourage covered farms to keep and maintain a documentation of such exchange of covered produce, but we do not believe a requirement for the covered farm to maintain documentation of each such transaction is warranted at this time given the small volume of produce that we expect would fall under such scenarios and their likely minimal contribution to the overall produce in the marketplace. We note that, under the Perishable Agricultural Commodities Act (PACA), which is administered by USDA, there are certain recordkeeping requirements for persons who buy or sell more than 2,000 pounds of fresh or frozen fruits and vegetables in any given day. Such records may be helpful in the event of a traceback. In addition, section 204 of FSMA mandates that FDA conduct a rulemaking on additional recordkeeping requirements for tracing of certain high risk foods. We will address issues related to traceability of high risk foods, in that rulemaking.

(Comment 79) One comment asks if FDA can consider a group of farms in one general location as one farm to lessen the cost of compliance.

(Response) A “farm” is defined for purposes of this rule in § 112.3(c), and all covered farms are required to comply with all applicable requirements of this rule. We encourage farms to work together to help each other achieve compliance to the extent practicable. For example, this rule allows for sharing water testing data under certain circumstances (see § 112.47(a)). In addition, farms may find it useful to share training materials or record templates. We are aware of certain pilot projects using a collaborative model, and we encourage industry to explore these innovative approaches to help achieve compliance. For example, AMS is piloting a Group GAP Certification Program (Ref. 92).

Definition of “manufacturing/processing”. In the final human preventive controls rule, we revised our proposed definition of “manufacturing/processing” (which we proposed in the 2013 proposed rule and the supplemental human preventive controls notice) in relation to our revision to the farm definition. We have established the revised definition in § 1.227, as explained in section IV of the

final human preventive controls rule (80 FR 55908 at 55934–55935). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “farm” and the corresponding revisions to the proposed definition of “manufacturing/processing.”

Consistent with the definition of “manufacturing/processing” in § 1.227, we are defining “manufacturing/processing” in § 112.3(c) to mean “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.”

Definition of “harvesting”. In the supplemental notice, taking into account public comment on our proposed definition of “harvesting” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “harvesting” as it applies to proposed part 117, we proposed to amend the definition of “harvesting” in proposed § 112.3(c).

We proposed to amend the originally proposed definition of “harvesting” to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed on farms for the purpose of removing [RACs] from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on [RACs] on a farm. Harvesting does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act] (21 U.S.C. 321(r)), into a processed food as defined in section 201(gg) of the [FD&C Act]. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling [RACs] grown on a farm are examples of harvesting.

In response to the supplemental notice and the supplemental human preventive controls notice, some

comments asked us to consider additional activities within the “harvesting” definition and to provide more examples of harvesting activities, in the regulatory text and in guidance. After considering these comments, we revised our proposed definition of “harvesting” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55932–55933). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “harvesting”.

Consistent with the definition of “harvesting” in § 1.227, we are defining “harvesting” in § 112.3(c) to apply to farms and farm mixed-type facilities and to mean “activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the [FD&C Act]. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.”

(Comment 80) Some comments ask us to include field coring as an example of harvesting activity, consistent with the definition proposed in the supplemental human preventive controls notice.

(Response) The revised definition of harvesting in § 1.227, which we are adopting in § 112.3(c), includes field coring in the list of examples of harvesting.

Definition of “holding.” In the supplemental notice, taking into account public comment on our proposed definition of “holding” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “holding” as it applies to proposed part 117, we proposed to amend the definition of “holding” in proposed § 112.3(c).

We proposed to amend the definition of “holding” to mean “storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same [RACs] and breaking down pallets)), but does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act], into a processed food as defined in section 201(gg) of the [FD&C Act]. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

In response to the supplemental notice and the supplemental human preventive controls notice, some comments asked us to consider additional activities within the “holding” definition and to provide more examples of holding activities, in the regulatory text and in guidance. After considering these comments, we revised our proposed definition of “holding” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55933–55934). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “holding”.

Consistent with the definition of “holding” in § 1.227, we are defining “holding” in § 112.3(c) to mean “storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the [FD&C Act]. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

Definition of “packing.” In the supplemental notice, taking into account public comment on our proposed definition of “packing” in the 2013 proposed rule and consistent with our proposed amendments to the

definition of “packing” as it applies to proposed part 117, we proposed to amend the definition of “packing” in proposed § 112.3(c).

We proposed to amend the definition of “packing” to mean “placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act], into a processed food as defined in section 201(gg) of the [FD&C Act].” (For reference, we previously proposed to define “packaging” (when used as a verb) to mean placing food into a container that directly contacts the food and that the consumer receives.)

In response to the supplemental notice and the supplemental human preventive controls notice, some comments asked us to consider additional activities within the “packing” definition and to clarify the distinction between “packing” and “packaging.” After considering these comments, we revised our proposed definition of “packing” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55935–55936). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “packing”.

Consistent with the definition of “packing” in § 1.227, we are defining “packing” in § 112.3(c) to mean “placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.”

(Comment 81) Some comments ask us to clarify that packaging and labeling activities include repackaging and relabeling, and state that repackaging or relabeling may be incidental to packaging and labeling activities and does not introduce new or different risks to public health.

(Response) We agree that packaging and labeling activities may include repackaging and relabeling and do not

necessarily introduce new or different risks to public health.

2. Additional Definitions

We are making various revisions to our proposed definitions, as discussed in this section (see Table 4). For the following terms, we did not receive any comments or received only general comments in support of the proposed definition and, therefore, we do not specifically discuss them in this section: “agricultural water,” “application interval,” “food-contact surfaces,” “manure,” “pest,” “pre-consumer vegetative waste,” “raw agricultural commodity,” “sewage sludge biosolids,” “spent sprout irrigation water,” “table waste,” “water distribution system,” and “we”. We are finalizing the definitions of these terms as proposed, except as described in Table 4.

Definitions of “adequate” and “adequately reduce microorganisms of public health significance”. We proposed to define “adequate” to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. We also proposed to define “adequately reduce microorganisms of public health significance” to mean reduce the presence of such microorganisms to an extent sufficient to prevent illness.

(Comment 82) Some comments state that these proposed definitions are not clear and, as proposed, they would not ensure uniformity or consistency in safe practices. Comments suggest clarifying the phrase “to an extent sufficient to prevent illness” to refer to “reducing the presence of microorganisms, for example, through cleaning and sanitizing using EPA-registered or FDA-regulated antimicrobials for food use or through other means such as heat and ozone.”

(Response) As explained in the 2013 proposed rule, the definition of “adequate” we are applying in this rule is the same as the long-standing definition used in relation to current good manufacturing practices in manufacturing, packing, or holding human food. We have provided clarification for how this term relates to specific requirements in part 112 through examples throughout the 2013 proposed rule and this final rule. We are finalizing the definition of “adequate” as proposed.

We finalizing the definition of “adequately reduce microorganisms of public health significance” as proposed. The extent of minimization of pathogens sufficient to prevent illness is usually determined by the estimated extent to which a pathogen may be present in the

food combined with a safety factor to account for uncertainty in that estimate and, therefore, is different for different circumstances. For example, as noted in our previous guidances to industry (Ref. 93) (Ref. 94), if it is estimated that there would be no more than 1,000 (*i.e.*, 3 logs) *Salmonella* organisms per gram of food, and a safety factor of 100 (*i.e.*, 2 logs) is employed, a process that adequately reduces *Salmonella* spp. would be a process capable of reducing *Salmonella* spp. by 5 logs per gram of food. In addition, we are not including the specific examples requested by the comment, or other examples of processes that achieve adequate reduction, within this definition as we believe that doing so would be confusing because this is only a definition of the term “adequately reduce the presence of microorganisms of public health significance,” and not a definition of commercial processing steps that achieve such reductions. We conclude that a better place for examples is in § 112.2(b), the exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, and we have included examples there, including new examples added in this rule (see section IX.A.4 of this document). We have not added the specific examples identified by the commenter in that section, however, because although use of certain antimicrobial substances, heat, or ozone treatments may adequately reduce pathogens depending on the circumstances, we cannot categorically conclude that they would do so under all circumstances.

Definitions of “agricultural tea” and “agricultural tea additive”. We proposed to define “agricultural tea” to mean a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. We also proposed that agricultural teas are held for longer than one hour before application.

We proposed to define “agricultural tea additive” to mean a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

(Comment 83) Some comments ask that we use the term “compost tea” instead of “agricultural tea.” Some comments also asked that we align our definitions of “agricultural tea” and

“agricultural tea additive” with similar definitions used by the NOP.

(Response) We believe “agricultural tea” is a more appropriate term for applicability to part 112 because we intend this definition to cover “teas” intended for agricultural use and prepared from various feedstocks, and not only those extracts prepared from compost. There also may be compost teas that are not intended for agricultural use and we do not intend to cover those.

With regard to the request that we align our definition of “agricultural tea” with the definition of “compost tea” used by the NOP, we note that the NOP does not have a definition of “compost tea” but the National Organic Standards Board (NOSB) 2006 recommendation has a definition of “compost tea” (Ref. 95). The NOSB recommendation defines “compost tea” as “a water extract of compost produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase, intending to maintain or increase the living, beneficial microorganisms extracted from the compost.” We believe these definitions are sufficiently aligned and see no benefit to narrowing the broader scope of FDA’s definition (including various feedstocks) to cover only teas prepared using stabilized compost as a feedstock. Because we are not making these changes to the definition of “agricultural tea”, we do not believe it is appropriate to modify our definition of “agricultural tea additive” (which is based on the definition of “agricultural tea”) to match the NOSB recommended definition of “compost tea additive.” Because the end product of composting is better described as “stabilized compost” rather than “humus,” we are changing this term in the definition of “agricultural tea.” We discuss this change in additional detail under the definition of “stabilized compost”. In addition, we are adding a sentence to the definition of “agricultural tea” to specify that “[a]gricultural teas are soil amendments for the purposes of this rule.” See section XIV of this document for discussion of this change.

Definition of “animal excreta”. We proposed to define “animal excreta” to mean solid or liquid animal waste.

(Comment 84) One comment requests that fish excreta be excluded from the definition of “animal excreta.”

(Response) All solid or liquid animal waste is considered animal excreta, and this includes fish excreta. See also discussion in section III.G of this document.

Definitions of “biological soil amendment” and “biological soil

amendment of animal origin". We proposed to define "biological soil amendment" to mean any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. In addition, we proposed to define "biological soil amendment of animal origin" to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination; and that it does not include any form of human waste.

Because the end product of composting is better described as "stabilized compost" rather than "humus," we are changing this term in the definition of "biological soil amendment." We discuss this change in additional detail under the definition of "stabilized compost".

(Comment 85) Some comments request that we align the definition of "biological soil amendment of animal origin" with that established by the American Plant Food Control Officials. Some comments also request that the definition clarify whether mortality compost is included.

(Response) We are not aware that the American Plant Food Control Officials have a definition of 'biological soil amendment of animal origin' and the comments did not provide such a definition for consideration. With regard to the question about mortalities as a feedstock, animal mortalities or animal mortality compost are materials of animal origin that could be used as a component of a biological soil amendment of animal origin within the terms of the definition. Since the comment requested clarity, we are adding animal mortalities as an example in the definition of biological soil amendment of animal origin.

(Comment 86) One comment asks that definitions clearly specify "treated" versus "untreated" biological soil amendments, to clarify that if one component of the "treated" biological soil amendment is untreated, then the entirety of the biological soil amendment should be considered "untreated."

(Response) Section 112.51 establishes the requirements for determining a biological soil amendment as treated (§ 112.51(a)) or untreated (§ 112.51(b)), and we do not think it is necessary to incorporate these concepts in the definition of biological soil amendment, or biological soil amendment of animal

origin. Under § 112.51(b), a biological soil amendment is untreated if, among other conditions, the biological soil amendment has become contaminated after treatment; has been recombined with an untreated biological soil amendment of animal origin; or is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness. Under these provisions, if the biological soil amendment of animal origin contains a component that is an untreated biological soil amendment of animal origin, or it contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with a foodborne illness, the entire biological soil amendment of animal origin is considered untreated.

Definition of "composting". We proposed to define "composting" to mean a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

(Comment 87) Some comments state this proposed definition does not sufficiently address the biological degradation and transformation of organic solid waste that has been subjected to controlled aerobic degradation at a solid waste facility in compliance with relevant requirements. Some comments also disagree that the process produces "humus." In addition, some comments note that the proposed definition does not encompass various processes that can be used to create safe, usable, and mature compost. For example, commenters point to mixing of organic waste with bulking agents, volatile organic compounds, heat, or water, and state that composting can occur under both thermophilic and mesophilic conditions, but is not always followed by curing. Some comments suggest establishing performance standards rather than establishing a definition for composting.

(Response) We have revised § 112.54 to indicate that "composting" is only one type of biological process that may meet the requirements in that section and § 112.55(a) and (b) (see section XIV of this document). However, we also continue to believe that the process of composting involves a time and temperature treatment, followed by curing. We agree that the end product of composting is better described as "stabilized compost" rather than "humus" and have made this change

both here and in the proposed definition of "humus," which we are now finalizing as a definition of the term "stabilized compost" and which we discuss in detail under the definition of "stabilized compost".

Definition of "covered activity". In the supplemental notice, we proposed to amend the definition of "covered activity" to mean "growing, harvesting, packing, or holding covered produce on a farm, and that "covered activity" includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RACs and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. We also noted that part 112 does not apply to activities of a facility that are subject to 21 CFR part 110.

(Comment 88) Some comments support the coordinated revisions to the definitions of covered activity, harvesting, holding, and packing to support the broader definition of farm, while others request FDA to provide additional clarity by adding specific examples to the definition of "covered activity."

(Response) We do not see the need for additional examples in the definition of "covered activity." Throughout the discussion of the definitions of farm, harvesting, packing, and holding, both here and in the final human preventive controls rule, we believe we have provided sufficient examples to help covered farms understand whether an activity is a covered activity subject to part 112 (see 80 FR 55908 at 55925–55932), and we will consider issuing guidance on these issues as appropriate.

We are revising the definition of "covered activity" to reflect new § 112.2(b)(6) (see section IX.A.4 of this document). We are adding a statement to this definition to make clear that providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) of this part are also covered activities.

Definition of "covered produce". We proposed to define "covered produce" to mean produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

(Comment 89) Some comments suggest stating, within the definition of "covered produce," that circumstances where contamination of crops during early stages of production does not pose a public health risk would not be covered under this rule. Other commenters request inclusion of a

statement that “covered produce” includes only the harvested portion of the plant.

(Response) Covered produce is produce that is subject to part 112 as provided in §§ 112.1 and 112.2, and our proposed definition already specified that this term refers to the harvested or harvestable portion of the crop. For the purposes of determining which produce should be subject to part 112, it would not be appropriate to exempt some produce based on the point in time at which contamination may occur. The fact that contamination may occur during the early stages of production does not, in and of itself, provide a reasonable assurance of lack of potential contamination at a later point in the growing, harvesting, packing, or holding of that produce. Note also, under § 112.2(a), we have exempted certain produce because it is rarely consumed raw, and in § 112.2(b), we have provided for produce to be eligible for exemption from the requirements of this rule if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

(Comment 90) Some comments suggest referring to produce covered under this rule as “fresh produce” rather than as “covered produce.”

(Response) The term “fresh produce” would not convey the meaning we intend to convey with the term “covered produce.” We use “covered produce” to describe produce that is within the scope of the rule under § 112.1 and not exempt from the rule under § 112.2. Not all “fresh produce” commodities fall within the scope of this rule. For example, although produce that is rarely consumed raw, for example, asparagus, may be viewed as “fresh produce” when they are presented to the consumer in their raw, natural, and unprocessed state, such commodities are not “covered produce” because they are exempt from this rule under the provisions of § 112.2(a)(1). The term “covered produce” helps us to distinguish the subset of “produce” (as defined herein) that falls within the scope of this rule. The term “fresh produce” is not an acceptable substitute.

Definition of “curing”. We proposed to define “curing” to mean the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

(Comment 91) Some comments suggest defining “curing” as the final stage of the composting process rather than the maturation stage, and that adequate curing would be achieved when a state of “stable” or “very stable” is reached.

(Response) We agree that “curing” may be more accurately described as the “final” stage of the composting process, so we are making this change. We have also replaced the term “humus” in the related definition of “composting” with “stabilized compost,” which captures the fact that the end product of the composting process is a stabilized product.

Definition of “direct water application method”. We proposed to define “direct water application method” to mean using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. We also noted in the preamble of the 2013 proposed rule, by cross-reference to the definitions of “covered produce” and “produce”, this term would only apply to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce.

(Comment 92) Some commenters believe direct water application methods should include postharvest water application, but not drip or trickle irrigation of root crops.

(Response) We have defined direct water application methods in terms of the intent or likelihood of contact as opposed to specific irrigation practices because it is contact of the agricultural water with the harvestable portion of the covered commodity that could result in contamination of the covered crop if the water is not appropriately managed. With respect to root crops, the analysis is the same. A water application method is a direct water application method if it is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. For example, irrigating carrots using drip irrigation that is intended to filter through the soil and contact the carrots growing underground is a direct water application method because the water is intended to, and likely to, contact the covered produce.

Definition of “food”. We proposed to define food to mean food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

(Comment 93) One comment requests that we definitively indicate that the seeds and sprouts included in the definition for food (as defined in section 201(f) of FD&C Act) are those for human

consumption and to differentiate such seeds and sprouts from those grown for planting or transplanting.

(Response) For the purposes of the produce safety regulation, in § 112.3, we define “food” to mean food as that term is defined in section 201(f) of the FD&C Act, and we explicitly include seeds and beans used to grow sprouts in this definition for clarity because sprouts are covered by this rule. Food is defined in section 201(f) of the FD&C Act, in part, as articles used as food or drink for man or other animals, and articles used for components of any such article. We have long considered seeds and beans used to grow sprouts to be “food” within the meaning of section 201(f) of the FD&C Act (Ref. 96). Seeds and beans used to grow sprouts are both articles used as food as well as articles used as components of articles used as food.

As defined, the terms “produce” and “covered produce” for the purposes of part 112 refer to the harvestable or harvested part of a crop. When seeds and/or sprouts are the harvestable or harvested part of a crop, they may be covered produce for purposes of this rule if they fall within the definition of produce and are not otherwise exempt. On the other hand, when seeds or sprouts are not part of the harvestable or harvested part of a crop, they are not covered produce for purposes of this rule.

Definition of “ground water”. As discussed under Comment 232, we are adding a definition for the term “ground water,” and making corresponding revisions to the term “surface water” to clarify the differences between the two sources of water.

Definition of “hazard”. We proposed to define “hazard” to mean any biological agent that is reasonably likely to cause illness or injury in the absence of its control.

(Comment 94) Comments express a view that the terms “reasonably” and “likely” used in this proposed definition are ambiguous, and request clarification.

(Response) We are revising the definition by replacing the phrase “that is reasonably likely to cause illness or injury” with “that has the potential to cause illness or injury” to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard.” This increases the alignment of the definition of “hazard” in this rule with the Codex definition of “hazard” and the definition of “hazard” in the PCHF regulation.

Definition of “microorganisms”. We proposed to define “microorganisms” to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and

to include species having public health significance. We also proposed that the term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

(Comment 95) One comment suggests that “microorganisms” should include non-bacterial agents of disease. Another comment believes that the term “undesirable microorganisms” should not include those that subject food to decomposition.

(Response) As discussed in section VI of this document, we focus the produce safety standards established under part 112 on biological hazards only. The biological hazards that are addressed through this regulation include bacteria, parasites, and viruses. With respect to the comment about “undesirable microorganisms,” we are retaining this term and its inclusion of microorganisms that subject food to decomposition because such decomposition microorganisms may also be undesirable for food safety or produce substances (for example, mycotoxins) that are undesirable for food safety. We believe it is appropriate to include microorganisms that subject food to decomposition to generally define microorganisms, although the standards in part 112 are not targeted at addressing undesirable microorganisms but at addressing microorganisms of public health concern (*i.e.*, pathogens).

Definition of “mixed-type facility”. We proposed to define “mixed-type facility” to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

(Comment 96) Some comments argue that Congress included provisions in both sections 418 and 419 of the FD&C Act to ensure an appropriate, coordinated, and targeted regulatory framework, with the intent that one operation would not be subject to multiple sets of regulations under FSMA, and that farms would continue to be exempt from the facility registration requirement. These comments ask FDA to adhere to congressional intent in defining “farm mixed-type facility” and to apply a

broad reading of the term farm and a narrow reading of the term facility.

(Response) We are revising the definition of “mixed-type facility,” consistent with the definition of this term in part 117, to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Whether a particular establishment that falls within the definition of “mixed-type facility” is subject to the requirements for hazard analysis and risk-based preventive controls of part 117 is governed by the exemptions established in § 117.5. The definitions of “farm,” “harvesting,” “packing,” and “holding,” too, reflect our careful consideration of the different types of activities that occur on-farm, off-farm, or on farm mixed-type facilities. We have been careful to establish that the activities of a farm mixed-type facility that fall within the farm definition are subject to the produce safety regulation and activities falling outside the farm definition are potentially subject to the PCHF regulation; we do not subject the same activity to duplicative requirements under both rules. In the revisions we have made to the “farm” definition we have made an attempt to interpret the activities that may occur on a farm very broadly, with a consequent reduction in certain activities that would be subject to part 117. See the final human preventive controls rule and the supplemental human preventive controls notice for discussion of related issues.

Definition of “monitor”. We proposed to define “monitor” to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

(Comment 97) Some comments suggest that the use of the phrase “when applicable” in this definition should be replaced with “when required.”

(Response) We agree with this suggestion, and we are making this change.

Definition of “non-fecal animal byproduct”. We proposed to define “non-fecal animal byproduct” to mean solid waste (other than excreta) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal,

bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

(Comment 98) Some comments support this proposed definition, although a few suggest making it clear that wastes generated by other operations, including fish waste, are included within this definition.

(Response) We are revising this definition to replace the phrase “other than excreta” with “other than manure.” Under this definition, solid wastes that do not fall within the definition of “manure” and that are generated by fish operations, such as fish meal and fish emulsions, are considered non-fecal animal byproduct. On the other hand, fish excreta is animal excreta. See discussion in section III.G of this document regarding aquaculture operations.

Definition of “packaging (when used as a verb)”. We proposed to define “packaging (when used as a verb)” to mean placing food into a container that directly contacts the food and that the consumer receives.

(Comment 99) Some comments express concern about establishing the definition of “packaging (when used as a verb)” in part 112. These comments ask us to clarify how this proposed definition relates to other uses of the word “packaging” in part 112, including use as an adjective in the common phrase “food-packaging materials”. Some comments focus on the differences between the definition of the term “packing” and “packaging” with respect to activities conducted on RACs. Some comments ask us to clarify how the term “packaging (when used as a noun)” would apply when used in part 112, even though we did not propose to establish a definition for “packaging (when used as a noun)” in part 112.

(Response) We have decided not to establish the definition “packaging (when used as a verb)” in part 112. That definition was established in the section 415 registration regulations and the section 414 recordkeeping regulations, in part, to identify those food establishments that would be subject to those regulations. In addition, the section 414 recordkeeping regulations established a definition of “packaging (when used as a noun)” because it was also necessary for the purposes of those recordkeeping regulations. However, the term “packaging” has long been used in our existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation (current 21 CFR part 110; “the Food CGMP regulation”)

to generally refer to the container that directly contacts the food, rather than to the outer packaging of food that does not contact the food (as it means in the section 414 recordkeeping regulations). Thus, the very specific connotation for the term “packaging (when used as a noun)” that was established in the section 415 registration regulations and the section 414 recordkeeping regulations does not apply, and is causing confusion. As the comments point out, our proposed definition is already causing confusion in the context of part 112. Therefore, for clarity and simplicity in part 112 we are not including in the final rule a definition of “packaging (when used as a verb).” This deletion is consistent with our decision to not establish such a definition in part 117. The definition of “manufacturing/processing” we are establishing in this rule makes clear that “packaging” (when used as a verb) is a manufacturing/processing activity. The comments that express confusion about the distinction between “packing” and “packaging (when used as a verb)” with respect to activities conducted on RACs no longer apply in light of the revised “farm” definition. The revised “farm” definition provides for packaging RACs when packaging does not involve additional manufacturing/processing (such as cutting).

Definition of “production batch of sprouts”. We proposed to define “production batch of sprouts” to mean all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit).

(Comment 100) Some comments note that various types and sizes of growing units are typically used by sprout operations, and the proposed definition would have varying impacts on sprouting operations based on their equipment type and capacity. Some comments state this proposed definition would disproportionately impact small sprout operations, which tend to germinate smaller batches of seed, because the sampling and testing requirements that relate to this definition are specific to each production batch, regardless of the amount of seed in each batch.

(Response) Our definition is intended to treat product that is exposed to the same conditions during sprouting as one production batch, and we are finalizing it as proposed. This definition is consistent with our 1999 guidance for industry on sampling and microbial

testing of spent irrigation water during sprout production (Ref. 97). We recognize there is a diversity of growing practices and a variety of growing units that may represent different product volumes and, therefore, production batches can vary greatly in size. However, as noted in the 2013 proposed rule, we are limiting the definition of “production batch of sprouts” to a single growing unit to prevent “pooling” of samples from multiple growing units within an operation whereby contamination in spent water in one unit could be diluted by non-contaminated water from other units, increasing the point that pathogens might not be detected. We discuss the related sampling and testing requirements of subpart M in section XVIII of this document.

(Comment 101) Some comments ask us to establish definitions for the terms “batch,” “sprouts,” and “soil-grown sprouts.”

(Response) We define “production batch of sprouts” in § 112.3 and do not see a reason to also provide an additional definition of “batch” in relation to sprouts. The requirements in subpart M of this rule relate to production batches of sprouts, making this the relevant term to define in this rule. We have added a new section, § 112.141, to clarify the types of commodities that are subject to the requirements of subpart M of part 112. See section XVIII of this document. With this addition, we conclude it is sufficiently clear what commodities are subject to subpart M and we need not also establish a definition of “sprouts” or “soil-grown sprouts” for this purpose.

Definition of “qualified end-user”. We proposed to define “qualified end-user,” with respect to a food, to mean the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located (1) in the same State as the farm that produced the food; or (2) not more than 275 miles from such farm. We proposed that the definition would also state that the term “consumer” does not include a business.

We are editing this definition to move the phrase “The term ‘consumer’ does not include a business” from out of paragraph (ii) and into a parenthetical phrase within the definition of “qualified end-user” because the term “consumer” is used in the definition of “qualified end-user” and not in paragraph (ii). We are also adding “or the same Indian reservation” to the definition of “qualified end-user” to clarify for purposes of this rule that “in the same state” under 21 U.S.C.

350h(f)(4)(A)(ii)(II) includes both within a State and within the reservation of a Federally-recognized tribe.

(Comment 102) Some comments argue that Congress only intended the 275 mile distance criterion in the definition of “qualified end-user” to be applied within the United States, its territories, and the Commonwealth of Puerto Rico. On the other hand, other comments asked FDA to clarify that the 275 mile criterion also applies within foreign countries, such that there is an equitable treatment of domestic and foreign farms.

(Response) The definition of “qualified end-user” in § 112.3(c) implements section 419(f)(4) of the FD&C Act. Section 419(f)(4)(A) of the FD&C Act does not provide for a different analysis for when an international border falls within the 275 miles and, therefore, we proposed that international borders would not affect the distance calculation. We are not aware of any basis from which to conclude that Congress intended the distance criterion to be limited to domestic application, or to be otherwise affected by international borders, and the comments did not provide any information from which we might draw such a conclusion. We see no reason to treat sales to restaurant and retail food establishment buyers within 275 miles of a farm differently based on the presence of an international border for the limited purpose of calculating which of a farm’s sales are to qualified end-users. We note that some of the commenters seem to confuse criteria for which sales may be counted as sales to qualified end-users with criteria for exemption from the rule. Sales to qualified end-users, in and of themselves, do not amount to exemptions from the rule. A farm must meet all the criteria provided in § 112.5(a) to be eligible for the qualified exemption. These criteria in § 112.5(a) are based only in part on sales to qualified end-users. For all of these reasons, we conclude that international borders do not affect the 275 mile distance calculation in the definition of qualified end-user. Therefore, for example, a farm in Mexico or Chile selling food to a restaurant or retail food establishment that is located in a neighboring country (for example, the United States and Argentina, respectively) that is within 275 miles of the farm would be able to count that sale as a sale to a qualified end-user. The same would also be true for United States farms that sell food to a restaurant or retail food establishment in a neighboring country that is within 275 miles of the farm. In short, a farm in any country can be eligible for a qualified

exemption, provided it meets the criteria established in § 112.5(a).

(Comment 103) Several comments ask FDA to clarify what would be considered a sale “directly to consumers” for purposes of the definition of “retail food establishment” in § 1.227(b)(11), which is used in the definition of “qualified end-user” in § 112.3(c). Some comments ask us to revise the definition of “restaurant or retail food establishment” to include enterprises such as supermarkets, supermarket distribution centers, food hubs, farm stands, farmers markets, and CSA.

(Response) FDA is addressing the definition of “retail food establishment” in a separate rulemaking. In a recent notice of proposed rulemaking titled, “Amendments to Registration of Food Facilities” (80 FR 19160; April 9, 2015), FDA proposed various amendments, including to the definition of “retail food establishment” in § 1.227(b)(11).

(Comment 104) Some comments suggest sales to qualified end-users should include internet or mail-order sales. Some comments suggest sales that they term “secondary” should be considered sales to qualified end-users. These commenters provide the example of dairy farmers who grow produce for what they consider to be “ancillary” or “incidental” sales.

(Response) The definition of “qualified end-user” implements section 419(f)(4) of the FD&C Act. A sale conducted online or through mail-order can be considered a sale to a qualified end-user if the buyer meets the definition of a qualified end-user. We note that the definition of “qualified end-user” includes the consumer of the food, without regard to that consumer’s location relative to the farm. We are not aware of any basis from which to conclude that Congress intended that what one commenter describes as “secondary” sales should be considered sales to qualified end-users on the basis of the farm’s impression that such sales are only ancillary or incidental to their business. Moreover, we note that for the purposes of determining eligibility for a qualified exemption under § 112.5, sales to a qualified end-user are calculated based on the sale of all “food,” and not on sales of “produce” only.

Definition of “known or reasonably foreseeable hazard” (proposed “reasonably foreseeable hazard”). We proposed to define “reasonably foreseeable hazard” to mean a potential hazard that may be associated with the farm or the food.

(Comment 105) Some commenters ask for clarification of the proposed definition, and express concern that it is

not sufficiently clear to ensure uniformity and consistency in safe practices. One commenter suggests including the word “biological” within this proposed definition, consistent with the proposed definition of “hazard”.

(Response) We are making revisions to define the term “known or reasonably foreseeable hazard” to mean “a hazard that is known to be, or has the potential to be, associated with the farm or the food” to better align with definition of the same term in the PCHF regulation. This term is used in section 419(c)(1)(A) of the FD&C Act, and is reflected in several requirements in part 112. We have provided clarification for how this term relates to specific requirements in part 112 through examples throughout this final rule. In addition, by cross-reference to the definition of “hazard,” a “known or reasonably foreseeable hazard” as defined for the purposes of part 112 is limited to biological hazards because those are the only hazards we are addressing in this rule. For clarity, we are adding the term “biological” to the definition of “known or reasonably foreseeable hazard.”

Definition of “sanitize”. We proposed to define “sanitize” to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

We are retaining this definition with one change. In the PCHF regulation, we defined “sanitize” to mean “to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.” We are making a corresponding revision to the definition of “sanitize” as it applies to part 112 by referring to adequately treating “surfaces” rather than “food-contact surfaces.” Adequately treating any cleaned surface—regardless of whether it is a food-contact surface—by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer, is “sanitizing” the surface. This change to clarify the definition of “sanitize” does not affect the requirements to sanitize,

when applicable, which are established throughout part 112.

Definition of “stabilized compost” (proposed “humus”). We proposed to define “humus” to mean a stabilized (*i.e.*, finished) biological soil amendment produced through a controlled composting process.

(Comment 106) Several comments disagree with our proposed use of the term “humus” (see also discussion of definition of “composting”). These commenters state that the term “humus,” as proposed, would be better described by reference to the static state of compost at the end of the composting process. These commenters note that the organic material at the end of the composting process is beyond the active stage, with reduced biological activity marked by reduced temperature and respiration rate. These commenters further explain that composting requires specific time and temperature conditions to achieve controlled biological decompositions and stabilization of organic material, and that it is in this stabilized state that the material is useful and beneficial to plant growth. Thus, these commenters argue that the biologically stable material that is derived from the composting process should be referred to as “compost” rather than “humus.” These commenters explain that humus forms naturally (in forests and other landscapes) as a component of soils, and may be only one component of finished or mature compost and should not be used to refer to “compost” as a whole. One comment asked that we align the definition of “humus” (compost) with the NOP definition of “compost”.

(Response) We agree the term “stabilized compost” is a better representation of the finished product of composting. We are revising the codified to use the term “stabilized compost” rather than “humus” everywhere it appears, and we are replacing the defined term “humus” with the defined term “stabilized compost” (with the same defined meaning). This change affects the definitions of “agricultural tea,” “biological soil amendment,” “composting,” “growth media,” “soil amendment,” “static composting,” and “turned composting.” We do not believe it is necessary to align our revised definition of “stabilized compost” with the NOP definition of “compost” in 7 CFR part 205. The NOP definition of “compost” includes a great deal of detail about the process of composting which we do not believe is necessary for our use of the term “stabilized compost” in part 112 and also could be viewed as limiting the mechanisms by which

compost can be made, which is not our intent.

Definition of “static composting.” We proposed to define “static composting” to mean a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. We further proposed to state that examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots, and that examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting materials or blow air into the composting material using positive pressure).

(Comment 107) Arguing that the definition should exclude passively aerated systems, some commenters recommend using the term “aerated static composting” to ensure proper treatment to achieve time and temperature conditions.

(Response) We disagree that the definition of “static composting” should exclude passively aerated systems. In fact, we indicate in the definition that passive diffusion is one method for introducing air to the composting material. Therefore, we decline to change the definition to “aerated static composting.” We recognize that composting that includes passively aerated systems may have cold spots due to uneven aeration; however, it is not our intent to narrowly limit the way compost is produced as long as the stabilized compost meets the standards of § 112.54(a) or (b).

As discussed previously, we are replacing the term “humus” with “stabilized compost” in the definition of “static composting.” We are also making a change to indicate that static composting may or may not involve the use of insulating material. The revised definition of “static composting” reads “static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting materials or blow air

into the composting material using positive pressure).”

Definition of “yard trimmings.” We proposed to define “yard trimmings” to mean purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

(Comment 108) We received mixed comments on the use of terms “yard trimmings,” “yard trash,” and “yard debris”. Some commenters suggest using the term “yard debris” to refer to plant material commonly created in the course of yard and garden maintenance through horticulture, gardening, brush, weeds, flowers, roots, windfall fruit, and vegetable garden debris. Some comments note that yard trimmings and pre-consumer vegetative waste could contain arthropods or dog waste, and suggest using a term that would be more restrictive so as to avoid such potential inclusions, such as “vegetation trimmings,” “vegetable debris,” “foliage,” “excess flora,” or “plants, bushes and tree parts.” Other comments recommend defining a new category of vegetative waste, referred to as “wood waste,” to include materials such as wood pieces or particles generated as byproducts from the manufacturing of wood products, construction, demolition, handling and storage of raw materials, trees and stumps, sawdust, chips, shavings, bark, pulp, hogged fuel, and log sort yard waste. These commenters note that wood waste does not include wood pieces containing paint, laminates, bonding agents, or chemical preservatives.

(Response) We are retaining the term “yard trimmings” to refer to purely vegetative matter resulting from landscaping maintenance or land clearing operations. Commenters were split on whether we should use this term or an alternate term such as “yard debris,” “vegetation trimmings,” or “wood waste” to express the same meaning, and no comment provided a reason to think “yard trimmings” would be confusing or problematic. The materials commenters listed as yard debris, vegetation trimmings, or wood waste are encompassed within our definition of “yard trimmings.” We use the term “yard trimmings” to avoid potentially negative connotations associated with the word “trash,” even though some components of our definition (e.g., untreated wooden pallets) arguably are not “trimmings.” Dog droppings and other animal wastes are not yard trimmings. However, we

recognize that even in purely vegetative material such as that described in the definition of “yard trimmings,” there is the potential for unknown and unavoidable contamination with animal waste. We have concluded that the likelihood of contaminating produce with pathogens by use of biological soil amendments that are not known to contain, and not likely to contain significant animal waste or human waste (e.g., yard trimmings, pre-consumer vegetative waste) is low, and therefore they are not subject to the requirements of this rule. We decline to define the term “yard trimmings” in a way that makes such materials subject to the requirements in this rule.

Definition of “you.” We proposed to define “you” to mean a person who is subject to some or all of the requirements in this part.

(Comment 109) Some comments ask that we revise this proposed definition to directly link it to the owner or operator in charge of the covered farm. One comment also states the person responsible for compliance with the produce rule is not necessarily the owner of the farmland, but could sometimes be the owner of the business or the person with effective operational control over the farm business, such as owners, tenants, partners, or employees.

(Response) We are revising this definition to state that “you,” for the purposes of part 112, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112. We are also making corresponding edits to the questions and provisions in §§ 112.4, 112.5, 112.6, and 112.7 to reflect this revision. Specifically these edits include replacing the term “you” or “I” with “farm(s).”

3. Other Comments

(Comment 110) Some comments state that terms such as “minimize,” “periodic,” “regular,” and “when necessary and appropriate” as used within the proposed provisions have no clear definitions, and suggest that these terms should be defined.

(Response) As explained in the 2013 proposed rule (see section IV.D of that document; 78 FR 3504 at 3529–3521), we developed the regulatory framework for this rule taking into account the need to tailor the requirements to specific on-farm routes of contamination. We have incorporated flexibility into our requirements, wherever appropriate, relying on an integrated approach that employs various mechanisms. In some cases, the produce safety standards in part 112 are very similar to those contained in the

Food CGMP regulation, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (e.g., personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We rely on this approach where possible, in part, because of the diversity of the industry with respect to size, agricultural practices, and knowledge of food safety. Such standards are intended to be flexible and inherently necessitate the use of terms such as “periodic,” “when necessary,” and “when appropriate.” While we believe these terms are generally understood, we have provided examples throughout the rule to help covered farms better understand the requirements.

(Comment 111) Some comments request that we define the term “crop” to mean both edible and inedible cultivated plants. These commenters state that such a definition is necessary to avoid confusion in instances where edible portions of a plant come into contact with harvested but inedible portions of the plant that may be used, for example, in the production of biofuels, clothing, and bio-degradable household products.

(Response) The science-based minimum standards that we are establishing in part 112 apply to the growing, harvesting, packing, and holding of produce for human consumption. Produce that is not reasonably expected to be directed to a food use (for example, produce that is reasonably expected to be used in the production of biofuels, clothing, or household products) is not subject to the requirements of part 112. Therefore, we do not agree that we should establish a definition for the term “crop” as suggested by these commenters.

(Comment 112) Some comments request that we provide clear definitions for the terms “greenhouse,” “germination chamber,” and “other protected environment production areas.” Some commenters request that FDA define the term “greenhouse” using the following statement in a **Federal Register** document issued by the International Trade Administration, Department of Commerce: “Controlled environment tomatoes are limited to those tomatoes grown in a fully-enclosed permanent aluminum or fixed steel structure clad in glass, impermeable plastic, or polycarbonate using automated irrigation and climate control, including heating and ventilation capabilities, in an artificial

medium using hydroponic methods” (78 FR 14967 at 14970).

(Response) None of these terms is used to describe any requirements in part 112, including in subpart L of 112, and, therefore, their inclusion in the list of definitions in § 112.3 is not necessary. We respond to comments about the applicability of subpart L to such buildings in section XVII of this document.

(Comment 113) Some comments ask that we establish a definition of the term “standard.”

(Response) As required by section 419 of the FD&C Act, we have established science-based minimum standards for the safe production and harvesting of produce in part 112, and we have included definitions that are relevant to those standards. We do not see the need to further establish a definition for the term “standard.” In addition, FDA has established many standards related to food safety and we believe this term is generally understood by the regulated community.

(Comment 114) Some comments request that we define the term “visitor,” and suggest that such definition should exclude visitors who visit the farm, but do not come into contact with produce or any other RAC being produced on the farm.

(Response) We stated in proposed § 112.33(a) that a visitor is any person (other than personnel) who enters your covered farm with your permission. We do not expect all visitors to present a reasonable likelihood of introducing hazards into covered produce. However, we decline to limit the requirements in this rule related to visitors to only those visitors who come into contact with produce or other RACs. See discussion under Comment 172. We do agree, however, that the definition of “visitor” that appeared in proposed § 112.33(a) should instead appear in § 112.3 with the other definitions, and we are making this change to § 112.3 and eliminating proposed § 112.33(a).

(Comment 115) Some comments request definitions for other terms related to biological soil amendments, including for the terms “aging,” “feedstock,” “green waste,” and “maturity.”

(Response) None of these terms is used to describe the requirements in part 112, including in subpart F of part 112, and, therefore, their inclusion in the list of definitions in § 112.3 is not necessary.

C. Small Businesses, Very Small Businesses, and Farms That Are Not Covered or Are Eligible for a Qualified Exemption

In the 2013 proposed rule, under proposed § 112.3(b), we proposed to establish the definitions for very small business and small business, and under proposed § 112.4, we proposed to apply part 112 only to farms above a certain specified average monetary value of sales (78 FR 3504 at 3549). We also proposed §§ 112.5 and 112.6 to establish the eligibility criteria and modified requirements related to farms with a qualified exemption. In addition, in the supplemental notice, taking into account public comment, we proposed to amend the originally proposed definitions of very small business and small business in § 112.3(b) as well as the provision in § 112.4 regarding farms not covered under this rule (79 FR 58434 at 58436–58438). In both the 2013 proposed rule and in the supplemental notice, we asked for public comment on our proposed provisions.

We are finalizing §§ 112.4, 112.5, and 112.6 with changes, and adding new § 112.7, as discussed in this section (see Table 4). In this section, we also discuss comments we received in response to the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the amended proposed provisions in the supplemental notice.

1. Suggestions Related to Farms Not Covered or Eligible for a Qualified Exemption

(Comment 116) Some comments suggest that farms not covered by this rule based on their size, or farms that are eligible for a qualified exemption from this rule should be regulated under scale-appropriate State-run food safety programs. Some comments also request that FDA provide support for States to implement such programs.

(Response) FDA is not requiring States to set up food safety programs for farms eligible for the qualified exemption, nor are we prohibiting States from establishing such programs. We do intend to continue to work collaboratively with our State and other partners in facilitating compliance with this rule. Such efforts will be appropriately focused on covered farms, not on farms eligible for the qualified exemption. However, we do anticipate that some of the materials and programs generated in that effort are likely to be helpful to farms eligible for the qualified exemption as well as to covered farms. Our existing guidance documents, such as the GAPs Guide, provide relevant

recommendations. In addition, we expect that the training materials being developed by the PSA and SSA will be useful resources, including for training farms eligible for the qualified exemption in safe produce growing, harvesting, packing, and holding practices.

(Comment 117) One comment recommends that farms not covered by this rule based on their size or eligible for a qualified exemption should not be allowed to supply produce to entities such as schools or hospitals.

(Response) We do not agree that farms not subject to coverage under part 112, or eligible for a qualified exemption should be precluded from marketing their produce to schools or hospitals. Produce marketed in the United States must be safe for consumption, regardless of whether the farm that grew the produce is required to comply with part 112. There is no reason to believe that produce is unsafe or otherwise unfit for consumption by individuals at schools or hospitals simply because it was produced by a farm not subject to part 112 or eligible for a qualified exemption.

(Comment 118) One comment requests that any requirements for supplier verification in other FSMA rules should not prevent other food businesses from purchasing produce from farms that are eligible for the qualified exemption from the produce safety regulation or otherwise not subject to the produce safety regulation.

(Response) Nothing in the produce safety regulation, PCHF regulation, or FSVP regulation precludes food businesses from purchasing produce grown, harvested, packed, or held by farms that qualify for a qualified exemption from the produce safety regulation or are otherwise not subject to the produce safety regulation. In the rulemakings establishing the PCHF regulation (80 FR 55908) and FSVP regulation (published elsewhere in this issue of the **Federal Register**), FDA explained how the supplier verification requirements in those rules relate to farms that are not subject to the produce safety regulation.

2. Calculating Farm Sizes

(Comment 119) Some comments request clarification on how sales will be calculated for the purpose of determining a farm's size and, therefore, whether the farm is a covered farm, eligible for a qualified exemption, and/or eligible for an extended compliance period. Comments ask whether the value of produce donated to non-profit organizations such as food banks and senior centers would be counted

towards sales. In addition, comments ask whether sales or donations to public institutions, such as prisons, would be counted towards sales.

(Response) For purposes of the sales thresholds in this rule, FDA does not consider a donation in which there is no payment of money or anything else of value in exchange for produce to be a "sale." Such donations, including to public institutions or non-profit organizations, are not counted toward a farm's sales revenue. However, sales of produce to any public institutions or non-profit organizations in which money or anything else of value is exchanged for produce must be counted as sales for purposes of this rule.

(Comment 120) Some comments seek clarification on the applicability of small or very small business definitions in proposed § 112.3 versus the eligibility criteria for a qualified exemption in § 112.5 in the circumstance where a farm meets the conditions for both. Some comments point out that because the monetary thresholds are based on produce sales for the former and all food sales for the latter, it would be possible for certain diversified farms to qualify for extended compliance periods (as small or very small businesses) as well as for a qualified exemption and modified requirements. Additionally, one commenter is concerned that this difference in monetary threshold basis means that a farm will have to be aware of the implications of its sale of "all produce" and "all food."

(Response) We acknowledge that because of the difference in the bases for monetary cut-offs established in § 112.3 and in § 112.5, there could be circumstances where a farm that is a small business or very small business (as defined in § 112.3) is also eligible for a qualified exemption (in accordance with § 112.5). Farms eligible for a qualified exemption (in accordance with § 112.5) that also qualify as a small or very small business (as defined in § 112.3(b)), must comply with the modified requirements of §§ 112.6 and 112.7 within the compliance periods established for either a small business or a very small business, whichever is applicable. A farm can be both a farm eligible for a qualified exemption and a small or very small business. We are revising the definitions of small business and very small business to acknowledge that such businesses may be subject to only some of the requirements of part 112, if they are also a farm eligible for a qualified exemption, and to all of the requirements of part 112 if they are only a small or very small business. We have replaced the phrase "if it is subject to

this part" with "if it is subject to any of the requirements of this part" in the definitions of both small business and very small business in § 112.3(b).

(Comment 121) Some comments ask whether annual sales will be calculated per owner or per operator, where the farm owner and operator are different. Other comments ask whether farms may alter their business structures for the purpose of evading this rule.

(Response) We have revised the definition of "farm" to make clear that the relevant entity is the farm business, which is either (1) A Primary Production Farm, an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities; or (2) a Secondary Activities Farm, an operation devoted to harvesting, packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. Thus, a farm's sales are those attributable to the farm business. Limits on permissible business structures for farms are beyond the scope of this regulation. Thus, it is possible that some farms may attempt to evade this regulation as suggested by the comment. However, we do not expect this to occur on a broad scale given that many farms currently already participate in voluntary industry guidelines or marketing agreements, many of which include provisions similar to those required under this regulation.

(Comment 122) One comment finds the requirements for calculating sales for the purposes of the coverage threshold and the qualified exemption to be confusing and notes that small farms may resist a financial evaluation to determine the applicability of this rule at the beginning of an inspection.

(Response) The \$25,000 coverage threshold is based on sales of produce, which we expect a farm to be able to demonstrate using existing sales records. The criteria for the qualified exemption are more complex, but are a product of requirements in section 419(f) of the FD&C Act. In section IX.C.5–7 of this document we discuss how a farm can demonstrate its eligibility for the qualified exemption and the associated requirement for farms to maintain necessary documentation. We expect that farms that are not covered by this rule, or that

are eligible for an exemption, will be willing to provide supporting documentation to FDA at relevant times, including during an inspection. We intend to target our education efforts on small farms to help them come into compliance. We also plan to work closely with State, territorial, tribal and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with this rule.

(Comment 123) Some comments recommend including a multiplier ratio in the sales thresholds to take into account the growing seasons of different areas. Another comment recommends replacing monetary income thresholds for farm size with either produce-unit thresholds or with the cost of non-farm inputs purchased.

(Response) We believe it is unnecessary to include a multiplier ratio because we consider total annual production, rather than seasonally-adjusted production. We use monetary value of sales of produce as a proxy for the quantity of produce sold in the United States marketplace. This provides a clearer picture of volume contribution to the United States marketplace than produce units or cost of non-farm inputs purchased, which do not appear to indicate consumption or even yield.

(Comment 124) Some comments recommend adjusting the sales thresholds for all purposes for inflation and recommend using 2011 as the baseline year for such adjustment, consistent with the monetary threshold for farms eligible for a qualified exemption (§ 112.5). One comment recommends including adjustments to the sales thresholds in the rule based on the Consumer Price Index to account for future inflation.

(Response) We do not agree that the monetary thresholds for determining whether a covered farm is a “small business” or “very small business” need to be adjusted for inflation. These thresholds are used only to determine the first date upon which a small or very small business must comply with the rule, with applicable compliance periods ranging from two years to a maximum of six years from the effective date of this rule. In contrast, the \$25,000 monetary threshold in § 112.4(a) affects whether or not a farm is covered under this rule, with indefinite effect. Therefore, we agree that this monetary threshold should be adjusted for inflation, and we are revising § 112.4(a) accordingly. With respect to the monetary threshold related to eligibility for a qualified exemption, we are

finalizing § 112.5, as proposed. Section 112.5(a)(2) provides that the \$500,000 figure will be adjusted for inflation, and § 112.5(b) provides that 2011 is the baseline year for calculating such adjustment. We intend to use the federal calculation for inflation adjustments provided by the Bureau of Economic Analysis (Ref. 98), and to make the adjusted dollar value available on our Internet site.

(Comment 125) One comment asks how farm size will be calculated if a farm has properties in two States.

(Response) We have revised the definition of “farm” to make clear that the relevant entity is the farm business. Thus, provided that a farm is limited to one general (but not necessarily contiguous) physical location, whether a farm’s operation crosses State borders does not affect the calculations of a farm’s size, which are based on annual sales.

(Comment 126) Comments request revisions and/or clarification on the applicability of the farm size monetary thresholds to foreign farms. Some comments express concern that applying the thresholds equally to domestic and foreign farms will have significant unintended consequences. Some comments state that the proposed \$25,000 threshold has significant consequences in relation to imported foods. According to these comments, foreign farms that export foods to the United States from around the world are often very small, and produce from these farms is aggregated for export to the United States. Another comment states that any gross sales threshold gives an unfair advantage to foreign farms who sell produce at a low price index, disadvantaging domestic farmers, who the commenter asserts will sell less produce than foreign farmers before exceeding any given threshold. This comment asks FDA to define farm size thresholds based on tonnage, with separate categories for different classes of produce, rather than on monetary value of sales.

(Response) We do not agree that the coverage threshold presents a particular problem with respect to imported produce. Produce is aggregated for sale both domestically and abroad. We conclude that the farms below the threshold do not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, have little measurable public health impact. We acknowledge that dollar amounts are directly related to product value, but nonetheless disagree that we should base the monetary thresholds in the rule on the volume or amount of product

sold. We see no practical way to identify a threshold based on volume or amount of product that could be applied across all applicable commodities and operations, and the commenter provided no specific suggestions for how this recommendation could be carried out.

(Comment 127) Some comments ask us to count only United States sales to calculate the size of foreign farms that export food to the United States. Some comments also assert that most foreign farms export only a small portion of their total produce to the United States, and that this limited volume of produce poses a relatively low risk to United States consumers. In addition, one comment also states that because the farm’s coverage or qualified exemption status would be influenced by fluctuations in foreign exchange rates, monetary thresholds based on global sales would jeopardize the predictability of business and have negative effects on trade.

(Response) We decline this request. The purpose of the definitions of “very small business” and “small business” in this rule is to allow such farms extended periods before their initial compliance with the rule. We are providing this flexibility because they may have fewer resources to direct to compliance with the rule under the shorter timeframes provided to larger farms. As such, we are applying this rule equally to foreign and domestic farms of the same size. Just like a similarly situated domestic farm, a foreign farm that sells more than the threshold dollar amount of food is likely to have the capability of complying with the rule within the applicable time period, even if not all of that dollar amount reflects United States sales. We also decline this request with respect to the monetary threshold in § 112.4(a), maintaining consistency to the maximum extent possible. The criteria for eligibility for a qualified exemption (and, therefore, associated modified requirements) established in § 112.5 are as mandated by section 419(f)(1) of the FD&C Act. Because these criteria are mandated by the statute, FDA must include them and we are finalizing them, as proposed.

Although it is true that foreign exchange rates fluctuate, we believe the effect of such fluctuations on a farm’s average revenue over a three year period would be minimal. Foreign exchange prices fluctuate, but so too, do crop prices. If a covered farm is able to make more money either by switching crops or selling to new markets overseas these changes in practice could affect the farm’s coverage. And while such opportunities may present themselves

in the short term, both crop prices and exchange rates tend to stabilize over the long term.

(Comment 128) Several comments request that farm sizes be based on the sale of “covered produce,” rather than on the sale of “all produce.” Although supportive of the change from “all food” to “all produce,” these comments urge FDA to calculate all monetary thresholds for businesses based on sales of covered produce to provide what the commenters believe would be a clear standard and support farm diversification efforts. Some comments argue that section 419 of the FD&C Act placed limitations on the scope of the rule that should be reflected in the rule’s calculation of sales by basing them only on food covered by the rule. One commenter asserts that it would not be difficult to determine produce that is “covered” versus “not covered” or to keep track of “produce sold” versus “produce grown for personal consumption.” Some commenters opine that defining coverage in terms of “covered produce” versus “all produce” would likely continue to cover only a small fraction of the total volume of covered produce in the United States food supply, resulting in minimal changes to total coverage of the rule. In contrast, some comments support FDA’s revised provisions, and state that basing farm monetary thresholds on “covered produce” might be too difficult to be practical in that, compared to “all produce,” identifying “covered produce” is distinctly more challenging and will change on a more frequent basis.

(Response) In the supplemental notice, we considered and rejected basing farm size on sales of covered produce, and commenters did not provide specific suggestions responsive to our stated concerns about the feasibility of this approach. This scenario continues to present a number of challenges, including the difficulty of determining the scope and public health impact of not covering farms based on the sales of covered produce, particularly considering the likely variability in produce commodities grown year to year; variability resulting from provisions under which certain commodities would not be considered “covered produce” (for example, produce that is rarely consumed raw); changes in the amount of produce that is used for personal consumption or for consumption on the farm or another farm under the same management; and whether and how to account for produce that would be eligible for exemption under certain conditions, which may be inherently variable based

on market conditions (for example, produce that is destined for commercial processing). We continue to find it difficult to quantitatively determine the extent to which businesses with an average annual monetary value of “covered produce” sold of more than \$25,000 would contribute to the overall produce market, or the public health impact of not covering such businesses under part 112. However, it can be reasonably expected that applying the same monetary thresholds to covered produce sales (rather than to total produce sales) would exclude more produce acres and, therefore, a larger volume of product potentially associated with foodborne illness. Moreover, the possibly frequent changes to a farm’s covered or non-covered status may also be challenging for compliance and enforcement purposes. We also disagree that our legal authority requires us to use “covered produce” only as the basis for sales thresholds in this rule. As explained elsewhere, the monetary threshold for a qualified exemption is established by statute as calculated based on all food, and we use this basis in § 112.5. Section 419 gives FDA the discretion to define the terms “small business” and “very small business,” and to determine which farms and which produce should be covered. For all of these reasons, we are not adopting this approach.

3. Definitions of Small and Very Small Businesses (§ 112.3(b)) and Extended Compliance Periods

(Comment 129) A number of comments asked us to raise the sales thresholds in the definitions of “very small business” and “small business” set forth in proposed § 112.3(b). These comments cite the relative proportion of farms that would meet each definition and the economic burden of compliance with the rule as justification. Sales thresholds suggested for “very small business” and “small business” ranged across the comments, including suggestions up to \$1,000,000 or even \$2,000,000 in average annual monetary value of sales over the previous 3-year period.

(Response) As required by section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, we have formulated this rule to provide sufficient flexibility to be practicable for all sizes and types of entities engaged in the production and harvesting of fruits and vegetables that are RACs, including small businesses and entities that sell directly to consumers, and to be appropriate to the scale and diversity of the production and harvesting of such commodities. Small businesses and very small

businesses are provided extended compliance periods as a means of providing such businesses with additional flexibility (see section XXIV of this document). In the supplemental notice, we revised the proposed definitions of small business and very small business by replacing the sales thresholds based on sales of all food with sales thresholds based on sales only of produce, which we expect would increase the number of farms that would fit within those definitions and therefore qualify for extended compliance periods (79 FR 58434 at 58437). Small businesses and very small businesses, as defined for the purpose of this regulation, together account for an estimated total of 17.2 percent of covered produce acres and about 13.6 percent of all produce acres in the United States, and are significant contributors to the volume of produce marketed in the United States. We considered the suggestions to set the monetary thresholds for very small or small businesses at \$1 million or \$2 million. Using these thresholds, applied to annual sales of produce, such businesses account for an estimated total of 40.6 percent of covered produce acres and about 32 percent of all produce acres in the United States for the \$1 million cutoff, and an estimated total of 54.6 percent of covered produce acres and about 43 percent of all produce acres in the United States for the \$2 million cutoff. Neither of these cutoffs is appropriate to consider a business as “very small business” or “small business” because it would delay compliance dates significantly for about a third of all produce marketed in the United States using the \$1 million cutoff, and for nearly a half of all produce marketed in the United States using the \$2 million cutoff. We also considered and rejected the possibility of basing the thresholds on sales of covered produce, as explained in Comment 128. Therefore, we believe that the sales thresholds in the definitions of very small business and small business, as revised in the supplemental notice, are appropriate, and we are finalizing them as proposed in the supplemental notice. We intend to target our education and technical assistance efforts to help these farms to comply with the standards established in part 112.

(Comment 130) One comment disagrees with providing extended compliance periods for small and very small businesses, stating that these provisions would allow such farms to operate at increased risk for a significant time.

(Response) We are providing extended compliance periods for small and very small businesses to incorporate additional flexibility into the regulation, consistent with the statutory provisions in section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, which direct us to provide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses. Small and very small businesses may have fewer resources available to, for example, invest in new equipment, or fewer staff with formal training in food safety and, therefore, may need additional time to come into compliance with the regulation. Providing extended compliance periods to small and very small businesses is consistent with our approach to compliance dates in recent rules directed to food safety (see, e.g., 74 FR 33029 at 33034, July 9, 2009 and 72 FR 34751 at 34752, June 25, 2007). This allowance for extended compliance periods does not eliminate or otherwise affect their responsibility under the FD&C Act to ensure the safety of their produce.

4. The \$25,000 Threshold for Coverage Under the Rule (§ 112.4(a))

(Comment 131) Several comments support the proposed threshold of more than \$25,000 in average annual monetary value of produce sales during the previous 3-year period. Some comments request that the threshold be raised. These comments recommend varying thresholds ranging from \$75,000 to \$5,000,000 of annual sales of either produce, covered produce, or all food. One comment suggests that the threshold should be higher than the majority of farms that could reasonably be considered viable family-sustaining businesses. Other commenters suggest using a threshold in line with an average single family income.

Other comments object to the inclusion of any monetary or otherwise size-based threshold for coverage under this rule. These comments argue that this approach creates an “uneven playing field” advantaging small farms over large farms, that pathogens do not discriminate based on the size of a farm, that such a threshold will minimize the impact of this rule in terms of consumer confidence in the safety of produce, and that small farms are nevertheless able to comply in a cost-effective manner with the same best practices for food safety that larger producers follow. Some comments also argue that inclusion of such a threshold puts pressure on State and local agencies to regulate the smallest farms, and that the smallest operations may be the highest risk for hazards and contamination because

large farms typically utilize third-party audits but smaller farms do not.

(Response) We believe it is appropriate to establish a threshold for coverage of this rule to establish only those requirements that are reasonably necessary to meet the public health objectives of the regulation. Because farms below the threshold do not contribute significantly to the volume of produce in the marketplace that could become contaminated, we conclude that imposing the requirements of part 112 on these businesses is not warranted. We note that farms that are not subject to this rule are and will continue to be covered under the adulteration and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. We recommend that farms that are not covered under part 112 follow good agricultural practices to ensure that the produce they grow, harvest, pack or hold does not serve as a vehicle for foodborne illness.

In the supplemental notice, we revised the proposed \$25,000 threshold for coverage by replacing sales of “food” with sales only of “produce.” We tentatively concluded that the farms below this revised proposed threshold would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. We believe that applying the limit to produce sales rather than all food sales would accommodate the concerns expressed by some comments without adversely affecting the level of public health protection envisioned under the 2013 proposed rule (79 FR at 58434 at 58437). We are finalizing the \$25,000 threshold, based on sales of produce, as proposed in the supplemental notice. Our analysis shows that farms with less than \$25,000 of annual produce sales account for an estimated total of 2.5 percent of covered produce acres, and about 2 percent of all produce acres in the United States. Such businesses do not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, we believe that imposing the requirements of part 112 on these businesses is not warranted. We also considered and rejected the possibility of basing the threshold on sales of covered produce, as explained in Comment 128.

We also considered alternative monetary value thresholds suggested by commenters. We find that setting a monetary threshold greater than \$25,000 based on sales of produce would adversely affect the level of public

health protection provided by this regulation. For example, if we were to set the coverage threshold at \$1 million or \$2 million, applied to sales of produce, an estimated total of about 32 percent of all produce acres in the United States for the \$1 million cutoff and an estimated total of about 43 percent of all produce acres in the United States for the \$2 million cutoff would not be subject to this rule. This would remove about a third to nearly half of all produce marketed in the United States from coverage, providing significantly less public health protection. We have incorporated flexibility in the rule to help smaller farms to comply. We also intend to work with our State, tribal, and local partners and target our education and technical assistance efforts to smaller farms to help farms meet the standards established in subparts A to O, within the specified compliance periods.

5. Qualified Exemptions Generally (§§ 112.5 and 112.6)

(Comment 132) Several comments express support for the qualified exemption provisions for farms, as proposed, and urge FDA to retain the modified requirements for such farms. Conversely, some comments oppose the proposed qualified exemption provisions and recommend that this exemption be eliminated, arguing that it is not science- or risk-based.

(Response) As explained in the 2013 proposed rule, the provisions in §§ 112.5 and 112.6 reflect the fact that section 419(f) of the FD&C Act mandates this exemption. Section 112.5 establishes the criteria for eligibility for a qualified exemption (and, therefore, associated modified requirements) based on a farm’s average monetary value of all food sold and direct farm marketing, as mandated by section 419(f)(1) of the FD&C Act. Similarly, § 112.6 establishes the modified requirements applicable to those farms that are eligible for a qualified exemption as mandated by section 419(f)(2) of the FD&C Act. Because these provisions are mandated by the statute, FDA must include them and we are finalizing them as proposed. We note, however, that the qualified exemption from part 112 does not eliminate a farm’s responsibility to comply with all applicable requirements of the FD&C Act. We encourage such farms to continue following procedures, processes, and practices that ensure the safety of produce grown, harvested, packed, or held on their farm or in their operation.

6. Criteria for Eligibility for a Qualified Exemption (§ 112.5)

(Comment 133) Some comments suggest altering the criteria for eligibility for a qualified exemption in various ways. One comment recommends exempting farms that sell at least 50 percent of their produce directly to consumers or retail stores within a 250-mile radius, and argues that buyers in such circumstances can visually inspect the growing areas, converse with farmers, and closely examine their purchasing options. Another comment recommends increasing the average annual sales monetary limit for eligibility for a qualified exemption from \$500,000 to a minimum of \$1,000,000. This commenter states that the \$500,000 limit in § 112.5(a) would not adequately protect smaller farms, particularly because it would be applied to all food sales. In this regard, the commenter also recommends that the monetary value limit should be applied to the sale of covered produce only, and not all food. Another comment recommends applying the monetary value limit to sales of produce.

(Response) Sections 112.5, 112.6, and 112.7 establish the criteria for eligibility for a qualified exemption and associated modified requirements, consistent with section 419(f) of the FD&C Act (21 U.S.C. 350h(f)). The criteria established in § 112.5(a), including the requirements related to sales directly to qualified end-users, are derived from section 419(f) of the FD&C Act. Similarly, the definition of a qualified end-user in § 112.3(c) implements section 419(f)(4) of the FD&C Act. Because these provisions are mandated by the statute, FDA must include them and we are finalizing them as proposed. We have identified no basis that would allow us to make the changes suggested by the commenters, such as applying a distance criterion of 250 miles, applying a monetary limit of \$1,000,000, or changing the basis for the monetary limit to apply to sales of produce or covered produce rather than all food. We also addressed this last request regarding monetary limit based on sales of covered produce in the supplemental notice (see 79 FR 58434 at 58438).

(Comment 134) Several comments request that FDA allow small farms that market through produce auctions or CSA operations to be eligible for the qualified exemption.

(Response) Consistent with section 419(f) of the FD&C Act, the provisions in § 112.5 do not identify any produce market arrangements as specifically eligible for the qualified exemption. Rather, these provisions establish the

criteria that must be met for any covered farm to be eligible for a qualified exemption. As we discussed in the 2013 proposed rule (78 FR 3504 at 3549–50), it does seem likely that many farms that use arrangements such as CSAs, you-pick operations, or farmers markets, will meet the established criteria for a qualified exemption. Each covered farm, including farms using such arrangements to market their produce, should analyze its sales under the terms of § 112.5 to determine its eligibility for the qualified exemption.

In the case of a CSA farm or a farm using a produce auction as a sales platform, the farm's direct sales to individual consumers enrolled in the CSA operation, or individual consumers at the auction, can be counted as sales to qualified end-users (because consumers are qualified end-users, regardless of location). A direct sale to a restaurant or retail food establishment enrolled in the CSA or at the auction can be counted as a sale to a qualified end-user if the restaurant or retail food establishment is located either in the same State or the same Indian reservation as the farm or is located not more than 275 miles from the farm. Considering sales of all food, if the farm's sales to qualified end-users exceeds sales to all other buyers, and the farm's average annual monetary value of sales over the previous 3-year period is less than \$500,000, the farm would be eligible for the qualified exemption.

The definition of a “qualified end-user,” which is derived from section 419(f)(4) of the FD&C Act, explicitly states that the term “consumer” does not include a business. In a circumstance where the CSA farm sells its produce to a separate business that runs a CSA, rather than directly to individual consumers enrolled in the CSA, these sales would not be sales to consumers. The analysis is the same in a circumstance where a farm sells its produce to a separate business that runs a produce auction, rather than directly to specific buyers at the auction. Such sales would only be sales to a qualified end-user if the CSA operation, or the produce auction, fits the definition of a retail food establishment or a restaurant, and meets the location requirements explained previously. As noted in response to Comment 103, FDA is addressing the definition of “retail food establishment” in a separate rulemaking. This rulemaking includes topics related to various types of sales platforms and the definition of “retail food establishment.”

7. Applicable Requirements for Qualified Exemption (§§ 112.6 and 112.7)

(Comment 135) One comment requests that we clarify the cross-references in § 112.6(a) regarding the subparts applicable to farms eligible for the qualified exemption.

(Response) We are amending § 112.6(a) to provide the requested clarification, separating applicable subparts and including their titles.

(Comment 136) Some comments ask whether the required content of the label and point of purchase display requirements in § 112.6(b) includes only the name and address of the farm, or whether the notification must also include a statement notifying consumers of the farm's qualified exemption from the produce safety regulation.

(Response) Label and point of purchase displays required under § 112.6(b) must include the name and the complete business address of the farm where the produce was grown. You are not required to include a statement notifying consumers of your qualified exemption.

(Comment 137) We requested comment on the feasibility of the labeling and point of purchase display provisions in § 112.6(b), particularly in the case of consolidating produce from several farm locations. One comment states that our request was confusing and, assuming that we meant produce from multiple locations of one farm is packed or held at one location, the farm name and business address that is required to be displayed under § 112.6(b) should be the name and business address of the farm that is eligible for the qualified exemption.

(Response) We agree that the relevant farm for purposes of the requirements in § 112.6(b) is the farm where the produce was grown that is eligible for the qualified exemption. We acknowledge that our request for comment was unclear. We did not receive comments suggesting that consolidating (or commingling) produce from different farms would create a feasibility problem with respect to this requirement. We are finalizing the requirement as proposed. If needed, we will consider issuing guidance in the future with respect to the application of this requirement when produce from different farms has been commingled.

(Comment 138) Some commenters question the requirement to disclose the name and business address of a farm eligible for the qualified exemption, citing concerns about biosecurity and unannounced or unplanned visitors to the farm. These comments suggest that

FDA consider alternative approaches. One comment points out that farms that sell to local retailers, restaurants, co-ops or that sell at produce auctions are often assigned a farm identification number as a means of traceability, and suggests that FDA consider relying on such identification. Another comment suggests providing flexibility for farms to choose whether to disclose its phone number, Web site, email address, or business address.

(Response) Sections 112.6 and 112.7 establish the modified requirements applicable to farms that meet the criteria under § 112.5 for a qualified exemption. As explained in the 2013 proposed rule, these requirements are derived from the provisions in section 419(f)(2) of the FD&C Act. We conclude that the use of the term “business address” in section 419(f)(2)(A) demonstrates Congress’ intent to require the farm’s full address, including the street address or P.O. box, to appear on labels or other required notifications when the farm qualifies for the exemption (under § 112.5). The use of the term “business address” in section 419(f)(2)(A) of the FD&C Act contrasts with Congress’ use of a different term, “place of business,” in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the “place of business” labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 419(f)(2)(A)(1) for the farm’s “business address” to appear on the food label (78 FR 3504 at 3550.). Similarly, if Congress had intended that other information (such as a farm identification number, phone number, Web site, or email address) could substitute for the required information, there would have been no need to impose the specific requirement for the business address to be disclosed. Section 112.6(b) does not prevent farms from voluntarily disclosing such additional information if desired. We consider that Congress has already struck the specific balance it intended between farms’ need to control visitor access to the farm for biosecurity purposes and the amount of information required to be disclosed to consumers when a farm is eligible for a qualified

exemption from this rule. Therefore, we are finalizing § 112.6(b), as proposed.

(Comment 139) Comments generally support FDA requiring farms eligible for the qualified exemption to maintain adequate documentation to demonstrate the basis for their qualified exemption, and to make such records available to FDA for inspection upon request. One comment asks that FDA not require farms eligible for the qualified exemption to submit documentation to FDA or to establish and maintain records in accordance with subpart O, and suggests issuing recordkeeping guidance for these farms instead.

(Response) If farms were not required to maintain adequate documentation of their eligibility for a qualified exemption, we would have no way to determine whether a farm claiming the qualified exemption, in fact, met the criteria for that exemption. This could be important, for example, if a farm claiming a qualified exemption is directly linked to a foodborne illness outbreak during an active investigation or if FDA determines, based on conduct or conditions associated with the farm that are material to the safety of the food produced or harvested at such farm, that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak to withdraw the farm’s qualified exemption (see discussion of subpart R in section XXIII of this document). In such circumstance, because the withdrawal procedures in subpart R would only apply to farms eligible for the qualified exemption, we would need to verify the status of a farm to consider appropriate follow-up actions, in accordance with subpart R. Therefore, we are adding a new provision § 112.7 to establish certain recordkeeping requirements in relation to a qualified exemption.

However, we agree that it is not necessary for farms to submit documentation to FDA of their status with respect to the qualified exemption, unless FDA requests such information for official review (for example, during an inspection or investigation). We also do not oppose the use of existing records or documents (for example, documents that are developed and maintained during the normal course of a farm’s business) to document the farm’s eligibility for a qualified exemption, provided that they meet all applicable requirements.

Specifically, in new § 112.7, we are requiring that, if you are eligible for a qualified exemption in accordance with § 112.5, you must establish and keep records required under this provision in accordance with the requirements of subpart O of this part. This means that

the general requirements for maintenance of records in subpart O apply to the records required under § 112.7, except that we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale (§ 112.7(a)). Under § 112.7(b), we are requiring that you must establish and keep adequate records necessary to demonstrate that you satisfy the criteria for a qualified exemption as described in § 112.5. Such records may include receipts of your sales to different buyers; the location of any buyers that are restaurants or retail food establishments; the monetary value of sales of all food, adjusted for inflation using 2011 as the baseline year; and any other documentation that FDA can use, as necessary, to verify your eligibility for a qualified exemption. For example, if you relied on records kept in the normal course of your business bearing on the criteria for the qualified exemption to determine your eligibility, you must retain such records. Under § 112.7(a) we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale. We are requiring that such receipts be dated, however, because the dates of sales are relevant to the computation of eligibility.

Because the criteria for eligibility for a qualified exemption are based on calculations regarding the preceding 3-year period (see § 112.5(a)(2)), you must review your sales annually to confirm your continued eligibility for the qualified exemption for the upcoming year. Under § 112.7(b), we are now specifying that you must establish and keep a written record reflecting that you have performed an annual review and verification of your farm’s continued eligibility for the qualified exemption. Under § 112.161(a)(4), these records must be dated, and signed or initialed by the person who performed the activity documented. Thus, we expect that the annual review and verification document will be signed and dated by the owner, operator, or agent in charge of the farm. We believe it is necessary for the party responsible for the covered farm to attest to the status of the farm with respect to the qualified exemption. As we noted with regard to § 112.161(a)(4) in the 2013 proposed rule, the signature of the individual who made the observation (in this case, the annual review and verification of eligibility for the qualified exemption) will ensure responsibility and accountability. Moreover, any FDA action related to withdrawal of the qualified exemption, if necessary,

would be directed to the owner, operator, or agent in charge of the farm, in accordance with subpart R of part 112. In accordance with subpart O, records required under this provision must be available and accessible to FDA for review upon request within 24 hours (see § 112.166). We will consider issuing guidance on the types of records or documents that may be used to demonstrate a farm's status with respect to the qualified exemption.

We also are establishing an earlier compliance date for the records that a farm maintains under § 112.7 to support its eligibility for a qualified exemption in accordance with § 112.5. Specifically, the compliance date for a farm to retain records to support its status under this provision (e.g., sales receipts and other records as applicable) is the effective date of this rule, i.e., January 26, 2016. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general

compliance date, however. Even with this earlier compliance date for the records supporting eligibility for the qualified exemption, we realize that although the calculation in the codified is based on 3 calendar years, there may be circumstances where a farm will not be required to have 3 calendar years of records as of their general compliance date. Under such circumstances, it would be reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years), and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances. When a farm does not begin operations until after relevant compliance dates have passed, it would be reasonable for the farm to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the farm's number of employees. After the farm has records for one or two preceding calendar years, it would be

reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years) and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances. See also section XXIV of this document.

X. Subpart B—Comments on General Requirements

In proposed subpart B of part 112, we proposed to establish the general requirements applicable to persons who are subject to this part (§ 112.11) and to establish a framework for alternatives to certain requirements established in this part that would be permitted, under specified conditions (§ 112.12). We asked for comment on all provisions in subpart B.

We are finalizing these provisions with revisions (see Table 8). We discuss these changes in this section. We are finalizing the other provisions of subpart B without change.

TABLE 8—DESCRIPTION OF REVISIONS TO SUBPART B

Final provision	Description of revisions
§ 112.12	<ul style="list-style-type: none"> —Revision to refer to new § 112.49, which lists all of the requirements in subpart E for which we allow the use of alternatives. —Revision to eliminate proposed § 112.12(a)(2), consistent with revisions to proposed § 112.54. —Revision to replace “listed in” in proposed § 112.12(b) and (c) with “specified in” to reflect new reference to § 112.49. —Revision to delete “(including the same microbiological standards, where applicable)” and “including agro-ecological conditions and application interval” as unnecessary in light of other revisions. —Revision to clarify in § 112.12(c) that “You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.”

A. General Requirement in § 112.11

(Comment 140) One comment states that the definition and application of the term “reasonably” is unclear in § 112.11, and expresses concern about disagreements between farmers and FDA over what measures are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards and provide reasonable assurances that the produce is not adulterated.

(Response) In § 112.3, we revised our proposed term “reasonably foreseeable hazard” and corresponding definition to now use “known or reasonably foreseeable hazard” to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food. We provide a definition for this phrase as it is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements that we are establishing in part 112. The use of this phrase in the produce safety

regulation is also consistent with its use in the PCHF and PCAF regulations.

(Comment 141) Some comments express concern about the possibility of indirect contamination of covered produce by animal excreta. Comments state that animal fecal matter could reach produce through indirect means, such as irrigation water, runoff, wind-blown dust, or vehicles, particularly in areas where dairies and feedlots exist close to farms producing covered produce. In addition, one comment suggests that farms should be required to assess their farm for the possibility of airborne contamination and should take reasonable steps to avoid it, whereas another comment suggests that farms should assess and mitigate the potential for contamination by runoff from storage areas.

(Response) We agree that animal fecal matter may reach produce through indirect means. However, various other provisions under part 112 (in particular,

within subparts E and F) that focus on the safety of agricultural water, biological soil amendments of animal origin, and other growing considerations already address the routes of contamination that we identified in the QAR. In addition, we have included a requirement in § 112.11, under which covered farms are required to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. As we explained in the 2013 proposed rule, among other things, § 112.11 accounts for the variety of possible circumstances that might arise in which unique farm circumstances

would justify preventive measures. Thus, for example, if a farm's circumstances are such that airborne or runoff fecal contamination is a known or reasonably foreseeable hazard to the farm's covered produce, the farm must take those measures reasonably necessary to prevent introduction of those hazards and to provide reasonable assurances that the produce is not adulterated on account of those hazards.

B. General Comments About Alternatives in § 112.12

(Comment 142) Several comments spoke to the use of alternatives generally. Some comments generally support the allowance for use of alternatives and state that alternatives provide flexibility for covered farms to consider and accommodate the particularities of the commodities, practices and conditions specific to their operations and new scientific information, as it becomes available. On the other hand, some comments express concern that the provision on use of alternatives is unclear, limited in scope, burdensome, and/or is not a realistic option for farmers. One comment states that by requiring farmers to have adequate scientific data or information to show that the alternative would provide the same level of public health protection as the applicable requirement, FDA is placing the burden on farmers and private entities to conduct research on public health risks generally. The commenter believes this is a research and investigative task that FDA should fulfill.

(Response) We agree that the allowance for use of alternatives in § 112.12 provides flexibility for covered farms and disagree that the allowance for the use of alternatives is unclear, too limited in scope, or burdensome. We are providing for the use of alternatives to certain minimum science-based requirements that we have established in part 112 in order to provide flexibility for farms to identify measures that are suitable for their operations, in light of conditions, processes, and practices on their farms and that provide the same level of public health protection as the applicable requirement. FDA has conducted the necessary scientific evaluation to determine reasonable measures that are broadly applicable across a wide range of conditions, and this scientific analysis is reflected in the codified requirements for which alternatives are permitted. Our decision to allow the use of alternatives in lieu of the established requirements does not negate the underlying scientific basis upon which those requirements are derived. Rather,

we determined that, in the case of certain specified requirements, alternative measures may be demonstrated to be scientifically valid, considering the practices and conditions on a farm and circumstances unique to a specific commodity or types of commodities and in light of evolving science. FDA cannot reasonably conduct the necessary scientific evaluation for every set of circumstances that exist on covered farms.

(Comment 143) Some comments assert that FDA should recognize certain guidance (commodity-specific or otherwise), as meeting the requirements for alternatives in § 112.12. See also comments under section IV.F of this document. For example, one comment states the Citrus GAPs developed and implemented by the citrus industry should be recognized by FDA as an acceptable alternative or variance under the produce safety regulation.

(Response) In accordance with § 112.12(c), for any alternative that you use under the provisions of § 112.12(a), you must establish and maintain documentation of scientific data or information in support of your alternative. The scientific data or information may be developed by you, available in the scientific literature, or available to you through a third party. Such scientific support may be derived from or include commodity-specific or other guidance or recommendations (or the science underlying such guidance or recommendations), including those developed by industry, academia, trade associations, or other stakeholders. Such guidance or recommendations, taken together with any other scientific data or information on which you rely, must satisfy the requirements in § 112.12(b) to support the use of the alternative.

We decline the request that FDA recognize certain commodity-specific guidelines developed by industry (such as the Citrus GAPs) as an acceptable alternative to the produce safety regulation. Alternatives are permitted for only certain of the specified requirements of part 112, specifically related to agricultural water, which are listed in § 112.49 and cross-referenced in § 112.12(a), and not for all of the provisions of the produce safety regulation, in general. Moreover, you do not need to notify or seek approval from FDA prior to establishing and using an alternative, and we are revising § 112.12(c) to add a sentence making this clear. To the extent this commenter requests FDA to consider existing commodity-specific industry guidelines under the variance provisions in subpart P, such requests must be submitted by a State, tribe, or foreign government to

FDA using the citizen petition process in § 10.30. We ask industry to work with their relevant State, tribe, or foreign government agencies to submit such requests to FDA, following the provisions in subpart P of part 112.

(Comment 144) One comment suggests that we should expand the entities eligible to establish alternatives beyond States and foreign governments to include entities such as commodity boards and State associations.

(Response) This comment appears to be confusing the provision allowing farms to establish certain alternative standards and processes in subpart B, § 112.12, with the provisions allowing States, tribes, and foreign governments to request variances from one or more requirements of the rule in subpart P, §§ 112.171–112.182. Unlike the variance provisions, the alternative provisions do not require submission of a request by a State, tribe, or foreign government to FDA before a covered farm may use a procedure, process, or practice that varies from the requirements established in this rule. See our discussion of the variance provisions and entities eligible to request a variance in section XXI of this document.

C. Alternatives for Additional or All Requirements

(Comment 145) Several comments ask us to permit the use of alternatives for all provisions of the rule, rather than to restrict the use of alternatives to only those specified by FDA in the regulation. Comments state that it is unclear why FDA limited the use of alternative approaches to only the provisions listed in proposed § 112.12, and argue that the same option of using alternative methods should be applicable to all requirements of the rule. Some comments specifically identified provisions related to animals (subpart I), worker health and hygiene (subpart D), microbial quality requirements (proposed § 112.44(a) for certain uses of agricultural water and proposed § 112.55 for soil amendment treatment processes), and water testing frequency (proposed § 112.45) as additional provisions for which we should allow alternatives.

(Response) As discussed in the 2013 proposed rule, given various considerations, we proposed an integrated approach that draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. In some cases, our standards are very similar to those contained in the Food CGMP regulation, especially where the routes of contamination are well-understood and

appropriate measures are well-established and generally applicable across covered produce commodities (e.g., personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because these measures are well-established, generally applicable, and flexible enough to apply across the spectrum of farming conditions and practices. Moreover, these types of provisions do not involve specific numerical criteria.

In other cases, our standards require the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (e.g., requirements for assessment related to animal intrusion in § 112.83 and inspection of agricultural water system in § 112.42). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because these provisions already provide built-in flexibility as a result of their monitor-and-respond structure. Moreover, these types of provisions do not involve specific numerical criteria.

In still other cases (e.g., sprouts), our standards require the farm to develop a written plan, committing itself to specific measures (e.g., sprout environmental testing and spent sprout irrigation water testing). The use of written plans is important, for example, where the details may change over time and a historical record of the evolution of the measures is important for the operator to assess whether further changes to the measures are needed (e.g., changes or rotation in the sampling sites for sprout environmental testing). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because they also provide built-in flexibility as a result of their structure. Moreover, these types of provisions do not involve specific numerical criteria.

Finally, in certain other cases, we are establishing specific numerical standards against which the effectiveness of a farm's measures would be compared and actions taken to bring the operation into conformance with the standards, as necessary (e.g.,

standards for agricultural water in subpart E; and standards for biological soil amendments of animal origin in subpart F). We rely on the numerical standards approach where our evaluation of current scientific information to determine reasonable measures allows us to establish numerical criteria that are broadly applicable across a wide range of conditions, while acknowledging that such criteria may be tailored, as appropriate, when applied specifically to a commodity (or group of commodities) or under a set of farm practices. It is in the case of this numerical standards approach that an allowance for alternatives may be warranted because, under this approach, there is a concrete measurable standard against which the effectiveness of measures that a farm may take for its operations can be evaluated. In the absence of specific numerical criteria, such as in the case of the other types of provisions explained previously, the use of alternative measures would not be needed because the standards are inherently flexible and already allow the farm to identify and take measures tailored to the practices, procedures, and processes specific to that farm's operations. In addition, alternatives can potentially be warranted for provisions with specific numerical standards in light of their relatively prescriptive nature, the diversity of operations, and the likelihood of new or emerging science.

The relevant numerical requirements in §§ 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i) and 112.46(b)(2)(i) for which we are allowing alternatives include measures that we conclude are appropriate to require under a wide range of conditions. However, recognizing that other measures, if properly validated, may also be suitable, we are providing for the use of scientifically-supported alternatives to these required measures.

With respect to application intervals for certain uses of soil amendments, in the 2013 proposed rule, we proposed specific minimum application intervals for use of raw manure (proposed § 112.56(a)(1)(i)) and compost (proposed § 112.56(a)(4)(i)), and we proposed to allow alternatives to these minimum application intervals. However, in the supplemental notice, we proposed certain amendments to proposed §§ 112.56(a)(1)(i) and 112.56(a)(4)(i) removing the application interval requirements, which makes the corresponding alternatives provisions unnecessary. We are finalizing § 112.56 with some changes, under which

alternatives continue to be unnecessary (see section XIV.G of this document).

For other provisions that include numerical criteria, i.e., §§ 112.44(a) and 112.55, we considered and have decided that the use of alternatives for these provisions is either not appropriate or not necessary. Section 112.44(a) lists certain uses of agricultural water that present a high risk because the conditions associated with those uses of water are conducive to multiplication of pathogens, if present. Even a low number of pathogens introduced into or onto covered produce through contaminated water during those uses could rapidly increase to levels that could present risk of serious adverse health consequences or death. Therefore, we adopt an appropriately protective generic *E. coli* standard (zero detectable generic *E. coli* per 100 mL) for uses of agricultural water specified in § 112.44(a), without further provision for use of an alternative standard. Section 112.55 establishes the microbial standards applicable to the treatment processes established as acceptable in § 112.54. We do not intend § 112.55 to require that farms test their treated biological soil amendments for compliance with the microbial standards. Rather, we intend these provisions to provide the standards against which treatment processes described in § 112.54 must be validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard in § 112.55 without the need to test the end products of their treatments to confirm that the microbial standard was achieved. Because our revisions to § 112.54(a) already provide for the use of any scientifically valid, controlled treatment processes that are demonstrated to satisfy the microbial standard in § 112.55(a) for *L. monocytogenes*, *Salmonella* spp., and *E. coli* O157:H7, further provision under § 112.12 for use of alternatives is not necessary. Similarly, because in revised § 112.54(b) we already explicitly provide for the use of any scientifically valid, controlled treatment process that is demonstrated to satisfy the microbial standards in § 112.55(b) for *Salmonella* and for fecal coliforms (see § 112.54(c)(3)), a corresponding alternatives provision under § 112.12 is not needed. Given these revisions to § 112.54 (see section XIV of this document), we have eliminated proposed § 112.12(a)(3) in finalizing § 112.12(a).

Furthermore, unlike alternatives, variances may be requested for any of the provisions of part 112 under the conditions provided in subpart P, which

involve the submission of a citizen petition by a State, tribe, or foreign government to FDA. This process builds additional flexibility into the rule within limits that allow for FDA to review and approve new approaches outside the alternatives allowed by § 112.12. An allowance for alternatives to be established and used for all provisions of part 112 would make the variance process superfluous.

For these reasons, we do not believe it is appropriate to provide for the use of alternatives for provisions of part 112 beyond those listed in § 112.12.

D. Additional Clarification

(Comment 146) A number of comments ask what is meant by the requirement in § 112.12(b) that an alternative “provide the same level of public health protection as the applicable requirement” and how that is to be measured. Some comments seek clarification on the types of scientific data and documentation necessary to support the use of alternatives.

(Response) Under § 112.12(a), you may establish an alternative to one or more of certain requirements established in subpart E, as specified in § 112.49. Because, for clarification, we have listed all of the requirements in subpart E for which we permit alternatives within new § 112.49, in § 112.12(a), we simply provide a cross-reference to § 112.49 rather than listing out each of the specific requirements for which alternatives are permitted (as we did under proposed § 112.12(a)). As a conforming edit, we are changing two occurrences of “listed in [§ 112.12(a)]” in § 112.12(b) and (c) to read “specified in [§ 112.12(a)].” As specified in § 112.49, in accordance with § 112.12, you may establish and use alternatives to the following specific requirements related to agricultural water: §§ 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i)(A), and 112.46(b)(2)(i)(A).

Sections 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i)(A) and 112.46(b)(2)(i)(A), all establish requirements for the microbial quality, testing, and taking action based on test results when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method.

The § 112.44(b) microbial water quality criteria are a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution) and a geometric mean

(GM) of 126 or less CFU of generic *E. coli* per 100 mL (GM is a measure of the central tendency of your water quality distribution). We are establishing these numerical criteria based on our analysis of current scientific information; it relies on an underlying dataset that has the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water. In addition, our microbial quality criteria use generic *E. coli* as an indicator organism because the intent is to detect measurable levels of fecal contamination and monitor the microbial quality of agricultural water (see discussion on 79 FR 58434 at 58443–445; see also (Ref. 44)). Nevertheless, we acknowledge that circumstances unique to a farm’s operation or commodities may justify the use of an alternative microbial quality criterion (or criteria). Under § 112.49(a), you may establish an alternative to the microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria we established in § 112.44(b). We recommend that the scientific data or information to support the use of an alternative indicator organism include peer reviewed scientific material. An example of a potential alternative microbial quality criterion is use of a different fecal indicator organism as a basis for a GM and STV that are demonstrated to detect measurable levels of fecal contamination in agricultural water used for the purposes identified in § 112.44(b). We expect any such alternative indicator to be as sensitive to the presence and level of fecal pollution as generic *E. coli*. We also expect that any alternative microbial quality criteria that you establish and use, in lieu of the FDA-established criteria, would be supported by an equally robust and rigorous scientific analysis and would be quantitatively demonstrated to be equivalent to the FDA-established criteria, thus “providing the same level of public health protection” as the FDA-established criteria and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated. In addition, for any use of an alternative indicator, you should also consider whether the microbial die-off rate that we established in § 112.45(b)(1)(i), if you choose to apply it in conjunction with your alternative microbial quality criteria, continues to be appropriate.

Similarly, under § 112.49(b), you may establish an alternative to the microbial

die-off rate between last irrigation and harvest and accompanying maximum time interval established in § 112.45(b)(1)(i). The microbial die-off rate of 0.5 log per day to determine an adequate time interval (in days) between last irrigation with untreated water and harvest is established in § 112.45(b)(1)(i). We derived this die-off rate based on a review of currently available scientific literature, and recognize that microbial die-off rates are dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. Our analysis led us to conclude that a rate of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables to include microbial characteristics, environmental conditions, crop type, and watering frequency (see discussion on 79 FR 58434 at 58445–446; see also (Ref. 45)). In final § 112.45(b)(1)(i), we also stipulate a maximum time interval of four consecutive days. Nevertheless, we acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity could result in higher die-off rates between last irrigation and harvest, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation and, therefore, we are providing for the use of appropriate alternative microbial die-off rate(s) and an accompanying maximum time interval. We expect that any alternative microbial die-off rate between last irrigation and harvest, and an accompanying maximum time interval, that you establish and use, in lieu of the FDA-established requirement, would be supported by an equally robust and rigorous scientific analysis specific to the region and crop, and would be quantitatively demonstrated to be equivalent to the FDA-established standard, thus “providing the same level of public health protection” as the FDA-established standard and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated.

In § 112.49(c) and (d), we are providing for the use of alternative water testing frequency in lieu of the FDA-established required number of samples for the initial survey (established in § 112.46(b)(1)(i)(A)) and

the annual survey (established in § 112.46(b)(2)(i)(A)) for the testing of untreated surface water. In the 2013 proposed rule, we proposed specific numerical requirements for frequency of testing agricultural water when used during growing in a direct water application method, and we did not propose to allow alternatives to these testing frequencies. In the supplemental notice, we made these requirements more flexible by proposing a tiered approach to testing untreated surface water used for this purpose (proposed § 112.45(b)), which we are retaining with some changes (final § 112.46(b)). This approach allows farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing. Among the testing requirements in § 112.46(b), we specify that a certain specified minimum number of samples must be collected for the initial and annual surveys. We derived these minimum testing frequencies (*i.e.*, the minimum number of samples) from our statistical analysis based on average variability among surface water sources (*i.e.*, a standard deviation of 0.4) (Ref. 99). In our review of available information (Ref. 44) (Ref. 99), we cited that among the water bodies studied by EPA in developing the recreational water quality criteria, EPA reported an estimate of average standard deviation of log *E. coli* abundance measurements in surface waters is 0.4 (Ref. 100). We acknowledge that circumstances unique to the variability of the microbial quality of a farm's water source may justify the use of an alternative water testing frequency. Therefore, if a covered farm determines through analysis of historical samples that the standard deviation of log₁₀ *E. coli* abundance measurements for their surface water source(s) is less than 0.4 and the difference is statistically significant, then the farm could utilize the lower variability rate to determine the appropriate minimum number of samples necessary to establish and characterize the microbial quality of the farm's water source(s). We expect that any alternative frequency of testing that you establish and use, in lieu of the FDA-established minimum number of samples in § 112.46(b)(1)(i)(A) or 112.46(b)(2)(i)(A), would be supported by an equally robust and rigorous scientific analysis and would be quantitatively demonstrated to be equivalent to the FDA-established testing frequency, thus "providing the

same level of public health protection" as the FDA-established standard and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated. Note also that this allowance for use of an alternative testing frequency relates only to the minimum number of samples required under § 112.46(b)(1)(i)(A) and 112.46(b)(2)(i)(A), and does not extend to the other required elements of testing, specified in § 112.46(b). Likewise, we are not providing for an alternative to the testing frequency specified in § 112.46(b)(1)(i)(B) or (b)(2)(i)(B) for the testing of untreated ground water when used during growing in a direct water application method because ground water sources are less influenced by external sources and, therefore, their water quality is less variable, and we conclude the testing frequency we established in § 112.46(b)(1)(i)(B) and (b)(2)(i)(B) is the minimum necessary to ensure the quality of ground water sources for that purpose.

These provisions for use of alternatives are also responsive to comments that expressed concern about FDA-established quantitative metrics for water quality or testing in the regulation because the commenters believed such generally-applicable numerical criteria may not adequately take into account the unique circumstances related to different commodities or practices. The allowance for alternatives also responds to comments that urged us to incorporate flexibility in any established requirement to allow for appropriate changes to the microbial quality standards based on advances in scientific information on water quality. In light of the specific provisions for which we are allowing alternatives in this rule, we are deleting two phrases from proposed § 112.12 as unnecessary: "including meeting the same microbiological standards, where applicable," and "including agro-ecological conditions and application interval."

The scientific analysis on which you rely may be developed by you, available in the scientific literature, or available to you through a third party. It does not need to be published in a peer-reviewed journal, although we encourage use of peer-reviewed data and information, to the extent available.

FDA is collaborating with partners on research that will add to the scientific information that may help inform specific alternatives. For example, in an effort to support scientific research in the area of agricultural water, one of FDA's Centers of Excellence, the Western Center for Food Safety at

University of California, Davis, partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical and/or region specific. Research areas that have received funding through this process include transfer and survival of organisms on produce after exposure from contaminated surface irrigation water, application of biocide technology on manure-contaminated irrigation water, the potential role of overhead sprinkler irrigation systems in the contamination of produce, and the survival of pathogens during the growing, harvesting, and storage of dry bulb onions after exposure with contaminated water. We intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

(Comment 147) Some comments recommend that FDA specifically state that individual producers or commodities, where there is commonality, should be able to rely on scientifically credible research and publications of commodity boards and trade associations that support potential alternative measures.

(Response) In § 112.12(c), we provide that the scientific data and information used to support an alternative may be developed by you, available in the scientific literature, or available to you through a third party. The scientific support you rely on to justify the use of an alternative can be developed by third parties such as industry or trade associations and commodity boards. You may establish the alternatives under § 112.12 for which you have adequate data and information to support a conclusion that the relevant standards are met in light of your covered produce commodities, practices, and conditions, in accordance with § 112.12(b). Thus, you must take your farm's specific commodities, practices, and conditions into account when evaluating the relevant scientific information. There may be circumstances in which scientific data and information specific to one commodity may be appropriately applied to other commodities, conditions, or practices, allowing that data to support alternatives across multiple commodities, conditions, or practices. However, such generalizations may not always be appropriate. We also intend to

disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

E. Prior Approval of Alternatives

(Comment 148) Some comments request us to provide a voluntary process for pre-approval of alternatives, either by FDA or by recognition of private sector experts. These comments seek protection for farms using pre-approved alternatives, as well as guidance for farmers and researchers to follow when developing alternatives that will meet FDA standards. Similarly, one comment suggests amending proposed § 112.12 to specifically state that use of alternative procedures does not require prior approval by FDA.”

(Response) We are not requiring you to notify or seek prior approval from FDA regarding your decision to establish or use an alternative or to otherwise submit relevant scientific data or information to FDA prior to using an alternative. We are adding an explicit

statement to § 112.12 that FDA pre-approval of alternatives is not required. However, we note that if FDA determines that the use of an alternative is not in compliance with the provisions of § 112.12, FDA may take enforcement or other action, as appropriate. However, we are requiring that you maintain a record of any such scientific data or information, including any analytical information, under § 112.12(c), and make such data and information available to us to evaluate upon request, under § 112.166. We are not establishing a voluntary pre-approval process; however, FDA intends to continue encouraging and supporting development of useful scientific data and information, as well as conducting significant education and outreach related to this rule. We also intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

XI. Subpart C—Comments on Personnel Qualifications and Training

In subpart C of proposed part 112, we proposed minimum standards directed to personnel qualifications and training that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed provisions, including the proposed requirements for training on principles of food hygiene and food safety and the feasibility of the proposed training requirements, particularly with respect to harvest activities.

We are finalizing these provisions with revisions (see Table 9). We discuss these changes in this section. For § 112.23, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss this provision.

TABLE 9—DESCRIPTION OF REVISIONS TO SUBPART C

Final provision	Description of revisions
§ 112.21(a)	—Revision such that required training must be repeated periodically thereafter, at least once annually.
§ 112.21(b)	—Revision to require that personnel must have a combination of education, training, and experience necessary to perform the person’s assigned duties.
§ 112.22	—Revision to change “should” to “must” in § 112.22(b)(1).
§ 112.30	—No change.

A. General Comments

(Comment 149) One comment expresses concern that under subpart C, as proposed, agricultural workers are viewed as “disease vectors” and a “potential pathway for contamination” rather than as “fundamental partners.”

(Response) Agricultural workers are invaluable and fundamental partners in ensuring food safety on the farm. However, as discussed in the 2013 proposed rule, it is well-documented in the scientific literature that bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food. In addition, our QAR demonstrates that humans (*i.e.*, workers and visitors) are potential carriers of foodborne pathogens and can be a source of contamination of produce. Therefore, farm workers need training on the importance of health and hygiene. In addition, employees need training on subparts C through O that are applicable to the employee’s job

responsibilities and on how to recognize and prevent potential contamination problems (*e.g.*, a leafy green vegetable contaminated with manure, contaminating the water supply during sample collection for testing, etc.) and to be trained to know what to do when those situations present themselves. The farm worker is a key component in the food chain for ensuring the safety of covered produce.

(Comment 150) Several comments object to proposed subpart C based on the size of the farm or number of full-time employees.

(Response) We have considered the burden to small businesses and provided sufficient flexibility within the final rule to be practicable for different sizes and types of businesses, including for small and very small businesses. See section IX.C of this document. We do not agree that additional flexibility should be incorporated by exempting farms from the training requirements

based on the size of the business. Training farm workers is important regardless of the size of the farm.

(Comment 151) Two commenters question the need for the provisions in subpart C and state that a farm should instead be responsible for developing its own training programs that are shown to meet specified regulatory outcomes.

(Response) The requirements in part 112 do not preclude farmers or industry associations from developing training materials or programs uniquely suited to their commodities or operations; however, we have determined that the training must cover the specified topics in order to ensure that farm workers have sufficient training.

(Comment 152) Some comments recommend that we develop a process or system whereby workers who are properly trained would receive a “training certificate” or a “food safety certificate,” which commenters believe would be particularly useful for workers

who work on multiple farms during the year. These comments suggest that such certificates may be received (and updated) after undergoing training using an FDA-approved standardized curriculum or an equivalent curriculum. According to these comments, such a certificate could be valid for a harvest season or a calendar period, such as one year, and could also be valid for multiple crops of a similar nature, such as all deciduous tree fruits. Some comments state that a certificate should not obviate the need for training upon hire, at the beginning of each growing season and periodically thereafter, but could provide covered farms with a better sense of the food safety capacity of their workforce.

(Response) We see the value of workers receiving a “training certificate” or a “food safety certificate” documenting the training they have received. However, at this time, we are not requiring use of such a program (either as a new requirement or to satisfy any of the requirements of this rule), nor are we able to develop such a system or recommend a specific certification process or certification body to enable such an approach. Note, under § 112.30(b)(1), you must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the person(s) trained. We are willing to work with an organization that is interested in developing and implementing a training certification program, including through the PSA and SSA and using corresponding training materials.

(Comment 153) Some comments urge the use of Web site(s) (or web-based training) for educating employees about food safety and hygiene as a means to reduce the cost burden of training requirements, especially for smaller farms. One comment notes the advantages of using online resources, including that it can be continuously updated over time.

(Response) Internet-accessible training materials are a convenient way for workers, supervisors, and other farm staff to obtain rapid access to training materials and other resources. We are considering whether and to what extent the Alliance courses can be made available online or offered as Internet-based training. At a minimum, we will make the standardized curriculum available online.

(Comment 154) One comment (from a foreign government) requests that we provide training materials or guidelines to the foreign government in a timely manner so relevant parties (including

manufacturers, exporters, and regulators) can understand and properly implement the rule.

(Response) We are working to ensure the Alliance courses and training resources to be generated by the NCC and RC are consistent with the requirements of this rule. We intend to publish a notice of availability of these documents in the **Federal Register**, and our domestic and foreign stakeholders will be informed of and have access to these documents. We will partner with our foreign government counterparts as well as industry stakeholders to identify areas for outreach and technical cooperation to achieve greater understanding and implementation of the Produce Safety standards. In this regard, organizations such as the PSA, SSA, and JIFSAN can aid in providing appropriate qualification and training materials for foreign governments as well as training of foreign industry entities.

B. Qualification and Training for Personnel Who Handle (Contact) Covered Produce or Food-Contact Surfaces (§ 112.21)

(Comment 155) Some comments suggest exceptions to proposed subpart C based on types of employees. Although many commenters believe all types of employees should be covered by the provisions, including temporary, part-time, seasonal, and contracted employees, some other commenters believe complying with proposed subpart C would be prohibitively difficult and, therefore, certain types of employees should be exempted. Comments state that requiring seasonal training for all employees, including long-term, non-seasonal workers, is unnecessary and wasteful. One commenter believes that training should not be required “periodically” but instead only for new hires, when rules are changed, or when problems are observed. Another comment is additionally concerned that, because the term “season” is not defined, the mandatory training provisions might be interpreted to require a separate training for each crop, some of which may have short planting-harvest cycles.

(Response) We continue to believe that adequate and appropriate training of all personnel who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, is an essential component of standards for produce safety. Therefore, we disagree that certain types of farm workers should be exempt from a requirement that they receive training. Rather, we agree the content of the required training can be tailored to the

specific duties of the type of farm worker or supervisor. Under § 112.21, all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors must receive training that is appropriate to the person’s duties (§ 112.21(a)), and must have a combination of education, training, and experience to perform their assigned duties in a manner that ensures compliance with part 112 (§ 112.21(b)).

With respect to the comments about when training should be conducted, all personnel who contact covered produce and food-contact surfaces must receive training when hired, before they participate in the growing, harvest, packing or holding of covered produce in which they contact covered produce, and must be periodically reminded about the need to follow these practices through refresher training. However, we acknowledge the concerns raised by commenters about our proposed requirement that training must be conducted at the beginning of each growing season, if applicable. We agree that requiring all personnel to receive training at the beginning of each growing season could be unduly burdensome for certain farms, such as those that grow multiple crops annually, grow crops with short harvest cycles, or grow certain types of year-round crops with no set growing season. Therefore, in lieu of the proposed requirement to train workers at the beginning of each growing season if applicable, we are revising the requirement to specify that periodic training must be conducted at least once annually. This requirement is in addition to the training that is conducted at the time of hiring. Periodic training can be conducted at a time that is appropriate, but must be conducted at least once annually. This allows farms to take into account such issues as the crop cycle, type and number of crops grown and harvested, and the timing when employee was hired and initially trained. As discussed in the 2013 proposed rule, periodic training serves to remind employees of the proper procedures including any changes in those procedures. Such updates may not need full training sessions, but only short descriptive sessions to ensure that all personnel remain aware of all procedures necessary to maintain the safety of produce.

(Comment 156) One comment asks us to recognize that “education or experience” can replace the need for specific training.

(Response) As discussed in the 2013 proposed rule, the standards in subparts

C through O often involve action by farm personnel (*e.g.*, assessment for animal intrusion, inspecting agricultural water system) that require specific knowledge, skills, and abilities, without which the standard cannot be properly achieved. Therefore, it is important those farm personnel have the training so they will have the necessary knowledge, skills, and abilities to perform their duties. In addition, experience at farming does not necessarily convey knowledge of food safety, particularly of microbial food safety hazards, and therefore specialized training is needed to address the specific concerns of on-farm food safety. Consequently, we disagree with the suggestion that education or experience can serve as a substitute for appropriate training.

(Comment 157) Some comments seek clarification on whether “pick-your-own” farms would be required to provide training to customers who pick their own produce.

(Response) We are establishing requirements for training of on-farm personnel. We are not establishing any requirements for training of visitors or customers at any farm, including at a “pick-your-own” farm. However, we note that this rule requires, in § 112.33, that covered farms make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures, and make toilet and hand-washing facilities accessible to visitors. As discussed in section XII of this document, for example, a “pick-your-own” farm could comply with these requirements by indicating the location of restrooms and hand-washing facilities that are accessible to visitors, and by clearly posting such information where it is likely to be seen and read by visitors at the beginning of their visit to the farm, such as near the entrance or a cash register of the farm.

(Comment 158) One comment states people harvesting remnant crops following the main harvest for non-profit organizations (referred to as “gleaners”), often for donation to food banks, should not be subject to training requirements. Another comment states that in scenarios where a farm has completed its main harvest, and a third party purchases and harvests the remaining unharvested crop, it should be the responsibility of the remnant harvesting entity to ensure that their harvesters are appropriately trained.

(Response) An operation that harvests crops but does not grow them, such as a “gleaner” operation or other remnant

harvester operation, may meet the revised definition of “farm” as established in the PCHF regulation and as we are establishing it in this rule (see definition of “farm” in § 112.3(c)). While we are not exempting operations that harvest remnant crops from the provisions of part 112, we believe that it is likely that most such operations (including those who do so for donation to food banks) will not be covered by this rule because they will have \$25,000 or less in annual sales of produce or will be eligible for a qualified exemption. Specifically, in response to the comment about harvesting remnant crops, we expect those farms conducting the covered activities (harvesting of remnant crop and any subsequent packing or holding) to comply with the applicable requirements of the rule. Personnel employed by such entities must be trained appropriately.

(Comment 159) One comment states that, when a farm contracts with another company for a contracted harvest crew, the company providing the harvest crew should be responsible for the initial, more comprehensive, food safety training, and the harvest crew should be made aware of food safety specifics at each farm at which they are harvesting, including standard operating procedures specific to the farm.

(Response) Where a covered farm uses contracted harvest crews to harvest covered produce on the farm’s behalf, the farm continues to be required to fulfill all relevant duties applicable under this rule. Thus, the farm is responsible for ensuring that the harvest crew has received required training. The farm may rely on the company that provides the harvest crew to provide or conduct the training, or the farm may provide or conduct the training. For example, if the harvest crew company provides training to workers who move from farm to farm under the employment of the harvest crew company, farms that employ such harvest crews may choose to rely on the harvest crew company to provide or conduct the training, request relevant certification from the harvest crew company, and maintain appropriate records to demonstrate compliance with the applicable training requirements.

In addition, as discussed previously, an operation that harvests crops but does not grow them, such as a contract harvest crew company, may meet the revised definition of “farm” as established in the PCHF regulation and as we are establishing it in this rule (see definition of “farm” in § 112.3(c)). Thus, if they are covered farms, contracted harvest crew companies also have duties to comply with this rule.

(Comment 160) Some comments object to the “education or experience” clause in proposed § 112.21(b). Comments argue the level of education or experience that would satisfy this requirement is unclear, and it would unnecessarily limit the pool of workers eligible to work on farms. One comment further notes a requirement for “experience” would, by definition, preclude inexperienced workers from seeking such employment, although training could provide the knowledge necessary to perform tasks appropriately. A few comments recommend revising this provision to use the phrase “must have the training, education or experience to perform the person’s assigned duties” whereas others recommend incorporating flexibility for personnel to be “otherwise qualified through job experience”, in the same manner as allowed in 21 CFR parts 120 and 123 and in the proposed human preventive controls rule.

(Response) We are revising this provision to require that personnel have “a combination of education, training, and experience necessary to perform the person’s assigned duties in a manner that ensures compliance with this part.” This provides flexibility for how personnel are qualified to perform their duties. Depending on the job duties, this could include training (such as training provided on-the-job), in combination with education, or experience (*e.g.*, work experience related to an employee’s current assigned duties).

(Comment 161) Several comments support making the trainings easily accessible and understood by all employees, regardless of native language or education level. One comment asks that we provide, via guidance, specific examples, such as pictograms, that can help facilitate understanding across language barriers.

(Response) We recognize that the goals of training cannot be achieved if the persons receiving the training do not understand the training. Training could be understood by personnel being trained if, for example, it was conducted in the language that employees customarily speak and at the appropriate level of education. In some cases, it may be necessary to use easily understood pictorials or graphics of important concepts. The PSA and SSA are developing training materials to be easily understood by farm workers of different languages, literacy, and educational levels by using pictorials or graphics of important concepts, along with offering the materials in multiple languages.

C. Training Personnel Who Conduct a Covered Activity (§ 112.22)

We are revising § 112.22(b)(1) to replace “covered produce that should not be harvested” with “covered produce that must not be harvested” to reflect the mandatory nature of the requirements in this rule and specifically, the requirements of § 112.112.

(Comment 162) Several comments request that we recognize existing food safety education and training programs that either meet or exceed the PSA materials, as an efficient way to gain compliance with subpart C. One comment asks that FDA allow existing educational programs that wish to gain equivalency with PSA materials to be able to modify their materials and program structure to fit the PSA learning objectives, rather than be required to adopt the exact format and materials developed by the PSA. The commenter further requests us to provide guidance on how existing programs can obtain equivalency with the PSA standardized curriculum, when it becomes available. Still other comments request that FDA develop approved curricula to meet the training requirements under subpart C. Yet another comment asks whether and what accreditation FDA would accept for training of on-farm trainers.

(Response) See our response to Comment 3. The PSA and SSA training materials will include a standardized curriculum. FDA is working with the PSA and SSA to ensure that FDA will be able to recognize this curriculum, once developed, as adequate (see requirement under § 112.22(c)). We expect this standardized curriculum to be available in time for covered farms to be able to use it, as they work toward achieving compliance with the produce safety regulation. Under § 112.22(c), at least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA. Accordingly, successful completion of training using the standardized curriculum by your farm personnel (at a minimum, by one supervisor or responsible party for your farm) is sufficient to satisfy the requirements of § 112.22(c). Alternatively, at least one supervisor or responsible party for your farm must successfully complete training using any other training material or program, provided such training is at least equivalent to the standardized curriculum, and all of your other farm personnel must be trained in accordance

with § 112.22(a) and, as applicable, § 112.22(b). We encourage trainers outside the PSA and SSA to evaluate their courses against the PSA and SSA materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance courses. We agree that existing programs can modify their training program structures and curriculum to ensure consistency with, and provide at least an equivalent level of instruction to, the standardized curriculum without necessarily adopting the PSA or SSA training structure or materials. We also intend to fund the development of certain alternate training programs for specific target audiences through cooperative agreements. The agency will work closely with the participants in those agreements and expects to recognize the training programs that are developed through these collaborations. We intend that the standardized curricula being developed by the Alliances and the alternate curricula to be developed through cooperative agreements are the only ones that will be officially recognized by the FDA. We emphasize, however, that official recognition by FDA is not required for training curricula to be “at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration” as stated in § 112.22(c). Any training curricula that are at least equivalent to the officially recognized curriculum satisfy this requirement. We have no plans to establish an accreditation system for the training of on-farm trainers, although it is an area that is being explored through the PSA and SSA.

(Comment 163) Some comments ask for clarification on the content of the food safety training based on the standardized curriculum recognized by FDA. One comment asks FDA to better define the elements of “food hygiene and food safety” that should be covered in comprehensive training, and offers suggestions on such elements.

(Response) FDA concludes that the broad topic areas addressed in § 112.22(a) are those minimum topic areas necessary to be covered during training for all employees who handle or contact covered produce. Training in the principles of food hygiene and food safety is a necessary component of such required training because it will provide an overall framework for job performance. We expect the standardized curriculum, when it becomes available, will provide information about the content to be

covered under these minimum required topic areas, including with respect to principles of food hygiene and food safety.

D. Records Related to Personnel Qualifications and Training (§ 112.30)

(Comment 164) One comment states it is not reasonable for operations to be required to keep training records for personnel who received training at another operation or for contract workers (e.g., harvest crew, sanitation crew). This comment recommends revising proposed § 112.30(b) to be limited to records of trainings performed or paid for by the operation, supplemented by additional records providing a rationale for personnel who did not receive such training at or by the operation.

(Response) We are not making the requested change. A covered farm must ensure and keep records that document the required training received by personnel, regardless of whether the training is offered and the applicable records are generated by the farm or by another entity, such as the harvest crew company (see also our response to Comment 159). The records required under § 112.30(b)(1) are intended to enable a covered farm to track the content and timing of training personnel have received, identify personnel and training topics for periodic updates, and identify personnel that have the necessary training for assignment to certain responsibilities; and to allow FDA to verify compliance with the rule’s training requirements.

XII. Subpart D—Comments on Health and Hygiene

In subpart D of proposed part 112, we proposed minimum standards directed to health and hygiene that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed standards directed to health and hygiene, including provisions related to use of gloves and antiseptic hand rubs (commonly referred to as “hand sanitizers”); provisions related to hand-washing; and our proposed requirements related to worker health.

We are finalizing these provisions with revisions (see Table 10). We discuss these changes in this section.

TABLE 10—DESCRIPTION OF REVISIONS TO SUBPART D

Final provision	Description of revisions
§ 112.31	—Fixed grammatical error in § 112.31(a) (deleted “a” before “communicable illnesses”).
§ 112.32(b)	—Updated list of examples of hand drying devices in § 112.32(b)(3) (deleted “clean cloth towels” and added “electric hand dryers”).
	—Revision to § 112.32(b)(3) to allow the use of “other effective surfactants” in lieu of soap during hand-washing.
	—Added new § 112.32(b)(5) to require removing or covering hand jewelry under certain circumstances.
	—Added new § 112.32(b)(6) to prohibit eating, chewing gum, and using tobacco products in areas used for covered activities (except that drinking beverages is permitted in designated areas).
§ 112.33	—Deleted proposed § 112.33(a) defining “visitor” (moved definition of visitor to § 112.3(c)).

A. General Comments

(Comment 165) We received several comments on this subpart, many of which support the proposed provisions under subpart D. Many commenters agree that personnel who work in an operation in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to protect against contamination. Several comments note the importance of health and hygiene and generally believe that the proposed provisions are similar to those already established and commonly recognized as basic requirements for personal sanitation and hygiene. Another comment supports the promotion of hand hygiene as a mandatory element for self-protection and protection of others for the agricultural sector, including among small farms.

(Response) Health and hygiene of personnel and visitors is a crucial component of produce safety, and we are establishing certain standards that are reasonably necessary to prevent personnel and visitors from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact substances in subpart D of part 112. Unless exempted or subject to any applicable modified requirements, covered farms conducting covered activities on covered produce are required to comply with the requirements for health and hygiene in subpart D.

(Comment 166) One comment suggests that FDA recognize that postharvest treatment of food is an inadequate substitute for the fundamentals of hygiene.

(Response) FDA generally agrees with this statement and encourages all firms to use appropriate hygienic practices in the production of produce, regardless of whether they are subject to this rule. Under § 112.2(b) covered produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption

from the requirements of part 112. In addition, produce that is rarely consumed raw (*i.e.*, it is typically cooked before consumption) is not subject to this rule under § 112.2(a). Thus, by definition, covered produce is produce that is not likely to receive a postharvest processing or treatment step that will adequately reduce the presence of microorganisms of public health concern. Therefore, personnel and visitor hygiene, while always important in the production of food, are particularly important with respect to covered produce under this rule. Our rule takes an approach consistent with the requirement in section 419(c)(1)(A) that this regulation set forth the procedures, processes, and practices the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables.

B. Ill or Infected Persons (§ 112.31)

(Comment 167) Some comments seek clarification on compliance with this provision and express concerns about the feasibility of continuously monitoring workers for signs of illness. Some comments state that ill workers do not notify supervisors of their illness, that workers hide their illness due to fear of not being able to work, and that employees may not be aware that they have an infectious disease until days have passed and covered produce has already been handled.

(Response) We are requiring you to take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea) (§ 112.31(a)). We are correcting a grammatical error that appeared in this section as proposed by deleting “a” before “communicable illnesses.”

One measure that you must take to satisfy this requirement is to exclude any person from working in any

operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person’s acknowledgement, or observation (for example, by a supervisor or responsible party) is shown to have, or appears to have, an applicable health condition, until the person’s health condition no longer presents a risk to public health (§ 112.31(b)(1)). Note also that all personnel who handle covered produce during covered activities or supervise such activities must receive training on the importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance (§ 112.22(a)(2)).

Another measure we require is that you instruct your personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition (§ 112.31(b)(2)). Consistent with the training requirement in § 112.22(a)(2), these requirements emphasize that individual workers have a responsibility to take action to prevent contamination due to their own illness or infection. Although we have not specified, under § 112.31(b)(1), when or how often workers’ health must be considered, we expect covered farms to take reasonable measures, as necessary, to exclude infected or ill employees from working in operations that may result in contamination of covered produce until the person’s health condition no longer presents a risk to public health. For example, where harvesting of covered produce is conducted over multiple days, a farm could have a supervisor inquire about the health of the harvest crew daily when they report to work, prior to allowing the crew to enter the field to begin harvesting, and make appropriate decisions about whether

any workers should be reassigned to different duties.

We provided other examples in the 2013 proposed rule. As one example, if an employee tells you that his or her physician (by medical examination) has diagnosed that the employee has a fever, and the employee normally handles your covered produce, you must take steps to ensure that the employee does not come into contact with your covered produce because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. FDA is not requiring (nor are we authorizing) you to obtain medical records of your employees to determine or verify their applicable health condition(s).

Similarly, if you see that an employee has an open wound, boil, cut, or sore, and the employee normally handles covered produce, you must take steps to ensure that he or she is excluded from handling covered produce if the wound, boil, cut, or sore could be a source of microbial contamination. However, the employee may be allowed to handle covered produce, for example, if the wound, boil, cut, or sore is adequately covered (*e.g.*, by an impermeable cover) in a manner that prevents it from becoming a source of contamination for the covered produce. In addition, note that applicable health conditions do not include non-communicable diseases such as cancer, diabetes, or high blood pressure, or non-communicable conditions such as pregnancy.

C. Personnel Hygienic Practices (§ 112.32)

(Comment 168) Some comments raise concern with the provision that would require washing hands after certain specified occasions. Some comments point out that some farmers rely on working animals, and state that a requirement to wash hands after every contact with animals would be impractical and unnecessary, especially when contact with produce following contact with animals, is not likely or expected. Instead, these comments recommend requiring hand-washing before handling produce and throughout handling, as needed, taking into account the presence of debris or other unsanitary conditions. Another comment incorrectly interprets proposed § 112.32(b) to require that hands must be sterile and free of microbial contaminants, and seeks clarification on the type(s) of microbial pathogens that must be avoided.

(Response) Section 112.32(b)(3) requires (in relevant part) the washing of hands thoroughly, including scrubbing with soap (or other effective

surfactants) and running water, on specified occasions, including as soon as practical after touching animals (such as livestock and working animals) or any waste of animal origin. Hand-washing, when done effectively, can significantly reduce both resident bacterial populations (such as on the hands of a worker who may not realize he or she is ill or infected) and transient microbial contamination (such as bacteria, viruses, and parasites that gets onto hands through contact with the environment). We are not requiring hands to be sterile and free of microorganisms. Instead, we are requiring reasonably necessary steps to be taken to reduce the likelihood of potential presence of pathogens. Hand-washing is a key control measure in preventing contamination of covered produce and food-contact surfaces.

We are not requiring personnel to wash their hands *immediately* after touching animals or after *every* contact with animals or their waste. Rather, we require washing hands as soon as practical after contact with animals or any waste of animal origin, a requirement aimed at minimizing the potential for transmission of pathogens from animals onto produce. We recognize the importance of working animals on farms. This provision ensures that farms are cognizant of the potential for animals (including livestock and working animals) or their waste to be a source of contamination of produce, and that appropriate measures are taken to minimize or avoid such potential. Personnel working with animals must know when and how to wash their hands. In addition, under § 112.32(b)(2), which requires taking appropriate steps to minimize the likelihood of contamination when in direct contact with working animals, particular attention should be given to clothing, especially footwear, to ensure that fecal material from barns and barnyards does not contaminate covered produce and food-contact surfaces.

Note also, consistent with the revision to § 112.130(b)(3), we are making a revision to the examples of hand drying devices in § 112.32(b)(3) to list “single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices.” We refer you to section XVII of this document for the corresponding discussion. In addition, we are updating this provision to allow the use of other effective surfactants in lieu of soap that is required during hand-washing. This revision is consistent with § 112.130(b)(1), which we are retaining as proposed.

(Comment 169) One comment suggests that FDA encourage use of

fluorescent substances to highlight unwashed or neglected areas of the hands.

(Response) We are not requiring this practice in this rule. However, technologies such as these, when used in conjunction with appropriate training, may be a useful tool to teach hand hygiene (Ref. 101) (Ref. 102).

(Comment 170) One comment seeks more specific provisions under proposed § 112.32(b)(4) on glove use, specifically the type of gloves to be used and the meaning of “sanitary condition.” The commenter notes that, for example, farm workers in California use both disposable gloves and reusable gloves for different activities, and that whereas disposable gloves can be easily replaced, cotton or leather gloves are more difficult to replace frequently and to determine whether they are in a sanitary condition.

(Response) We are not requiring the use of gloves, or that gloves, when used, be of a certain type (*e.g.*, disposable, cotton, leather, or other types). Under § 112.32(b)(4), if gloves are used in handling covered produce or food-contact surfaces, you are required to maintain the gloves either in an intact and sanitary condition, or else replace them. We recognize that heavier gloves are commonly used during certain covered activities, such as harvesting (for example, of tomatoes or peppers), to protect workers’ hands from cuts or blisters. We are not aware of any reason to require that covered farm workers use only certain types of gloves, and therefore we decline to do so. We recognize that different types of gloves, or no gloves, may be appropriate depending on the circumstances, and § 112.32(b)(4) as written provides covered farms with flexibility to choose the practice that is appropriate for their operations. Regardless of the type of gloves that a farm may choose to use, gloves would not be in an intact and sanitary condition if, for example, they have visible feces on them or have holes or cracks in them such that soil or contaminants can enter the inside of the glove.

(Comment 171) Some comments recommend that FDA expand requirements for hygienic practices to include prohibitions on jewelry, gum, spitting, chewing, eating, and drinking (excluding drinking water) in growing areas.

(Response) We are revising § 112.32(b) to add two new provisions. New § 112.32(b)(5) requires removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand. This provision

addresses the potential biological hazard posed by jewelry that is not effectively cleaned and could serve as a harborage for pathogens. New § 112.32(b)(6) requires not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas). Eating, chewing gum (and potentially spitting the gum out), and using tobacco products (and potentially dropping used cigarettes or cigars or spitting chewing tobacco juice) all constitute potential avenues of dissemination of enteric foodborne pathogens (Ref. 103) (Ref. 104) (Ref. 105) (Ref. 106). However, we are not prohibiting the consumption of beverages by personnel in designated areas. For example, drinking beverages is often necessary to prevent dehydration during outdoor activities, including in growing areas. The best practice is to have water (or other beverage) and drinking cups readily accessible to workers near an area where they are working outdoors, such as at the end of a row of covered produce being harvested.

These requirements are consistent with, although not identical to, the requirements for food facilities, under the PCHF regulation (§ 117.10(b)(4) and (b)(8)), and our long-standing provisions in the Food CGMP regulation (§ 110.10(b)(4) and (b)(8)).

In addition, these requirements are consistent with the Industry Harmonized GAPs standard for field operations and harvesting, which recommends that operations have a policy that personal effects such as jewelry, watches, or other items must not be worn or brought into production areas if they pose a threat to food safety. This standard also states that smoking, chewing, eating, or drinking (other than water) should not be permitted in any growing areas, and recommends that operations adopt a policy to prohibit these practices except in designated areas (Ref. 49) (Ref. 50). Section 112.32(b)(5) is also similar to provisions in another industry guidance (Ref. 60) and the Codex Guide. Section 112.32(b)(6) is also similar to provisions in the AFDO Model Code (Ref. 62), a marketing agreement (Ref. 40), and the Codex Guide. In addition, the AFDO Model Code (Ref. 62) and a marketing agreement (Ref. 40) direct farms to have a written policy regarding jewelry. We believe many farms are already implementing the measures required by § 112.32(b)(5) and (6) based on these industry recommendations, and we believe they are practical measures for produce safety that are reasonably necessary to prevent the introduction of

known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

D. Visitors (§ 112.33)

(Comment 172) One comment questions whether or how proposed § 112.33 would help prevent the spread of foodborne illness, especially if the visitor does not come into contact with the food and merely tours the facility and observes the farm's operations. Other comments express concern that these provisions hold the farm accountable for the actions of customers who visit their operation. One of these comments requests that we establish a requirement that farm visitors who are sick must not enter areas where covered activities are taking place, or that visitors who will be handling covered produce must notify a farm of any significant health conditions before entering the farm.

(Response) As with workers, visitors can transmit microorganisms of public health significance to covered produce or food-contact surfaces. For example, a visitor who is ill or infected touring a produce field during a harvesting activity can be an indirect source of contamination, even if the visitor does not come into direct contact with the covered produce or a food-contact surface. We recognize that visitors to a farm often enter areas where covered produce is grown or harvested, particularly in the case where a farm offers consumers the opportunity to pick their own fruits or vegetables. Section 112.33 is not aimed at restricting visitors from entering your farm as part of the routine course of your business. Rather, they are measures that reasonably minimize the potential for visitors to become a source of produce contamination, provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

As noted in response to Comment 114, we have included a definition for the term "visitor" within § 112.3(c) using the text in proposed § 112.33(a). As a result, we have eliminated proposed § 112.33(a), and we are renumbering proposed § 112.33(b) and (c) as final § 112.33(a) and (b), respectively.

Under final § 112.33(a), you must make visitors aware of your policies and procedures to protect covered produce and food-contact surfaces from contamination by people, and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. For example, a farm

could comply with § 112.33(a) by explaining the importance of health and personal hygiene, including proper hand-washing procedures and the potential for contamination from ill or infected visitors, to all visitors who are likely to come into contact with covered produce or food-contact surfaces, at the beginning of a visitor's visit. As another example, a farm could clearly post the rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor's visit, such as near the entrance or cash register at a "pick-your-own" farm operation. As another example, a farm might choose to voluntarily establish a policy that visitors who are visibly ill may not enter specific areas of the farm (and/or during specific times, such as during harvesting). We are not requiring farms to establish such a policy, however. For a farm with such a policy, informing visitors of the policy and taking steps to implement it would satisfy the requirements of § 112.33(a).

We believe that the requirements of § 112.33 are those reasonably necessary to prevent contamination of covered produce by visitors. As such, we decline to include requirements that apply directly to visitors.

(Comment 173) Other comments express concern with proposed § 112.33(c). Comments state that requiring full-scale bathroom and hand-washing facilities in the fields would not be practical, and points out that many operations can provide only portable toilets and hand sanitizers for visitors. Stating that it is common courtesy for farms to provide toilet facilities to visitors, another comment finds FDA's requirement related to this issue unnecessary for the purpose of ensuring food safety. This commenter also states that having personnel and visitors share the same toilet facilities would increase the likelihood of spreading infections. Another comment requests that proposed § 112.33(c) include a "grandfather clause" for current farms.

(Response) As discussed in section XVII of this document, under the requirements outlined in subpart L of part 112, covered farms are required to have clean and well-maintained toilet and hand-washing facilities for their personnel as a measure to prevent contamination of produce and food-contact surfaces (see §§ 112.129 and 112.130), and § 112.33 establishes only the incremental requirement that such facilities must be made accessible to visitors. This provision does not prescribe the number, specific location, type, or designated use of such facilities. Therefore, it is not required for a

covered farm to provide “full-scale” bathrooms in the field for visitors to use; nor is it required for a covered farm to provide separate toilet or hand-washing facilities for visitors and for farm personnel. For example, portable toilets may be a feasible option for use by personnel and/or visitors when in the field. Note, however, that the general requirements that apply to toilet facilities and hand-washing facilities are specified in §§ 112.129 and 112.130, respectively. As noted in the 2013 proposed rule, a farm could comply with the requirements of § 112.33 by, for example, indicating the location of restrooms and hand-washing facilities that are accessible to visitors and clearly posting rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor’s visit, such as near the entrance or cash register at a “pick-your-own” farm operation. Given the minimal nature of this requirement, we disagree that this provision causes undue economic burden to farms or is impractical, or that a specific exemption(s) is warranted for certain farms. We also disagree that visitors and personnel sharing the same restrooms and/or hand-washing facilities would increase the risk of spreading communicable disease and thereby contaminating covered produce. Compliance with the provisions of the rule related to hand-washing requirements and hygiene generally for personnel (§ 112.32), adequacy of toilet and hand-washing facilities (§§ 112.129 and 112.130), and visitors (§ 112.33) are expected to minimize risk, not to increase risk. Any possible increase in use of toilet or hand-washing facilities caused by visitors should not increase the risk presented to covered produce if

the farm is in compliance with these relevant provisions.

XIII. Subpart E—Comments on Agricultural Water

In subpart E of proposed part 112, as described in the 2013 proposed rule and the supplemental notice, taken together, we proposed science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. In addition, in the supplemental notice, taking into account comments on the 2013 proposed rule, we proposed to amend our water quality and testing requirements in proposed §§ 112.44 and 112.45 (79 FR 58434 at 58440–58457).

In the 2013 proposed rule and the supplemental notice, we asked for comment on our proposed provisions, including the proposed requirements that all agricultural water must be safe and of adequate sanitary quality for its intended use; the measures that must be taken with respect to agricultural water sources, water distribution systems, and pooling of water; the treatment of agricultural water; the microbial quality standards required for agricultural water used for certain specified purposes; the testing required for agricultural water, including our tiered approach to testing; the measures that must be taken for agricultural water used during harvest, packing, and holding activities for

covered produce; and the requirements regarding records related to agricultural water.

In this section of this document we discuss comments we received on the standards directed to agricultural water in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the new and amended proposed provisions in the supplemental notice.

We are finalizing these provisions with several changes. We re-structured subpart E to better organize the requirements related to agricultural water into the following categories: (1) General requirements for agricultural water quality (§ 112.41); (2) Inspection of agricultural water distribution systems and pooling of water (§ 112.42); (3) Treatment of agricultural water (§ 112.43); (4) Specific microbial quality criteria for certain uses of agricultural water (§ 112.44); (5) Follow-up measures or corrective actions if agricultural water does not meet applicable requirements, including microbial quality criteria (§ 112.45); (6) Frequency of testing of agricultural water (§ 112.46); (7) Who must perform water tests and what analytical methods must be used (§ 112.47); (8) Agricultural water that is used during harvesting, packing, and holding (§ 112.48); (9) Permitted alternatives (§ 112.49); and (10) Records requirements (§ 112.50). In Table 11, we identify the new final provision corresponding to each proposed provision, and describe the nature of substantive revisions to that proposed provision. We discuss all of the revisions to the proposed requirements in this section.

TABLE 11—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART E

Proposed provision	Final provision	Description of revisions
§ 112.41	§ 112.41	—No change.
§ 112.42(a), (b), (c)	§ 112.42 (a), (b), (c)	—Revision to clarify inspection requirement in § 112.42(a) applies to the extent agricultural water distribution systems are under your control, but including consideration of factors that may not be under your control. —Revision to replace “the entire agricultural water system” with “all of your agricultural water systems” and corresponding edits to refer to “water sources” and “water distribution systems” given a farm may have multiple agricultural water systems. —Revision of § 112.42(a) to clarify inspection is required at the beginning of a growing season, as appropriate, but at least once annually. —Revision of § 112.42(a)(4) to make clear both adjacent and nearby lands are to be included in required considerations. —Reordered § 112.42(b) and (c). —Revision of § 112.42(b) to clarify maintenance requirement for agricultural water distribution systems applies to the extent such systems are under your control. —Revision of § 112.42(c) to clarify measures required to adequately maintain agricultural water sources.

TABLE 11—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART E—Continued

Proposed provision	Final provision	Description of revisions
§ 112.42(d)	§ 112.45(a) and 112.45(b)	—Revisions to clarify measures that are required when agricultural water is not safe or of adequate sanitary quality for its intended use; does not meet the microbial quality criterion in § 112.44(a); or does not meet the microbial quality criteria in § 122.44(b). —Revision to replace “the entire agricultural water system” with “the entire affected agricultural water system” to clarify re-inspection requirement.
§ 112.42(e)	§ 112.42(d)	—Revision to clarify the intent to focus on reducing the potential for contamination as a result of “contact of covered produce with” pooled water.
§ 112.43(a), (b), (c)	§ 112.43(a) and (b)	—Revision to clarify that treatment of water is one among other permitted options to ensure the safety of water for its intended use. —Revision to clarify that water treatment options are not limited to chemical methods, and to include physical treatment, including using a pesticide device, and other suitable method as additional treatment options.
§ 112.44(a)	§ 112.44(a)	—Revision to separate testing requirements and required follow-up measures from microbial quality criteria. —Revision to prohibit use of untreated surface water for purposes listed in § 112.44(a). —Revision to delete proposed § 112.44(a)(3) reference to water used to make agricultural teas.
§ 112.47(b)		—Rearrangement of requirements to use specified analytical methods into a separate provision within § 112.47. —Requirement that samples must be aseptically collected.
§ 112.44(b)	§ 112.45(a)	—Revisions to clarify measures that are required when agricultural water is not safe or of adequate sanitary quality for its intended use, and/or does not meet the microbial quality criteria in § 112.44(a).
§ 112.44(c)	§ 112.44(b)	—Revision to separate testing requirements and required follow-up measures from microbial quality criteria.
	§ 112.47(b)	—Rearrangement of requirements related to analytical methods as a separate provision within § 112.47. —Requirement that samples must be aseptically collected.
§ 112.44(c)(1), (c)(2), and (c)(3)	§ 112.45(b)	—Revisions to clarify measures that are required when agricultural water does not meet the microbial quality criteria in § 112.44(b), including the timing when such measures must be taken. —New limitation in § 112.45(b)(1)(i)(A) that a time interval of no more than four consecutive days may be applied between last irrigation and harvest to achieve the microbial quality criteria in § 112.44(b) —Revision to provide that an alternative microbial die-off rate permitted under § 112.45(b)(1)(i)(B) may be accompanied by a maximum time interval, in accordance with § 112.49.
§ 112.44(d)	§ 112.49	—Consolidation of all provisions that provide for the use of alternatives into new § 112.49, with additional provisions to permit alternatives to testing frequencies required under § 112.46(b).
§ 112.45(a)	§ 112.46(a)	—Revision to add reference to relevant EPA definition of a State approved to administer the SDWA public water supply program, in 40 CFR 141.2.
§ 112.45(b) and (c)	§ 112.46(b)	—Revision to combine testing requirements for untreated surface water and untreated ground water used for purposes specified in § 112.44(b), differing only in number of samples required for initial and annual surveys. —Revision to require updating the microbial quality profile annually, using annual survey data and based on a rolling dataset of 20 samples for untreated surface water or 4 samples for untreated ground water. —Revision to require that previous years’ data, when used, must be limited to samples collected within the previous 4 years. —Elimination of requirement to re-characterize the water quality profile every 10 years. —Corresponding revisions to requirement to re-establish the microbial quality profile if you know or have reason to believe that your microbial quality profile no longer represents the quality of water.
§ 112.45(c)	§ 112.46(c)	—Revisions to clarify timing of sample collection.
§ 112.45(d)	§ 112.44(a)	—Revisions to separately state testing requirements for use of untreated ground water for uses specified in § 112.44(a). —Revision to prohibit the use of untreated surface water for the purposes specified in § 112.44(a).
§ 112.45(e)	§ 112.47(a)	—No substantive change.
§ 112.46	§ 112.48	—No substantive change.

TABLE 11—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART E—Continued

Proposed provision	Final provision	Description of revisions
§ 112.50	§ 112.50	<ul style="list-style-type: none"> —Revision to combine two proposed records requirements related to test results (proposed § 112.50(b)(2) and (5)) into one requirement (§ 112.50(b)(2)). —Revisions corresponding to elimination of § 112.161(b), requiring records of actions taken in accordance with § 112.45, and establishing specific requirements for application of time intervals under § 112.45(b) (§ 112.50(b)(6)). —Revisions to require records of scientific data or information related to use of alternatives permitted under § 112.49 (§ 112.50(b)(8)). —Addition of new § 112.50(b)(9) to require documentation of any analytical methods used in lieu of the prescribed method in § 112.151(a).

A. General Comments

1. Research

(Comment 174) Several comments state that further research is needed to determine appropriate standards for water quality, and recommend that FDA partner with various land grant universities, and other agencies, including NRCS and EPA, utilizing both funded research programs and incentive-based programs to promote safe water management practices. Some comments suggest that FDA conduct a risk assessment based on research findings and seek public comment on the results of the risk assessment, prior to finalizing a standard(s) for the quality of agricultural water. Other comments offer various suggested topics for future research, including some comments that maintain that landscapes, weather patterns, and water sources vary significantly and, therefore, further research should be done to understand the physical differences of the national landscape as it pertains to produce safety.

(Response) We do not agree that more research, followed by a risk assessment based on that research, is needed for us to finalize the provisions of this rule relating to agricultural water. As discussed in the 2013 proposed rule, the supplemental notice, and in the paragraphs that follow, there is sufficient scientific information from which we conclude that the requirements in this rule minimize the risk of serious adverse health consequences and death, and are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. In addition, as discussed in section V of this document, we have conducted a qualitative assessment of risk of hazards associated with produce production, which indicates that agricultural water is a potential route of contamination of

produce during growing, harvesting, and on-farm postharvest activities and that use of poor agricultural practices could lead to contamination and illness even where the potential for contamination is relatively low. The science-based minimum standards established in subpart E of part 112 address this on-farm route of contamination.

However, we do support additional research as a means of facilitating implementation of this rule and continuing advancement of scientific knowledge in this area. As discussed in the 2013 proposed rule, we are pursuing regulatory science and research activities in collaboration with various partners. We have supported extramural research and collaborated with other federal agencies, academic institutions, and industry-supported entities to leverage research efforts, expertise, and resources (such as experimental stations for field research). For example, we are working with USDA to conduct research of mutual interest in key areas, including agricultural water.

In addition, FDA has provided funding to develop a produce safety research network at the Western Center for Food Safety (WCFS) at the University of California, Davis. Research studies at WCFS include projects related to the microbiological quality of irrigation water in catchments and distribution systems; evaluation of agricultural water quality parameters and the cost-benefit of farm-level interventions; and microbial water quality of moving surface waters. We intend for these collaborative efforts to result in the collection of data that will help advance the state of scientific knowledge on the safe use of agricultural water. WCFS also partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical

and/or region specific. WCFS has further partnered with academic institutions located in various regions in the United States, including in California, Florida, Hawaii, Oregon, and Washington, to conduct research on a variety of commodities including apples, citrus, and onions. We intend to disseminate useful scientific information obtained from these efforts, when available. We support additional research as a means for forming a basis for possible future rulemaking in this area.

2. Generic *E. coli* as an Indicator

(Comment 175) Some comments consider testing for indicators of water quality to be inappropriate because the final objective is to prevent pathogen contamination. Therefore, these commenters believe the microbiological standards for agricultural water in this rule should be based on direct pathogen detection rather than on indicator organism(s). These comments recommend that FDA provide a list of pathogens of concern and specify the levels in agricultural water at which they pose a risk. Some comments also suggest where water exceeds any specified level of indicator organism, the farm should not be required to discontinue use of the water, and instead should directly test for specified pathogens of concern.

(Response) We discussed our review of current scientific literature, potential approaches, and complexity associated with microbiological indicators of water quality in the 2013 proposed rule (78 FR 3504 at 3561–3563; 3567–3568). As described in that document, we considered two general approaches to establishing a microbiological water quality testing program, *i.e.*, to either test for the presence of an indicator organism(s) that may signal the presence of pathogens or test for pathogens themselves.

In the United States, bacterial indicators have a long history of being

used to demonstrate the safety of drinking water and adequacy of its treatment. They have also been used to monitor the status of drinking water in distribution systems and determine if surface waters are microbiologically safe for recreational use (e.g., swimming) and shellfish harvest (Ref. 107). Although no single indicator is universally accepted, indicator microorganisms are widely used in water quality testing because of their broad utility across many types of water (Ref. 107). We acknowledge that pathogen detection has the obvious advantage of directly targeting microorganisms in water that are a risk to public health; however, we continue to believe sampling water for pathogens presents additional challenges, including significantly larger sample sizes, inherently higher costs, and the wide array of potential target pathogens (i.e., the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). The comments did not provide information from which we could conclude that pathogen testing would be a viable approach, either for initial testing or for follow-up testing as suggested by some comments. Therefore, rather than requiring testing for the presence or levels of various pathogens of public health significance, we are requiring testing for a microbial indicator as a measure to monitor and assess the potential for contamination in agricultural water.

(Comment 176) Some comments support our proposal to use generic *E. coli* as an indicator of water quality in the proposed standards for microbial quality of water. These comments agree that, while imperfect, it is the most indicative of currently available indicators of fecal pollution and support its use to monitor the quality of agricultural water. In contrast, some other comments argue that *E. coli* is not a suitable indicator for monitoring water used in an agricultural setting, and cite different reasons, including that (1) in the view of these commenters, the correlation between pathogen presence and *E. coli* presence is not strong and *E. coli* cannot predict the presence of certain bacterial and non-bacterial pathogens; (2) pathogens may be present even if the *E. coli* threshold in the microbial quality standard is not exceeded, or conversely, that pathogens may not be present even if the threshold is exceeded; and (3) although the proposed indicator may provide valid information in one region of the country, it may not provide valid information in another region. Some

commenters also view current data on the use of *E. coli* as an indicator organism to be conflicting and, therefore, recommend waiting until science on this issue evolves to identify better indicator(s) of fecal pollution, rather than developing microbial quality standards based on *E. coli* as an indicator, which they believe could be overly burdensome.

(Response) A number of indicator microorganisms have been used to predict the presence of fecal pollution (thereby the potential for enteric pathogens) in water, with varying degrees of success. These include total coliforms, fecal coliforms, enterococci, generic *E. coli*, and coliphages. However, as comments noted, the presence of indicators does not always signal the presence of pathogens, and the absence of detection of indicators does not guarantee that pathogens are absent (Ref. 108) (Ref. 109) (Ref. 110) (Ref. 111).

We reviewed the most widely used fecal indicator(s) or indicator groups for their potential in assessing the microbial quality of water used for purposes described in § 112.44(a) and (b). We considered total coliforms and fecal coliforms as indicators of fecal contamination but determined that neither of them can serve as reliable indicators of a fecal contamination event (Ref. 112) (Ref. 113) (Ref. 114). Generic *E. coli* is a member of both the coliform and fecal coliform groups and it has been shown using various detection methods to be the coliform most consistently associated with fecal contamination (Ref. 112) (Ref. 113) (Ref. 115) (Ref. 116) (Ref. 117). Generic *E. coli* alone, as an easily distinguishable member of the fecal coliform group, is more likely than the fecal coliform group as a whole to indicate fecal pollution (Ref. 118). Used in this way, indicator organisms are not used specifically to predict the presence of pathogens, but are useful predictors of undesirable conditions (e.g., ineffective treatment or presence of fecal material) that may lead to contamination of water used in an agricultural setting.

As explained in the 2013 proposed rule, generic *E. coli* has an extensive history of and support for use as an indicator of fecal contamination. Recently, it has emerged as the preferred indicator for monitoring water quality, not only because of the problems with other fecal indicator groups noted previously, but also due to the development of superior methods of detection with greater accuracy, sensitivity, and simplicity over those previously used (Ref. 113). Generic *E. coli* is also recognized as a water quality

criterion indicative of the suitability of water for domestic, industrial, and other uses (Ref. 100) (Ref. 116). We also recognize that, despite widespread use of and support for generic *E. coli* as an indicator of fecal contamination, its ability to signal contamination events is not without challenges. Sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Ref. 107) (Ref. 119). Thus, non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. Further, the persistence and transport of generic *E. coli* takes different paths in different watersheds, and reservoirs have been identified, particularly sediments, where *E. coli* may escape detection in the water column (Ref. 110) (Ref. 120) (Ref. 121) (Ref. 122). Nevertheless, based on our review of current literature, we conclude that generic *E. coli* serves as the most appropriate microbial indicator of fecal contamination of water at this time. We are not aware of any new scientific data or information, nor have the comments submitted any such data or information, to support a different conclusion. Therefore, we are finalizing our microbial quality criteria for agricultural water in § 112.44(a) and (b) relying on generic *E. coli* as the indicator organism.

We acknowledge the difficulty of associating specific indicator concentrations with specific produce related health risks. Even so, we conclude that such difficulty does not negate the value of applying generic *E. coli* test results to the criteria in § 112.44(a) and (b) because elevated indicator organism concentrations indicate increased levels of fecal contamination and therefore elevated likelihood of the presence of human pathogens of fecal origin (Ref. 107) (Ref. 111).

(Comment 177) Some comments recommend that FDA should allow covered farms to develop alternative microbial water quality criteria to those in proposed § 112.44(c) using indicator organisms other than generic *E. coli*.

(Response) Sections 112.12(a) and 112.49(a) allow for the use of an alternative microbial water quality criterion (or criteria) based on an indicator of fecal contamination, in lieu of that established in § 112.44(b) (proposed as § 112.44(c)). A potential example of such an alternative microbial quality standard is the use of a different fecal indicator organism as a basis for a corresponding GM and STV that are demonstrated to detect measurable levels of fecal

contamination in agricultural water used during growing of produce (other than sprouts) using a direct water application method with at least equivalent sensitivity to the criteria we established in § 112.44(b). Farms may establish such alternative microbial criterion (or criteria), provided that the farm has adequate scientific data or information to support a conclusion that the alternative criterion (or criteria) would provide the same level of public health protection as the criteria in § 112.44(b) and would not increase the likelihood that the covered produce will be adulterated.

3. Scope of “Agricultural Water” and Applicability of Subpart E

(Comment 178) Several comments request clarification on whether the requirements in subpart E apply to water used during growing of various types of crops. For example, some comments ask whether subpart E applies to water used to irrigate root crops, such as onions and carrots, using drip irrigation. Some comments also ask us to clarify whether and how subpart E applies to water used during growing those commodities, such as tomatoes, cantaloupe, or cucumbers, where the produce may contact the ground or be in a splash zone versus those commodities, such as tree crops, that do not come in contact with the ground or irrigation water. One comment suggests produce grown using drip irrigation or otherwise not directly exposed to irrigation water should not be covered under subpart E.

(Response) Section E establishes requirements applicable to agricultural water. Whether or not water used during the growing, harvesting, packing, or holding of covered produce is subject to the requirements of subpart E depends on whether the specific use of the water fits within the definition of “agricultural water.” If a specific use of water does not fit within the definition of agricultural water, then the provisions of subpart E do not apply to that specific use of water. Because irrigation practices vary widely, we do not believe it is necessary or appropriate to categorize specific commodities or types of irrigation, generally, as being subject to or not subject to the requirements of subpart E. In addition, we note that subpart E applies to more than just water used during growing (*e.g.*, irrigation water).

For purposes of this rule, we define agricultural water as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used

in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Related to this definition is our definition of “direct water application method,” which means agricultural water used in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water (§ 112.3(c)).

Water that is intended to or likely to contact covered produce that is a root crop, including water used for drip irrigation of root crops, fits within the definition of “agricultural water” and the definition of “direct water application method.” For example, irrigating carrots using drip irrigation that is intended to filter through the soil and contact the carrots growing underground is agricultural water applied using a direct water application method because the water is intended to, and likely to, contact the covered produce. Similarly, water used to make a crop protection spray applied to tree fruit just before harvest is agricultural water applied using a direct water application method. However, irrigation water that is neither intended to nor likely to contact covered produce, such as water used for drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground, is not “agricultural water” and, therefore, not subject to subpart E.

B. General Agricultural Water Quality Requirement (§ 112.41) and Corresponding Corrective Measures (§ 112.45(a))

(Comment 179) A number of comments agree that agricultural water can be a source of contamination of produce and, therefore, support the proposed requirement that all agricultural water must be safe and of adequate sanitary quality for its intended use. Several comments suggest modifying proposed § 112.41 to require that all water used in the production of covered produce, not just agricultural water as defined in the 2013 proposed rule, must be safe and of adequate sanitary quality for its intended use. These comments state that water outside the definition of agricultural water could still spread contamination through runoff or practices such as dust abatement in close proximity to covered produce.

(Response) Our QAR shows that water used in ways that are intended to, or likely to, contact covered produce or food-contact surfaces is more likely to contaminate produce than water that is not intended to, or not likely to, contact covered produce or food-contact surfaces. This rule, therefore, targets the hazards associated with water that is intended to, or likely to, contact covered produce or food-contact surfaces (“agricultural water” as defined in the rule). We are not expanding the scope of “agricultural water” (see section IX.B of this document) or the applicability of the requirement in § 112.41, to include water that is not intended to, or not likely to, contact covered produce or food-contact surfaces because we conclude it is not reasonably necessary to apply the requirements in this rule, or in § 112.41 in particular, to such water to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated.

We agree, however, that water that is not intended to or likely to contact covered produce or food-contact surfaces can still present a possibility of produce contamination, albeit with lower likelihood than that associated with agricultural water as defined in the rule. Therefore, the safe and appropriate use of all water that is used in growing, harvesting, packing, and holding of produce is important, including water that is outside of the scope of “agricultural water” and, therefore, not subject to the standards in this rule. Uses of such water that are outside the scope of “agricultural water” subject to the standards in this rule may adulterate produce under section 402(a)(4) of the FD&C Act if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is detected in or on produce, such produce would be considered adulterated under section 402(a)(1) of the FD&C Act, in that it bears or contains a poisonous or deleterious substance which may render it injurious to health.

(Comment 180) Some commenters request clarification regarding the specific standard(s) that must be met to ensure agricultural water is safe and of adequate sanitary quality in compliance with proposed § 112.41. Comments also ask how the microbial quality criteria in proposed § 112.44 should be interpreted in relation to the requirement in proposed § 112.41.

(Response) As discussed in the 2013 proposed rule, the principle of “safe and of adequate sanitary quality for its intended use” contains elements related both to the attributes of the source water used and the activity, practice, or use of the water. The way in which water is used for different commodities and agricultural practices can affect the risk of contamination of the produce, for example, the use of overhead irrigation on lettuce versus drip irrigation of tree crops. Moreover, as discussed in the QAR, the timing of irrigation water application also plays a role in minimizing the persistence of contamination.

The requirements for agricultural water in subpart E of part 112 reflect our consideration of these issues. We are establishing a general requirement in § 112.41 that all agricultural water used in the growing, harvesting, packing, or holding of covered produce must be safe and of adequate sanitary quality for its intended use. We view this requirement as a general standard of water quality applicable to all covered activities that involve the use of water where the water is intended to or likely to contact covered produce or food-contact surfaces. In addition to this general water quality requirement, we are establishing two separate microbial water quality criteria specifically to address the potential for fecal contamination and relying on generic *E. coli* as an indicator. These criteria apply to agricultural water when used for certain purposes: The microbial water quality requirement of zero detectable generic *E. coli* for agricultural water applies to those purposes specified in final § 112.44(a); and the microbial water quality criteria of certain GM and STV values of generic *E. coli* applies to agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method as stated in final § 112.44(b). Each of these microbial quality requirements has a different purpose, as discussed in the paragraphs that follow.

First, the microbial quality requirement of zero-detectable generic *E. coli*, in final § 112.44(a), for the purposes specified in that provision, is intended to address the known or reasonably foreseeable hazards associated with fecal contamination of agricultural water. In addition, it is targeted at uses of agricultural water where if pathogens or fecal contamination are present, it is reasonably likely they could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the water.

In this regard, we consider the agricultural water that does not meet the microbial quality requirement in final § 112.44(a) also does not meet the general requirement of safe and of adequate sanitary quality in final § 112.41. Therefore, in final § 112.45(a), we establish certain immediate corrective measures that you must take if you determine that your agricultural water does not meet the microbial quality requirement in § 112.44(a), which are the same corrective measures that are necessary when your agricultural water does not meet the general requirement in § 112.41.

We note, however, that agricultural water that meets the microbial water quality criterion in § 112.44(a) may not necessarily be safe or of adequate sanitary quality for its intended use. Section 112.44(a) addresses the potential for agricultural water to be a source of fecal contamination, and we have concluded that, at this time, generic *E. coli* is the preferred indicator of fecal contamination. Nevertheless, we acknowledge that generic *E. coli* has limitations as an indicator organism and, therefore, non-detection of generic *E. coli* cannot be considered absolute confirmation that fecal contamination has not occurred. However, generic *E. coli* has been shown using various detection methods to be the coliform most consistently associated with fecal contamination. See discussion in the 2013 proposed rule (78 FR 3504 at 3562). Therefore, although a test result indicating the agricultural water does not meet the applicable microbial water quality requirement in § 112.44(a) demonstrates that the water is not safe or of adequate sanitary quality for those specified uses, the converse is not necessarily true. That is, agricultural water that meets § 112.44(a) may not be safe or of adequate sanitary quality, for example, due to the presence of pathogenic organisms.

Second, the microbial quality criteria of specified levels of GM and STV values of generic *E. coli*, in § 112.44(b), for agricultural water used in a direct application method during growing of produce (other than sprouts), like § 112.44(a), are intended to address the known or reasonably foreseeable hazards associated with fecal contamination of agricultural water. However, we view this provision as a water management tool for use in understanding the microbial quality of your water over time, and determining how to appropriately use water from that source, rather than as a direct indicator of the safety or adequacy of the sanitary quality of water for its immediate purposes. Consistent with

our intent for § 112.44(b) to support your long-term strategy for use of water sources, under final § 112.45(b), if your water does not meet the microbial quality criteria in § 112.44(b), we require you to take certain corrective measures as soon as practicable, and no later than the following year. Those corrective measures provide additional means by which to achieve the microbial quality criteria, allowing you to continue to use agricultural water that does not initially satisfy those criteria but that satisfies the criteria after accounting for microbial die-off. Moreover, our corresponding testing scheme (§ 112.46(b)) similarly facilitates a long-term strategy to help covered farms to understand the quality of their water sources and plan the use of water from those sources accordingly, per § 112.45(b).

The stringency of the applicable microbial quality criteria (and related flexibility) varies between § 112.44(a) and (b), reflecting the likelihood of microbial contamination of covered produce from agricultural water when used for the respective specified purposes. In both cases, however, meeting the microbial quality criteria in § 112.44 ((a) or (b)) does not automatically ensure that the requirement in § 112.41 is satisfied. See also examples discussed under Comment 246.

(Comment 181) Several comments state that many farms effectively have only a single source of water that can be used to irrigate their crops and that this is often a surface water source with the only alternate source of water potentially requiring the construction of a new ground water well. Some comments also note that, for many farms, constructing a new well is often geologically or economically not feasible and that this is a significant problem if the current water source is not safe and of adequate sanitary quality for its intended use as required by proposed § 112.41.

(Response) Under final § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary quality for its intended use (including when water does not meet the microbial quality criterion in § 112.44(a)) (see § 112.45(a)) or when agricultural water does not meet the microbial quality criteria in § 112.44(b) (see § 112.45(b)).

Under § 112.45(a), a covered farm can re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably

foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate steps to determine if the changes were effective, and, as applicable, adequately ensure that the agricultural water meets the microbial quality criteria in § 112.44(a). The covered farm may also treat the water in accordance with the requirements in § 112.43. Depending on the circumstances, the farm may be able to use the water for a different purpose, as appropriate (for example, agricultural water that does not satisfy the more stringent microbial quality criterion in § 112.44(a) may be appropriate for use as irrigation water for produce (other than sprouts) if it meets the criteria in § 112.44(b)). See examples under Comment 246.

Under § 112.45(b), specifically in relation to irrigation water and other water directly applied to covered produce other than sprouts during growing, we have incorporated flexibility by providing additional means to achieve the microbial quality criteria. A covered farm may apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day, but not more than four consecutive days (§ 112.45(b)(1)(i)); and/or apply a time interval (in days) using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing, provided the farm has adequate supporting scientific data and information for the microbial die-off and/or removal rates (§ 112.45(b)(1)(ii)). We also provide for the use of an alternative microbial die-off rate between last irrigation and harvest and an accompanying maximum time interval, in new § 112.49(b). We expect covered farms will be able to consider and implement these options, as appropriate. In particular, we expect the increased flexibility provided in § 112.45(b)(1) to reduce the likelihood that a covered farm will need to alter the source of its irrigation water. In addition, when water subject to the § 112.44(b) standard does not meet that standard, a farm may re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria (§ 112.45(b)(2)). It would also be

an option for the farm to treat agricultural water in accordance with § 112.43 (§ 112.45(b)(3)). See examples discussed under Comment 246.

We note, however, that there will likely be some situations in which a farm's water source is unsafe and/or of inadequate sanitary quality for a particular use, or where it cannot and does not meet the microbial quality criteria in § 112.44(b), such that it may not be used for that specific purpose in compliance with this rule unless it is treated in accordance with § 112.43. Violation of this rule is a prohibited act that may subject a farm to enforcement or other appropriate action (see § 112.192).

(Comment 182) Some comments ask for clarification on whether recycled, reclaimed, or gray water may be used during growing of covered produce.

(Response) The requirements for agricultural water quality established in §§ 112.41 and 112.44, apply regardless of the source or type of water that you use as agricultural water, except that untreated surface water is not permitted for uses identified in § 112.44(a). You must determine the appropriate use of agricultural water in light of the conditions and practices on your farm, and taking into account the general safe and of adequate sanitary quality standard in § 112.41 as well as any specific microbial quality criteria relevant to your intended use(s) of that agricultural water in § 112.44. See also Comment 222. We will consider providing guidance on the use of various types of water, including recycled, reclaimed, and gray water, in the future.

C. Agricultural Water Sources, Water Distribution Systems, and Pooling of Water (§ 112.42)

(Comment 183) Several comments express concern regarding the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in proposed § 112.42(a). These comments state that it is unclear what specifically should be considered to be reasonably foreseeable hazards in making such a determination.

(Response) In § 112.3, we define "known or reasonably foreseeable hazard" to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food. We are establishing a definition for this term as this term is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements in part 112. Under final § 112.42(a), you are required to inspect all of your

agricultural water systems to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions. The specific known or potential hazards that may be associated with your farm and food, in relation to your agricultural water, will likely vary dependent on your specific agricultural water source(s), water distribution system(s), practices on your farm, and your covered produce. Section 112.42(a) requires you to identify and characterize those activities and situations that may lead to contamination of your agricultural water with pathogens. Some examples of such activities and situations are described in the 2013 proposed rule (see 78 FR 3504 at 3565). For example, we noted that ground water could be compromised and its water quality degraded if wells are improperly constructed, poorly maintained, or improperly located (e.g., near areas of extensive livestock production). As another example, we noted that if you use water from a river and are downstream from a waste water treatment plant that discharges into that river, this provision would require you to consider the likelihood that the wastewater treatment plant introduces hazards into the water before it reaches your farm, such as the likelihood of accidental discharge of untreated municipal sewage into the river. We will consider providing guidance on the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards in the produce safety regulation implementation guidance to be issued in the near future.

(Comment 184) Several comments express concern about the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces when the source of the hazards is out of their control. A comment, agreeing with the proposed requirement in § 112.42(a), states that farms should not shoulder the burden of ensuring the quality of agricultural water when the source of water contamination is off-farm. Several comments state that a farm cannot assess the presence of hazards before the water reaches the farm and external water sources (e.g., a canal) are neither under control of the farm nor subject to decisions that are within the farm's control.

(Response) As discussed in the 2013 proposed rule, inspection of your water source(s) provides an opportunity to identify and characterize activities and situations that may lead to contamination of your agricultural water with pathogens. Inspection results (and initial survey results, when required under § 112.46(b)) provide you with historical knowledge of your water sources, their quality, and factors that may affect their quality. Inspection of the water sources and any equipment used to obtain the water from the source (e.g., well head, pumps, pipes) can ensure that the portions of the agricultural water system(s) that are under your control are not likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. We recognize that not all aspects of a water source or system may be under your control and, therefore, under § 112.42(a)(2), we are requiring you to consider the extent to which you have control over your agricultural water source(s) to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. For example, you may have more control over a ground water source such as a small spring if the expanse of the spring is under your control and you are able to protect the spring from the influence of surface activities. You may have greater access to and control of on-farm surface water sources such as impoundments, catches, and ponds, than you would for flowing surface waters that only course through but do not originate on your land. Similarly, under § 112.42(a)(4), we are requiring you to consider the use of adjacent and nearby land. While you may have little or no control of other agricultural water user practices, this requirement to consider those nearby uses of which you are aware will help you determine appropriate and safe use of your water source(s). Under § 112.42(a)(5), we are requiring you to consider the likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your farm. This, too, is something over which you may have little or no control. Considering factors such as these, which may affect the quality of your water source(s) even though they are not necessarily under your control, is an important part of evaluating whether your water source(s) meets the requirement in § 112.41 that your agricultural water must be safe and of

adequate sanitary quality for its intended use.

We are also revising § 112.42(c) to clarify that adequate maintenance of your agricultural water sources includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces; and correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections), in addition to keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(Comment 185) One comment recommends that farm operators should be allowed to design a water sampling program for their operations based on the level of control over the water source and the manner in which water is used. Acknowledging that proposed § 112.42 requires every covered farm operator to conduct an inspection of their water systems to evaluate the associated risk of microbial contamination, the comment proposes that farm operators should then be allowed to use information from their inspection to tailor operation-specific sampling frequencies and start-stop acceptance criteria based on the capacity of their system.

(Response) In the supplemental notice, which we issued subsequent to the submission of these comments, we proposed to provide tiered approaches for specific water testing frequency requirements to test untreated surface water as well as untreated ground water, which would entail testing at a reduced frequency than that proposed in the 2013 proposed rule. Under these tiered approaches to testing, we are establishing a sampling design that incorporates flexibility for covered farms to adjust the frequency and timing of sampling and number of samples beyond the minimum necessary parameters, based on the farm's operations. In light of comments in response to the supplemental notice, some of which similarly request additional flexibility to tailor water testing frequency based on operations on the farm, we are providing, in new § 112.49(c) and (d), for the use of an alternative testing frequency for untreated surface water sources (in lieu of those required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A)), under the conditions specified in § 112.12.

(Comment 186) We received several comments that request clarification on the phrase in § 112.42(a), "the entire agricultural water system under your control." The requests for clarification include questions regarding how far upstream farms are responsible for monitoring for potential sources of contamination and whether the responsibility stops at the farm's property line or extends to properties beyond the farm's control. Comments also state that many water systems are vast and incredibly complex, and the 2013 proposed rule does not adequately or realistically account for such complexity.

(Response) The agricultural water systems referred to in § 112.42(a) include the water source(s), water distribution system(s), facilities, and equipment. (See also Comment 192 regarding multiple water sources and water systems.) Recognizing the diversity in water sources and the extent to which you can protect the water source or its distribution system, we incorporated into § 112.42(a) a list of factors that must be considered during an inspection of your agricultural water system(s). The identification of potential hazards related to agricultural water systems must consider the nature of each agricultural water source (for example, ground water or surface water), the extent of the farm's control over each agricultural water source, the degree of protection of each agricultural water source, the use of adjacent and nearby land, and the likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm. We understand that water systems can be complex, and we are not requiring covered farms to inspect portions of an agricultural water system that are beyond their control. However, the extent to which you control your agricultural water source(s), and certain factors over which you may have little or no control will likely influence the identification or characterization of potential hazards associated with your agricultural water system(s), and evaluating these factors as part of your inspection under § 112.42(a) will help you determine the appropriate and safe use of the agricultural water from your water source(s). To make our intent clear, we are revising "under your control" in § 112.42(a) to read "to the extent they are under your control," and making similar changes in descriptions of maintenance requirements for water distribution systems and water sources

in §§ 112.42(b) and (c). See also the discussion under Comment 184.

(Comment 187) Several comments request clarification of the timing of inspection, particularly in circumstances where crops are grown throughout the year (such as almonds) or where covered farms have multiple or year-round growing seasons. To account for such circumstances, some comments suggest that the phrase “at the beginning of the growing season” in § 112.42(a) should be replaced with “as applicable or at least annually.”

(Response) We recognize that many crops have year-round growing seasons and also that covered farms may have operations or multiple crops with year-round or staggered growing seasons throughout the year. In light of these comments, and to make our intent clear, we are revising § 112.42(a) to require inspection of agricultural water systems “at the beginning of a growing season, as appropriate, but at least once annually.” Thus, for example, a farm that has multiple crops that have different growing seasons is only required to inspect once annually, at the beginning of one of the growing seasons. As another example, a farm that has a single crop with a continual, year-round growing season is also required to inspect at least once annually, and such a farm may consider an appropriate time to be the beginning of the growing season. We have incorporated flexibility in this requirement to allow farms to independently determine the appropriate timing and number of inspections that are necessary to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of the covered produce, practices, and conditions and based on the knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination.

(Comment 188) A comment suggests that the language of § 112.42(a)(4) should be limited to adjacent land, and not include “nearby land” because “adjacent” is not the same as “nearby”.

(Response) We agree that “adjacent” and “nearby” have different meanings, and we intend to require you to consider both adjacent land and nearby land uses in identifying and characterizing the potential hazards affecting your agricultural water system. By “adjacent” land we are referring to land sharing a common border with the farm’s land. By “nearby” land we are referring to a broader category of land, including land that does not adjoin the farm’s land but has the potential to affect the farm’s water source(s) based

on the land’s location. For example, agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that are used as agricultural water even if the upstream operations’ lands are not adjacent to your farm’s land. While you may have little or no control of other agricultural water users’ practices, this requirement to consider those adjacent and nearby land uses of which you are aware will help you determine the appropriate and safe use of that water source. We are revising this provision to read “use of adjacent and nearby land” to make clear that both adjacent and nearby land uses are included.

(Comment 189) Several comments request clarification on whether, if there is a reason to believe that a farm’s agricultural water is not safe and of adequate sanitary quality for its intended use, the farm is required to take measures specified in proposed § 112.42(d)(1) or proposed § 112.42(d)(2), and whether or not the farm is required to follow proposed § 112.42(d)(2) if the requirements in proposed § 112.42(d)(1) are met. In addition, one comment focusing on proposed § 112.42(d) states that although it may be feasible and reasonable to discontinue the use of water used in postharvest activities when there are doubts about the sanitary quality of water that is being used, immediately discontinuing the use of water used in irrigation is not a feasible option for the health or maintenance of the crop. This commenter also suggests specific thresholds or “action levels” that could be identified for water used during postharvest and growing activities.

(Response) See our response to Comment 181 and Table 11. We have now consolidated proposed § 112.42(d) and proposed § 112.44(b) into final § 112.45(a), which establishes the corrective measures that must be taken, and the required timing, when agricultural water does not meet the general requirement in § 112.41 and/or when it does not meet the microbial quality requirement in § 112.44(a) for those specified purposes. In addition, in final § 112.45(b), we specify the corrective measures that must be taken, and the required timing, when agricultural water does not meet the microbial quality criteria in § 112.44(b) for the specified purpose.

Specifically, § 112.44(a) establishes the microbial quality requirement for certain specified uses of agricultural water. Water used for washing hands during and after harvest, sprout irrigation, directly contacting covered

produce during or after harvest (such as in washing and cooling, or to make ice that directly contacts covered produce), and water or ice that will contact food-contact surfaces that contact covered produce presents a greater likelihood of microbial contamination of covered produce and, therefore, we are applying a more stringent standard for water quality without options to account for die-off or other microbial reduction for these intended uses. For these specified uses, we are retaining the requirement, in final § 112.45(a), for you to immediately discontinue the use of the water that does not meet the applicable microbial quality requirement until you take the necessary required measures in § 112.45(a)(1) or (a)(2).

In addition, with respect to the microbial quality criteria in § 112.44(b) for agricultural water used during growing for covered produce other than sprouts using a direct water application method, we are retaining our proposed flexible options in the final provisions §§ 112.45(b)(1) and 112.49, making it less likely that a farm will have to discontinue use of the water used for these purposes due to small fluctuations in water quality. In addition, under § 112.45(b)(2) and (3), farms also have similar options to those in § 112.45(a). Moreover, under § 112.45(b), these corrective actions are not required to be taken immediately. They are required to be taken as soon as practicable, and no later than the following year. See examples discussed under Comment 246.

With respect to thresholds suggested by one commenter, we have also made revisions to the water testing requirements that eliminate the need to re-characterize the water quality profile for § 112.44(b) uses in response to specific annual survey results that are over a particular “threshold” (final § 112.46(b)). This structure was a limitation to our proposed tiered-approach that we acknowledged in the supplemental notice (79 FR 58434 at 58453), which we believe is now adequately addressed under our revised final testing scheme. See also Comment 244.

(Comment 190) Some comments, referring to proposed § 112.42(e), note that water pooling in produce fields occurs often and it would be impractical to expect that all pooling water can or should be eliminated. Some commenters also believe it is unclear how pooled water increases the likelihood of produce microbial contamination, particularly if agricultural water and soil amendments with only a rare probability of containing human pathogens (in

accordance with proposed requirements) are used. Another comment states that there should be a length of time identified for how long water can stand before it is considered a potential hazard. This commenter states that seasonal flooding causing water to pool and drain naturally should not be considered the same as overflow from a polluted source of water.

(Response) As noted in the 2013 proposed rule, we acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature are temporary and occur in the normal course of irrigation practices. We are not suggesting that it will always be possible to eliminate pooling. However, pooled water that remains for extended periods of time can be a source of contamination (Ref. 14) (Ref. 40) and pooled water in close proximity to the crop may serve as an attractant for pests and other animals, which may in turn introduce hazards into the pooled water that may contaminate produce. Therefore, we are retaining this proposed requirement with some revisions. In final § 112.42(d), we clarify our intent to reduce the potential for contamination as a result of contact of covered produce with pooled water. After the phrase “reduce the potential for contamination . . .” we have replaced “as a result of pooling of water” with the phrase “as a result of contact of covered produce with pooled water.” However, we believe additional specificity in this requirement beyond this revision, such as establishing a maximum acceptable length of time for standing of pooled water, is unnecessary and would not provide sufficient flexibility for covered farms to implement measures as necessary and appropriate.

(Comment 191) Regarding proposed § 112.42(c), one comment suggests adding the phrase “under your control” to the first sentence as a qualifier applied to “agricultural water distribution systems.”

(Response) We agree with this recommendation, and are revising final § 112.42(c) to refer to agricultural water distribution systems to the extent they are under your control.

(Comment 192) One comment states that agricultural water entering the produce production areas may be serviced by more than one “water system” that is in turn fed by one or more water sources. The commenter recommends that inspections should be conducted at each water source and re-inspections under proposed §§ 112.42(d)(1) and 112.44(b) and (c)

should be limited to locations serviced by the source where the problem was identified. The commenter suggests clarifying the codified text to read “the water system under your control that is serviced by that source.”

(Response) We consider each agricultural water source in your operation to be from a discrete body of water (e.g., a canal, a pond, a river) that represents the microbial quality of agricultural water as it is used in your growing, harvesting, packing, or holding activities. Where this rule establishes a testing requirement for a water source, that requirement applies to each discrete source of water used for the relevant purpose, regardless of whether the water is used for multiple commodities, or applied over non-contiguous fields. The annual agricultural water system inspection required under § 112.42(a) includes each discrete water source if a farm has more than one water source, and must also include all relevant water distribution systems, facilities, and equipment. We are revising § 112.42(a) to reflect this by clarifying that you must inspect “all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment).”

When a re-inspection is conducted to satisfy § 112.45(a)(1) or (b)(2) after identification of a problem with agricultural water, such re-inspection can be limited to the affected agricultural water system with which a problem was identified, but the entirety of the affected system must be re-inspected to enable potential problems to be identified. We are revising § 112.45(a)(1) and (b)(2) to specify that such requirements apply to the “entire affected agricultural water system,” which includes the relevant water source(s), water distribution system(s), facilities, and equipment. For a discussion on identifying a “source,” see our response to Comment 237.

(Comment 193) Referring to proposed § 112.42(d)(1), which requires covered farms to take certain steps “when you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use,” a commenter asserts that this provision leaves the decision to test or not to test agricultural water up to farms—and that such decision is dependent upon knowing or having reason to believe that water is not safe or of adequate sanitary quality for its intended use.

(Response) We disagree with the interpretation offered by this commenter, which appears to be based

on proposed § 112.42(d)(1) alone, disregarding other applicable provisions in subpart E of part 112. Other provisions in subpart E establish the minimum science-based microbial quality standards for agricultural water for specified intended uses and for testing agricultural water (including minimum sampling requirements) to ensure its safe and appropriate use (§§ 112.44, 112.45, and 112.46). See the discussion in section XIII.G of this document.

D. Treatment of Agricultural Water (§ 112.43)

(Comment 194) Several comments express concerns about the potential adverse environmental impacts that could occur as a result of implementation of the water treatment provisions in proposed § 112.43. For example, one comment states that widespread use of antimicrobial pesticides on ground water and surface water sources by farms across the country would have a detrimental effect on the environment, water quality, and human health. Citing the potential for environmental contamination and destruction to soil health, some comments also recommend that FDA should not encourage chemical treatment of irrigation water. Some comments also worry that proposed § 112.43 would encourage the use of pesticides to treat agricultural water because treating water may be the most viable option for some farms, particularly when they are limited to a single water source. One comment maintains that it is unlikely that any untreated surface water would meet the proposed microbial standards and that, as a result, farmers would be forced to either treat their water or find a different water source. Another commenter states that some farms may use unorthodox approaches to treating water, such as pouring bleach into a pond, which could result in environmental problems. Yet another comment recommends that FDA provide an option to develop practices, such as an interval between irrigation and harvest, to reduce the potential for antimicrobial treatment of irrigation water. Another comment asserts that packing shed discharge may create significant impacts on downstream water quality. In addition, some comments support § 112.43(a), as proposed, and affirm that treatment of water should be an option available to farms who believe their water is contaminated, based upon their experience and risk assessment. In contrast, other comments state that the use of chemical sanitizers to treat

irrigation water should not be allowed, encouraged, or required.

(Response) Certain methods of treating water and wastewater are effective means of achieving microbial reduction (Ref. 123). However, water treatments that are inadequate or improperly applied, interrupted, or intermittent have been associated with waterborne disease outbreaks (Ref. 124). Failures in treatment systems are largely attributed to suboptimal particle removal and treatment malfunction (Ref. 125). For this reason, when treating water, it is important to monitor the treatment parameters to ensure the treatment is delivered in an effective manner. Therefore, we are retaining the provisions for treatment of water in § 112.43, with some revisions as explained here.

In § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary quality for its intended use and/or to not meet the relevant microbial quality criteria in § 112.44(a) or (b), and treatment is only one of those options. In Comment 181 and Comment 189, we discuss the flexible options provided in final §§ 112.45(a) and (b) and 112.49, and we anticipate that covered farms will consider and implement these options, as appropriate, prior to or in conjunction with considering whether to treat water to ensure that it meets the applicable requirements for its intended use. As such, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. Indeed, we believe some of these other options are likely to be more feasible than the option to treat water. Moreover, covered farms will have two additional years (beyond the date of compliance for the remainder of this rule) to comply with many of the water provisions of this rule for covered activities involving covered produce (except sprouts), which is intended to help farms to consider and implement measures that are most appropriate for their operations. See our discussion of compliance dates in section XIII.K of this document.

We acknowledge that proposed § 112.43 might have been read to suggest that the treatment of water is always a required measure to ensure the safety of water for its intended use. We did not

intend such a meaning. In light of comments we received, and to make our intent clear, we are revising the question and paragraph (a) in final § 112.43 to read as follows: “§ 112.43 *What requirements apply to treating agricultural water?* (a) When agricultural water is treated in accordance with § 112.45 of this part:” In addition, in final §§ 112.43(a)(1), 112.43(a)(2), and 112.43(b), we are revising the purpose of treating water to acknowledge that treatment is an option that a farm may use either to meet the general requirement in § 112.41 and/or to satisfy the microbial quality criteria in §§ 112.44(a) and/or (b).

We recognize that improper use, management, or disposal associated with chemical treatment of agricultural water can create adverse environmental impacts. Subsequent to publishing the 2013 proposed rule, FDA determined that the proposed produce safety rule may significantly affect the quality of the human environment (21 CFR 25.22(b)), and, therefore, an EIS is necessary for the final rule. In accordance with the National Environmental Policy Act (NEPA) and its implementing FDA regulations, we have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. This analysis includes potential impacts related to pesticide use, chemical treatment of agricultural water, changes in ground water demand, and existing water quality standards.

With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use. The FIFRA provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. For more information, see <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#laws> (Ref. 127). The EPA receives and examines large amounts of test data from producers of pesticides demonstrating that their products, if used, will not harm the

environment or human health. These data are reviewed by EPA during their determination of whether to issue a registration for a pesticide product and/or a specific use of that product (Ref. 52).

(Comment 195) Several comments discuss the potential use of chlorine, in particular, to treat agricultural water to meet the proposed water quality standards. Noting that chlorine is likely to be used to disinfect agricultural water because it is inexpensive and readily available, these comments express various concerns, including that: chlorine products pose a hazard to farmworker health and safety; chlorine products can cause corrosive damage to stainless steel and aluminum farm equipment; many crops and plants experience chlorine damage, such as salt injury to fruit trees; applying large volumes of chlorinated surface irrigation water on agricultural lands could result in the formation of trihalomethanes; chlorine interacts with many crop protection chemicals, potentially resulting in crop damage and reduced efficacy; and water treated with chlorine can infiltrate soil, run off into surface waters, and contaminate ground water, with potentially toxic effects to soil microbes and aquatic organisms. Another comment questions the ability of chlorine to kill pathogenic bacteria, and states that its use to treat water can increase costs and contaminate the environment, without concurrent benefit. Yet another comment suggests that chlorine treatment of water is logistically challenging for orchardists, in particular, due to the volume of water needed for irrigation and cooling within orchards. Several comments also suggest that FDA recommend that the residual effluent of any use of chlorine should be limited to 4 ppm, consistent with the organic certification and Safe Drinking Water Act standards.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water does not meet the applicable requirement for its intended use. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. When a covered farm does choose to treat water, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA; EPA-registered antimicrobial pesticide product; or other suitable method).

FDA has analyzed the potential environmental impacts of the agricultural water standard in Chapter 4.2 of the EIS. As part of the analysis, FDA has determined that presently, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (Ref. 128). FDA does not have specific information on the pesticides that might be submitted to EPA for registration for uses to control specific target organisms, such as pathogens, specifically in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1 and 4.2 of the EIS, we agree that the most commonly used antimicrobials for microbial population reduction are chlorine chemicals, specifically sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. It is anticipated that chlorine compounds would be among the preferred chemicals for which industry would be likely to seek FIFRA registration. FDA has considered the potential impacts of this rule on the environment and worker health as part of the EIS (Ref. 126). With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use (see Comment 194).

Should a covered farm choose to treat their agricultural water to ensure it meets the applicable requirements for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, and local regulations.

(Comment 196) Several comments discuss EPA's registration requirements related to pesticide use. Acknowledging our statement in the 2013 proposed rule that no EPA registrations currently exist under FIFRA for chemicals used in the treatment of irrigation water, comments express concern about the current lack of available EPA-approved antimicrobial treatments for irrigation water and the purported lack of an available EPA process by which such chemicals could be approved. Such comments state diverse concerns, including that: providing treatment of irrigation water as an alternative under the produce safety regulation may not be a viable option; the absence of available treatment methods may jeopardize the use of some agricultural water sources and could force some farms to stop irrigating crops and to suffer economic hardship; treating irrigation water without available registered options is illegal, in that the use of unapproved

substances would violate both State and federal pesticide-use regulations; and, due to the lack of approved treatments, farms may treat water with unapproved methods that could lead to environmental and public health concerns. Another commenter recommends eliminating proposed § 112.43(a) because no approved treatment products for this use currently exist. Similarly, another commenter recommends that the water treatment provisions should not be implemented until a registry of approved water disinfection agents exists.

Several comments also request that FDA work with EPA and other relevant agencies to provide clear direction to industry regarding acceptable and available water treatment options. One commenter believes that reliance on a process that is regulated by another government agency may create uncertainty for farms. This commenter recommends that FDA collaborate with EPA to: 1) Identify and make information available about currently-registered compounds and 2) establish a priority review process to ensure that farms have effective options available for the treatment of irrigation water prior to the compliance dates for the water requirements. One comment requests clarification on the approval that would be required to use an existing microbial pesticide to meet the requirement in § 112.43.

Other comments state that EPA-approved products for treating irrigation water are currently available. For example, one comment reports that the National Pesticide Information Retrieval System (NPIRS) database shows that nearly 90 federally-registered disinfectant products are available for uses in fruit or vegetable wash water or processing water, and that other products are labeled for use in treatment of agricultural and irrigation water systems, including drip irrigation systems. Another comment provides an example of a treatment, asserting that it is registered with EPA for use in all types of irrigation water systems, including in USDA-inspected fruit and vegetable wash water operations.

(Response) We are retaining § 112.43 with some modifications, as explained under Comment 194. This provision applies to agricultural water (as defined in § 112.3) that is used in growing, harvesting, packing, and holding activities related to covered produce. We consulted with EPA on currently available options for treating agricultural water in a manner consistent with § 112.43.

At this time, no EPA registrations exist for chemical substances (classified

by EPA as "pesticide products") for antimicrobial treatment of agricultural water used during the growing of crops (Ref. 128). However, as discussed in Chapter 4.2 of the EIS, EPA maintains a list of "Antimicrobial Products Registered with the EPA as Sterilizers." Each of these products received approval under FIFRA as amended in 1996 (40 CFR parts 152, 156, and 158). Like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. Among compounds on the list of EPA's registered antimicrobial products as sterilizers are certain registered antimicrobial washes, which are authorized for use during postharvest fruit and vegetable washing. These products can be used to treat agricultural water that is used to wash produce postharvest, such as in packing houses. However, because these antimicrobial products are not authorized by EPA for use on agricultural fields, they cannot be used to treat irrigation water that is applied prior to harvest. Also on this list are certain registered antimicrobial products for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth. However, because these antimicrobial products are not authorized by EPA for use to control human pathogens or indicator organisms, they cannot be used to treat irrigation water to comply with the microbial quality criteria in § 112.44(b).

We anticipate that the delayed compliance dates for certain water quality provisions in this rule (see our discussion of compliance dates in section XIII.K of this document) provide adequate time to address the current lack of EPA-registered chemical treatments for agricultural water used in growing activities. We will work with EPA, as appropriate, regarding registration of pesticide products for treatment of agricultural water during growing. In response to comments requesting priority review for registration of irrigation water chemicals, we note that EPA has statutory timelines under which it must consider registration applications (*i.e.*, 15 to 21 months for a "new food use" of a compound). Information about EPA's pesticide registration process is available on its Web site at <http://www2.epa.gov/pesticides> (Ref. 129), and is also explained in chapters 3.8 and 4.2 of the EIS.

Section 112.43 also allows for non-chemical suitable methods for treatment

of agricultural water. Unlike pesticide products, pest control devices that work by physical means and are classified by EPA as "pesticide devices" do not require registration by EPA under FIFRA. According to EPA, FIFRA defines a device as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom (Ref. 130). (Note that "pesticide devices" do not include medical devices, which are regulated by FDA.) Although not required to be registered, pesticide devices are regulated by EPA in that false or misleading claims cannot be made about the effectiveness of the device. Physical treatment of agricultural water, including using a pesticide device(s), or by any other suitable treatment method can be employed provided the method is effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. In addition, the treatment must be delivered and monitored in a manner and with a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable, as required under final § 112.43(a)(2) and (b). Examples of pesticide devices used to treat water include filter units, ultraviolet light units, and ozonator units. Information about EPA's regulation of pesticide devices is available on its Web site (Ref. 130), and we advise you to consult EPA for information about appropriate use of pesticide devices. Note also that some States require registration of pesticide devices, and we refer you to the appropriate State pesticide regulatory agency for more information on a particular State's requirements related to pest control devices (Ref. 131). Information about EPA's Tribal Pesticide Programs is available on EPA's Web site at: <http://www2.epa.gov/pesticide-advisory-committees-and-regulatory-partners/tribal-pesticide-programs> (Ref. 132). In addition, information regarding current EPA-registered pesticide products is available on EPA's Web site at: <http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1> (Ref. 133).

With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use (see Comment 194).

(Comment 197) One comment expresses concern that adding an antimicrobial treatment to irrigation water would be considered a point source discharge of a pollutant, requiring farms to obtain a National Pollution Discharge Elimination System (NPDES) permit, and that implementation of agricultural water treatment in compliance with § 112.43 would expose farms to liability under the Clean Water Act (CWA), including a potential citizen suit. The commenter also maintains that requiring farms to treat surface irrigation water with antimicrobial pesticides could subject farms to liability under the ESA or potential increased scrutiny regarding their effects on anadromous (*i.e.*, ascending rivers from the sea for breeding) species. The commenter notes that the 2013 proposed rule did not indicate whether FDA would conduct ESA consultation, and recommends that we outline our intentions with respect to ESA compliance and the potential impact of implementation of the produce safety regulation.

(Response) We have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. With respect to the CWA, only a portion of agricultural facilities are considered point source dischargers that would require NPDES permits. This form of regulatory oversight is discussed in Chapter 3.1.2 of the EIS. The provisions of the produce safety regulation do not authorize covered farms to violate existing laws and regulations, including the CWA. This rule also does not affect the status of any farm that is currently subject to NPDES permits.

We also considered the effects of the produce safety regulation on threatened and endangered species. In the supplemental notice, we proposed a new provision § 112.84 that explicitly states that part 112 does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in

violation of the ESA, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. We are finalizing this provision, as proposed. FDA has concluded informal consultation with FWS under the ESA. We have also been involved in conversations with National Marine Fisheries Service regarding our ESA obligations. See (Ref. 134) (Ref. 135) for additional information.

(Comment 198) Several commenters discuss the interface between proposed § 112.43 and State or regional policies related to water or water treatment, such as permit requirements. One comment notes that, in most States, application of pesticides to any surface waters (including irrigation waters) is subject to permit requirements. Another comment mentions that, if a farm installs a chlorination facility in order to comply with the produce safety regulation, then the applicable State and/or Regional Water Board might issue a permit to that farm to make sure that any disinfection by-products running out of the farm's fields do not damage the environment or water quality. This comment asserts that the issuing of such permits could be a significant burden on farms and on State and Regional Water Boards. One comment mentions that water treatment products used in California must be registered with the California EPA's Department of Pesticide Regulation (CDPR). This comment speculates that if the produce safety regulation results in significant increase in use of pesticides to treat water, that the CDPR's requirement to register treatment products may result in time delays and antimicrobial products may become less available.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality criteria in § 112.44. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. When a covered farm does choose to treat water to ensure its safety for its intended use, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA; EPA-registered antimicrobial pesticide product; or other suitable method).

Nothing in the regulations in part 112 requires or authorizes farms to take measures in conflict with existing federal, State, or local regulations related to water treatment. We also considered the environmental impacts associated with the standards for agricultural water, as discussed in the final EIS (Ref. 126).

When agricultural water is treated to ensure that it is safe and of adequate sanitary quality for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, or local regulations. For example, any pesticide chemicals used in the treatment of water require EPA registration before they can be lawfully used.

(Comment 199) Several comments request that we provide additional clarification, instruction, and/or examples regarding how farms can treat water in order to comply with proposed § 112.43. One commenter claims that proposed § 112.43 is vague, in that it outlines neither the level of microbial reduction that must be achieved nor the microbial standard that must be met. Several comments request that FDA clarify which economical water treatments exist that might be used to bring water into compliance with levels established in the rule, and ask that we give examples of such treatments, provided that they do not conflict with other federal or State regulations. Other commenters maintain that farms need agricultural water treatment alternatives to chlorine, and request that FDA clarify which water treatments beyond chlorination are available to comply with proposed § 112.43. Another comment asks that, if FDA chooses to provide examples of water treatment methods, that we cite methods, such as hydrogen peroxide and UV treatment, which minimize the potential for environmental and public health impacts. Relatedly, another commenter contends that FDA should explicitly recommend methods of water treatment that do not involve chemicals. Although supporting the requirement in proposed § 112.43(c)(2) that any treatment of agricultural water must be monitored, some comments seek additional specification, such as a defined interval for monitoring, the resulting water quality, and the point of monitoring (either at the place where the treatment is added or at the point of use of water).

(Response) If a covered farm chooses to treat agricultural water to make the water safe and of adequate sanitary quality for its intended use and/or to meet the relevant microbial quality criteria in § 112.44, § 112.43 requires that the treatment that is applied,

regardless of the specific method employed, must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. The required quality is dependent on the intended use of the agricultural water, with specific microbial quality criteria established in § 112.44(a) for certain specified uses; in § 112.44(b) for use during growing of produce (other than sprouts) using a direct application method; and in § 112.41, generally.

The specific level and frequency of treatment, the point at which treatment should be applied, and the intervals for monitoring treatments required under § 112.43 also vary, and are dependent, in part, on the method of treatment and the farm's operations, including its water source, intended use of the water source, and the water distribution system. As discussed in the 2013 proposed rule, an example of an effective monitoring program for use of a chemical treatment method would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, adequate monitoring of water treated with hypochlorite in an orange postharvest wash must include, at a minimum, monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (e.g., soil, plant debris) and pH values outside its effective range (pH 6.0–7.5) (Ref. 136) (Ref. 137) (Ref. 138) (Ref. 139). The concentration of active disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency at which you monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criteria in § 112.44, as applicable. Research has shown that, in other settings, monitoring of physical parameters, such as temperature, pH and disinfectant concentration, can be done in real-time and in an inexpensive, automated manner, facilitating good control of the treatment process (Ref. 136). As a verification that the treatment process, monitored in accordance with § 112.43(b), is effective in achieving a certain microbial quality requirement (e.g., no detectable generic *E. coli* in 100 mL of water), you may choose to

perform periodic microbiological analysis of the treated agricultural water. Although not a requirement, we encourage farms to perform such testing to provide further assurance of the effectiveness of their treatment under the specific conditions that exist on their farm. We will consider discussing these issues further in the Produce Safety Regulation implementation guidance to be issued in the near term.

(Comment 200) Several comments focus on the treatment of harvest and postharvest water. For example, one comment requests clarification on whether the proposed standard would require water for dump tanks to have an added disinfectant, whereas another commenter recommends that farms should use, as appropriate, antimicrobials in fruit and vegetable wash water for pathogen reduction. Comments also provide other suggestions, including: (1) That farms with more than \$5 million in gross sales should be required to include a disinfectant in their wash water, if such farms are immersing in dump tanks either leafy greens or produce that can take up water through a temperature differential; (2) that farms should be permitted to continue their current use of a chlorine-free product to treat water in a dunk or flume, which in the commenter's view renders the proposed water standards excessive; and (3) that the provisions should address the use or validation of compounds authorized for use.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44, as applicable. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. This includes agricultural water used during or after harvest. Under § 112.44(a)(2), agricultural water must contain no detectable generic *E. coli* per 100 mL when it is applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities. This microbial quality criterion, therefore, applies to wash

water in dump tanks, flumes, or wash tanks used to wash covered produce. Where water does not meet this microbial quality requirement, farms have different options to ensure the water is safe to use for this purpose. A covered farm may choose to add an EPA-approved disinfectant to the wash water in dump tanks to ensure the water contains no detectable *E. coli* and is safe and of adequate sanitary quality for its intended use. However, treatment of water is not the only option. In addition to treatment, another option available to farms includes re-inspecting the entire affected system, identifying conditions that are reasonably likely to introduce hazards, making changes to the system and re-testing the water successfully (§ 112.45(a)(1)) or using water from a different source that does meet the microbial quality requirement.

The commenter who suggested a sales-based requirement for use of a disinfectant in wash water did not provide a rationale for such a requirement. We are establishing a microbial quality requirement for such water in § 112.44(a), and options for taking action when water does not meet that standard in § 112.45(a). We are not requiring any farms to treat wash water regardless of whether it meets the quality requirement, nor are we requiring only certain farms to do so based on their sales or the type of commodity they produce.

With respect to comments asking us to address the use or validation of compounds authorized for use, we note that although some antimicrobial substances are regulated by FDA, most antimicrobial substances that might be used by covered farms in agricultural water are regulated by the EPA. A decision tree regarding whether an antimicrobial substance would be regulated by the EPA or the FDA is available at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm> (Ref. 140). See also the discussion of available antimicrobial products registered with EPA as sterilizers in Comment 194.

(Comment 201) Several commenters assert that proposed § 112.43 would create a preference for the use of antimicrobial pesticides as an appropriate water treatment method; these comments point out that the proposed provision provides only an example of using an EPA-registered antimicrobial pesticide product to treat water, without offering any additional examples. Another commenter observes that the proposed provision appears flexible, but that the related

commentary in the preamble only discusses chemical treatment of water. This commenter also notes that various non-chemical treatment methods, such as mechanical or physical methods (e.g., filtration) are currently being explored.

(Response) As noted in response to Comment 194, when a covered farm chooses to treat its agricultural water to ensure it is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criteria in § 112.44, as applicable, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA; EPA-registered antimicrobial pesticide product; or other suitable method). We recognize that methods other than chemical treatment are either available or being explored for the treatment of agricultural water, for example, pesticide devices (such as filter units, ultraviolet light units, and ozonator units), reverse osmosis, and solar methods (Ref. 141). We also agree that water treatment options should not be, and are not, limited to chemical methods. As part of the EIS, FDA has considered a range of management decisions that a farm might take to be in compliance with the water quality requirements. These management decisions are outlined in Table 2.1–2 of the EIS and discussed in further detail in Chapter 4.2 of the EIS (Ref. 126). To make clear that water treatment options are not limited to chemical methods, we are revising § 112.43(a) to include additional examples besides chemical treatment methods.

(Comment 202) Some comments state that, under the NOP standards, only certain specified substances may be used as disinfectants and sanitizers in organic crop production (provided that the use of such substances does not contribute to contamination of crops, soil, or water), and that currently no pesticide chemicals are allowed under the NOP that organic farmers would be able to use to treat water. Similarly, a trade organization comments that they are unaware of any antimicrobial pesticide that would be effective, allowed for use under the NOP, and allowed for use according to its label. A State department of agriculture states that a surface water irrigator treating water with antimicrobial pesticides could result in organic producers located downstream to use water that has been treated, which could cause them to have their organic certifications revoked. Another comment expresses concern that water treatment chemicals will damage the microbiology of the soil, thus compromising the ability of

organic farmers, who depend on the soil biology ecosystem, to grow safe and healthy food.

(Response) Throughout the development of the produce safety regulation, we have been working with USDA on a number of issues, including on whether and how this rule affects compliance with the NOP regulations. Compliance with the provisions of this rule does not preclude compliance with the requirements for organic certification in 7 CFR part 205. As discussed previously, this rule does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44, as applicable. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. Thus, this rule does not require organic farms to use a substance that is prohibited in organic production.

We understand that substances which are prohibited in organic production are described in 7 CFR 205.105. We advise you to consult with the NOP for additional information related to concerns about downstream effects of chemical treatment of water. In addition, as discussed previously, current options for EPA-registered pesticide chemicals for use in agricultural water are limited for all produce production, including organic produce. However, non-chemical water treatment options (such as filter units, ultraviolet light units, ozonator units, reverse osmosis, and solar methods) are either currently available or being explored, and such treatments may be used in compliance with § 112.43. In addition, options other than treating agricultural water are also available under this rule for organic farms, just as for all other covered farms. See also our responses to Comment 194 and Comment 196.

FDA has acknowledged in Chapter 4.2 of the EIS that certified organic farms are restricted to pesticides approved on the National List of Allowed and Prohibited Substances. However, FDA has determined that sustained, long-term water treatment may not be required because the added flexibility to account for microbial die-off and/or removal may be as simple as allowing sufficient time between final application of irrigation water and harvest. Certified organic farms will have sufficient flexibility to choose management decisions that allow them to retain their certification, including non-chemical

water treatments, postharvest options with and without chemicals, using alternative water sources and others as discussed in further detail in Chapter 4.2 of the EIS. The EIS also considers impacts of water quality criteria established in this rule on various resources, including soils (Ref. 126).

(Comment 203) Some comments discuss the costs associated with treating water under proposed § 112.43. Comments assert that some irrigation districts, municipalities, and farms lack the necessary infrastructure or financial resources to build such infrastructure. An additional comment states that increased use of antimicrobials in postharvest water will increase farm operating costs, and could lead to capital costs to mitigate increased amounts of contaminated waste water discharges.

(Response) See our responses to Comment 194, Comment 195, Comment 200, and Comment 201. We also recognize that covered farms will need time to consider the various options, and may need some adjustments to their existing practices or operations, to comply with the water provisions in this rule. Therefore, for covered activities involving covered produce (except sprouts), we are providing extended compliance periods for certain water provisions, as explained in section XIII.K of this document. We also intend to work with our State, tribal, and local partners and target our education and technical assistance efforts to smaller farms to help farms meet the requirements of the rule.

With respect to the comment about increased costs, we estimate costs of antimicrobial use and related capital investments in our RIA. See the final RIA for a discussion of costs (Ref. 142).

(Comment 204) One comment asks that we clarify that agricultural water should not be treated under § 112.43 if such treatment would conflict with applicable laws.

(Response) There is nothing in § 112.43, specifically, or in part 112, generally, that requires or authorizes violations of other applicable laws. Should a covered farm choose to treat their agricultural water to ensure it meets the applicable requirements for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, and local regulations.

E. Microbial Quality Criterion for Agricultural Water Used for Certain Specified Purposes (§ 112.44(a)) and Corresponding Corrective Measures (§ 112.45(a))

(Comment 205) Some comments support the applicability of the microbial quality criterion in proposed § 112.44(a) (*i.e.*, no detectable *E. coli*) for uses of water specified under this provision. Some comments also state that water used during harvest, packing, and holding activities should be tested on a more frequent basis than other water used for agricultural purposes, and request FDA to provide guidance on the specifics of a sampling plan.

(Response) We are finalizing proposed § 112.44(a), such that the no detectable *E. coli* requirement applies to agricultural water that is used for purposes specified in that section. We are deleting proposed § 112.44(a)(3) because we received comments indicating that this reference to treated agricultural teas in subpart E was confusing (see Comment 270 and Comment 271). We have amended § 112.51(a) and (b) in subpart F, and the definition of “agricultural tea” in § 112.3(c), to clarify the requirements applicable to water used to make an agricultural tea.

We address testing frequency requirements in Comment 224. In addition, we refer you to the discussion under Comment 180 and Comment 181, where we explain the requirements for corrective measures that must be taken, and the timing for when such corrective measures must be taken, in accordance with § 112.45(a), when your agricultural water does not meet the microbial quality criterion in § 112.44(a) for those specified purposes.

In the supplemental notice, we did not propose specific testing frequency requirements applicable to untreated surface water that is used for the purposes in § 112.44(a). Instead, we proposed that you must test the quality of each source of the untreated surface water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard and that you must have adequate scientific data or information to support your testing frequency (proposed § 112.45(d)). We also noted that although we were not restricting use of untreated surface water solely to growing activities (*e.g.*, irrigation, crop protection sprays), we anticipated that the primary use of untreated surface water would be during growing activities. Thus, in the supplemental notice we did not specifically prohibit a farm from using untreated surface

water for any purpose described in § 112.44(a), provided that the water meets the no detectable *E. coli* standard for those purposes. We asked for comment on the prevalence of use of untreated surface water for the purposes listed under § 112.44(a), and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. We also asked for comment on whether we should require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical (79 FR 58434 at 58454).

Some comments that responded to this request ask for clarification on what would be an adequate frequency or for guidance on an appropriate sampling plan. We continue to find it challenging to establish a generally applicable sampling scheme or frequency that would provide sufficient confidence that any source of untreated surface water, given the inherent variability associated with such sources, will consistently meet the no detectable *E. coli* microbial water quality criterion in proposed § 112.44(a). Moreover, none of the comments explicitly recommended or supported retaining this testing requirement as a means to allow use of untreated surface water for the purposes in 112.44(a). Under the Surface Water Treatment Rule (40 CFR 141.70–141.75), EPA requires public water systems to treat surface water or ground water sources under the direct influence of surface water to meet the requirements of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*). The intended uses listed in § 112.44(a) have high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. Considering this, as well as the inherent variability of the quality of untreated surface water sources; the absence of an identifiable, appropriate testing and sampling scheme to ensure the safe use of such untreated surface water for the purposes of § 112.44(a); and the lack of comments persuading us to retain proposed § 112.45(d), we are eliminating proposed § 112.45(d) from subpart E and adding a prohibition in § 112.44(a) on using untreated surface water for any of the purposes identified in that section.

(Comment 206) One comment recommends that we establish less protective water quality requirements than those in proposed § 112.44(a) and

§ 112.44(c) that would be applicable to produce commodities that may be cooked or that are often cooked, and that we establish for such commodities a labeling requirement similar to “Safe Handling” labeling instructions for consumers that appear on meat products.

(Response) We do not agree that such an approach would appropriately minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. We believe the provisions in §§ 112.2(a) and 112.2(b) sufficiently address the circumstances where produce is either rarely consumed raw or receives commercial processing to adequately reduce pathogens. For produce that is not “rarely consumed raw” or receives commercial processing to adequately reduce pathogens, we do not believe that less protective water requirements along with labeling instructions would be appropriately protective of public health or fulfill our FSMA mandate to establish science-based minimum standards for the safe production and harvesting of produce that minimize the risk of serious adverse health consequences or death. It is unclear how we could determine appropriate microbial criteria for such a “less protective” set of microbial water standards. It is also not clear that consumers would always cook such produce even if it were labeled with instructions that it should only be consumed after cooking or that consumers would understand why there were cooking instructions on a product that is often consumed uncooked.

(Comment 207) Some comments suggest the microbial quality requirement in proposed § 112.44(a) should apply to postharvest activities only.

(Response) As discussed in the QAR, water used for the purposes listed in § 112.44(a) has high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. We explained our rationale for subjecting the intended uses of agricultural water listed in § 112.44(a) to the stringent zero detectable *E. coli* microbial quality standard in the 2013 proposed rule (see 78 FR 3504 at 3568). Therefore, we disagree with the commenters’ suggestion that the microbial quality criterion in § 112.44(a) should be limited to postharvest uses only (See

also discussion in section XIV.A.1 of this document).

(Comment 208) One comment points out that under the proposed provisions of part 112, on-farm postharvest handling of produce (such as packing) grown on the farm or other farms under the same ownership would be required to comply with the proposed § 112.44(a) requirement to test water used for the listed purposes to ensure there is no detectable generic *E. coli*; but that the same activities, when subject to proposed part 117 (e.g., when the produce is packed off-farm, or on-farm packing of produce from a farm under separate ownership) would not be subject to specific provisions requiring testing of such water.

(Response) First, we note that there is no requirement to test water from certain types of public water systems used for the purposes listed in § 112.44(a), nor is there any requirement to test water treated in accordance with § 112.43 used for the same purposes (see § 112.46(a)). See Comment 222. In addition, we are prohibiting use of untreated surface water for these purposes (see § 112.44(a)), which means that only untreated ground water must be tested when used for these purposes (see § 112.46(c)).

Second, as discussed in section IX.B. and in the supplemental notice, we have revised the definition of “farm” so that farms that pack or hold produce RACs that are grown on a farm that is under different ownership would no longer necessarily be “farm mixed-type facilities” subject to the requirements of the PCHF regulation. Rather, packing or holding others’ produce RACs on a covered farm will be subject to this rule unless the farm or the produce is otherwise exempt or not covered. Thus, there is no longer a difference in what requirements will apply to testing water used in on-farm postharvest handling of produce based on where the produce was grown. Moreover, we are also revising the definition of “farm” to include certain operations (Secondary Activities Farms) devoted to harvesting, packing, and/or holding of RACs, provided that the Primary Production Farm(s) that grow or raise the majority of the RACs harvested, packed, and/or held by the Secondary Activities Farm own, or jointly own, a majority interest in the Secondary Activities Farm. Thus, farm-owned cooperative packing houses, for example, will be considered Secondary Activities Farms, and water used in their postharvest handling of produce will be subject to this rule unless the farm or the produce is otherwise exempt or not covered.

This rule does not apply to activities of a facility subject to section 418 of the FD&C Act. Such activities are addressed in the final human preventive controls rule and the final animal preventive controls rule (80 FR 55908 and 80 FR 56170, respectively).

F. Microbial Quality Criteria for Agricultural Water Used for Direct Application During Growing Activities of Produce (Other Than Sprouts) (§ 112.44(b) and Corresponding Corrective Measures (§ 112.45(b))

1. Microbial Quality Criteria (§ 112.44(b))

(Comment 209) Several comments assert that the use of EPA’s Recreational Water Quality Criteria (RWQC) is inappropriate or insufficient for use in setting the microbial quality standard for agricultural water, as established under proposed § 112.44(c). Comments express various concerns, including that: (1) FDA has not established a correlation between the RWQC and food safety and applying recreational water standards to irrigation water does not meet the statutory obligation to establish science-based standards for food safety; (2) the RWQC were developed more than two decades ago and do not reflect current science; (3) FDA has not provided sufficient explanation for how the RWQC would serve to minimize risk of known or reasonably foreseeable hazards, and that FDA, itself, acknowledges the limitations of using the RWQC; (4) the RWQC are likely appropriate for some, but not all, crops; and (5) the RWQC may not be achievable in areas of the country that use surface water for irrigation. These comments recommend that any microbial quality standard established in a final rule should be based on data that are specific to produce safety and agricultural water. In contrast, some comments support the use of RWQC in developing the microbial quality criteria in proposed § 112.44(c).

(Response) We disagree with the assertion that the use of the science underlying the RWQC is inappropriate for informing the development of microbial quality criteria for agricultural water used in direct application during growing of produce (other than sprouts), which are now established in final § 112.44(b). We agree that the RWQC (which are based on data collected from recreational waters), in and of themselves, do not sufficiently reflect the circumstances associated with agricultural water used in produce production. However, we are not simply applying the RWQC as the safety standard for agricultural water. Rather,

as discussed in the supplemental notice, we find that the science underlying the RWQC provides a starting point for quantitative microbial criteria that are generally applicable to minimize the risk of known or reasonably foreseeable hazards associated with the use of agricultural water on produce (other than sprouts) during growing using a direct water application method. The RWQC, which have been updated in 2012, are based on several recent epidemiological studies and use a broader definition of illness to recognize that gastrointestinal symptoms may occur without a fever (Ref. 100). Among other evidence, EPA considered the latest research and epidemiological data that demonstrate a link between fecal contamination in recreational waters and illness, and characterizes the rate of illness based on the epidemiological data. Using those data, the EPA criteria demonstrate the microbial threshold at which an exceedance of the threshold increases illness occurrence to protect primary contact recreation where immersion and incidental ingestion are likely (Ref. 100). In addition, the EPA analysis does not distinguish the illness rates between different bodies of water (*i.e.*, marine or fresh) due to incidental ingestion. Overall, we find the scientific rigor underlying the RWQC to be sufficient for us to rely on to inform our thinking on agricultural water used in produce production, which is also consumed *via* incidental ingestion. We described the rationale for our use of the science underlying the RWQC and our thinking on its relevance to agricultural water in a reference memorandum that accompanied the supplemental notice, and we reiterate those conclusions here (Ref. 44).

In the supplemental notice, we acknowledged that there are different ways to determine STV, including through sample-based empirical estimation and model-based calculation, and requested comment on whether there is a specific statistical method(s) that we should either require or recommend be used for the derivation of GM and/or STV values (79 FR 58434 at 58453). We did not receive comments recommending any specific method(s) for calculation. On further evaluation, we find a parametric estimation method based on the lognormal distribution to be appropriate for deriving the STV for purposes of determining the microbial water quality criteria and any necessary follow-up measures specified in §§ 112.44(b) and 112.45(b)(1), respectively. Unlike empirical methods, model-based methods of calculating the STV are more sensitive to the range of

extreme values that may be obtained among the sample outcomes when the STV is being determined based on a relatively small number of samples. Therefore, we are specifying that the STV of your water samples calculated to determine whether your water meets the microbial quality criteria specified in § 112.44(b), must be derived as a model-based calculation based on the lognormal distribution. (See Comment 229 where we address guidance related to this issue.)

Therefore, we are finalizing the microbial quality criteria for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method of: (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and (2) a statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

Using the RWQC as a starting point, we then considered available scientific information and recommendations to account for circumstances that are unique to produce growing (including irrigation), such as microbial die-off after application of water, which are factors that were not accounted for in formulating water quality requirements in the EPA RWQC (Ref. 123) (Ref. 143). We considered the World Health Organization's (WHO) *Guidelines for the Safe Use of Wastewater, Excreta, and Greywater, Volume II, Wastewater Use in Agriculture*, which were developed with the primary aim of "maximizing public health protection and the beneficial use of important resources" (Ref. 123). These guidelines are intended to be relevant "to the intentional use of wastewater in agriculture and [are] also relevant where faecally [sic.] contaminated water is used for irrigation unintentionally" and provide "an integrated preventive management framework for safety." These guidelines recommend various health protection measures that can be used alone or in combination to achieve a specific microbial log reduction, or range of reductions, necessary to meet the desired health outcome. The health protection measures reflected in the WHO guidelines are intended to achieve a tolerable disease burden from consumption of raw food crops irrigated by treated wastewater of 10^{-6} disability-

adjusted life years per person, per year (Ref. 44). The post-irrigation microbial die-off and/or microbial removal provisions in final § 112.45(b)(1) were informed by our analysis of these WHO guidelines.

(Comment 210) In the supplemental notice, in relation to the microbial quality criteria in proposed § 112.44(c), we asked for comment on whether we should establish a single sample maximum level of *E. coli* above which the water should not be permitted for use in direct application (until specific follow-up actions are taken to ensure it meets the recommended microbial quality requirements) and, if so, what would be an appropriate maximum level (78 FR 58444). Some comments oppose a maximum threshold level of *E. coli*, arguing that it could lead to discontinuation of water unnecessarily because of the variability in quality of irrigation water, and one of these comments argues that any such maximum levels should be included in guidance rather than in regulation.

(Response) We are not establishing a single sample maximum threshold of generic *E. coli* in relation to the microbial quality criteria in § 112.44(b). Our approach to developing the standard for safe use of agricultural water during growing covered produce (other than sprouts) relies on measures taken by covered farms to know and respond to the quality of their agricultural water over the long term. Rather than setting a single sample maximum generic *E. coli* standard, we are establishing a STV of 410 CFU or less generic *E. coli* per 100 mL of water. The STV is a value that is derived as a model-based calculation based on the lognormal distribution and approximates the 90th percentile of the water quality distribution. The use of an STV rather than a single sample maximum is designed to account for the variability of water sources, in particular of surface water sources.

(Comment 211) Several comments recommend FDA set an "interim" microbial water quality requirement in proposed § 112.44(c), and then pursue additional research to inform the development of a final microbial quality standard that accounts for the diversity in farming practices and produce commodities. Such comments advise that such an "interim" standard should include a mandatory sunset provision, which they expect would provide an opportunity for stakeholders to work together to conduct research and develop meaningful commodity- and situation-specific microbial quality standards for agricultural water.

(Response) As previously noted, we do not agree that more research is needed for us to finalize the provisions of this rule relating to agricultural water. We also disagree that we should establish requirements with sunset provisions as suggested by these commenters. As discussed in the 2013 proposed rule, the supplemental notice, and in this document, there is sufficient scientific information from which we conclude that the requirements in this rule minimize the risk of serious adverse health consequences and death, and are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. However, we do support additional research as a means of facilitating implementation of the rule and continuing advancement of scientific knowledge in this area, and we are pursuing regulatory science and research activities in collaboration with various partners (see Comment 174).

(Comment 212) Several comments recommend other approaches for us to consider in establishing microbial quality requirements for § 112.44(b) uses, including: (1) Using the WHO standard, asserting it may be easier to implement and more easily understood by foreign producers; (2) adopting a qualitative standard to require that water must be of adequate quality for its intended use; and (3) applying the microbial standard for drinking water to agricultural water for a certain specified period prior to harvest, and evaluating whether water meets this standard using a single water test taken at a certain time prior to harvest. In addition, several other commenters argue that any agricultural water requirement for this purpose should be no more restrictive than the WHO standard.

(Response) See Comment 209. The WHO guidelines present several illustrations for how to reduce risks associated with consuming raw crops irrigated by wastewater. However, these are only examples of how to apply the guidelines to reach the health-based target. They do not represent specific water quality criteria for particular commodities. The guidelines recommend several health protection measures, each of which can be used alone or in combination to achieve a specific microbial log reduction or range of microbial reductions necessary to meet the desired ($\leq 10^6$ disability-adjusted life years) health outcome. This rule draws upon the WHO water guidelines, but not as a fixed microbial quality standard, *per se*. As discussed in the supplemental notice, the WHO values (*i.e.*, 1,000 CFU per 100 mL and

10,000 CFU per 100 mL for root crops and surface crops, respectively) are better explained as illustrations of how specific health protection measures could be used together after waste water treatment to achieve the additional log reductions recommended for waste water reuse, and were not intended as absolute end points or maximum permitted levels for generic *E. coli* in irrigation water. As explained in (Ref. 44) regarding the review of water quality standards in development of the microbial quality criteria in § 112.44(b), the WHO guidelines do not include any specific criteria for maximum acceptable *E. coli* levels in wastewater for agricultural use in the growing of produce. We also conclude that a quantitative microbial quality requirement that is enforceable and requires action by industry to ensure the criteria are met would be both more practicable and more protective of public health than a qualitative water quality standard alone. The microbial quality criteria we have established serve as objective measures to be applied to indicate the quality of agricultural water when used for certain specified purposes. Note that we are also retaining the general “safe and of adequate sanitary quality” qualitative standard in § 112.41, which applies to all agricultural water regardless of the specific intended use.

In response to the comment suggesting requiring agricultural water to meet the drinking water standard for a specified period of time pre-harvest and only requiring a single test, we do not believe it is necessary to require water used in the field to meet the drinking water standard in light of the die-off of microorganisms that can be expected to occur after application of agricultural water. As described in Comment 214, we conclude it is appropriate to account for microbial die-off between last irrigation and harvest, as well as between harvest and end of storage, as provided in § 112.45(b)(1).

(Comment 213) Several comments support the use of the GM and STV as proposed in the supplemental notice and prefer that approach over the original approach in the 2013 proposed rule (using a GM and a single sample maximum). These comments state that the GM and STV approach is risk-based, appropriately protective, flexible, and does not unduly burden farmers. However, other comments state the calculations related to GM and, in particular, STV required under proposed § 112.44(c) are complicated and are likely to be confusing and challenging for farmers to implement. Some comments request that FDA

provide assistance to farms regarding the calculation of GM and STV, and the application of the microbial die-off and/or removal provisions. Comments also ask FDA to develop guidance and web-based tools to help with these calculations.

(Response) We appreciate the comments that recognize the value of the GM and STV approach as opposed to our original proposed approach that included a single sample maximum. However, we also recognize the need for outreach regarding how to calculate the GM and STV, how to use microbial die-off and/or removal rates, and how to calculate related time intervals. We intend to provide guidance on these topics in the Produce Safety Regulation Implementation guidance, which we expect to issue in the near future. In addition, we are exploring the development of an on-line tool that you can use to derive the GM and STV values and appropriate time intervals (in days) between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that a farmer would not need to perform the necessary calculations themselves.

2. Allowance for Microbial Die-Off and/or Removal (§ 112.45(b)(1)) and Other Corrective Measures (§ 112.45(b)(2) and (b)(3))

(Comment 214) Several comments support proposed § 112.44(c)(1) and (c)(2) that would allow farms to account for microbial die-off or removal between last irrigation and harvest and between harvest and end of storage, or during activities such as commercial washing. These comments state these mechanisms provide flexibility; serve as a reasonable approach to identifying practices that reduce risk; and minimize the need for chemical water treatment. In addition, several comments suggest that these provisions should be expanded and applied to operations where there is no reasonable likelihood of direct water contact with the harvestable portion within a specified number of days before harvest.

(Response) We are retaining the microbial die-off and removal provisions in final § 112.45(b)(1)(i) and (b)(1)(ii). For the purposes of this rule, we define agricultural water as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities and in harvesting, packing, and holding activities. Moreover, we use “covered produce” to refer to the harvestable or harvested part of the crop. Therefore,

the provisions in subpart E, including § 112.44(b) and corresponding § 112.45(b), do not apply to water that is not intended to or likely to come into contact with covered produce, and we are not establishing microbial quality criteria (or related microbial die-off or removal provisions) for such water. See also Comment 179.

We are also making other revisions within final § 112.45(b) to consolidate and clarify applicable options for corrective measures when agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method does not meet the microbial quality criteria in § 112.44(b). That is, available options include (1) applying a time interval (in days) between last irrigation and harvest (§ 112.45(b)(1)(i)) and/or between harvest and end of storage and/or applying a (calculated) log reduction during activities such as commercial washing (§ 112.45(b)(1)(i)); (see also Comment 218 discussing certain revisions to these provisions); (2) re-inspect your entire affected agricultural water system to the extent it is under your control, and among other steps, make necessary changes and adequately ensure that your water meets the criteria in § 112.44(b) (§ 112.45(b)(2)); or (3) treat the water in accordance with § 112.43 (§ 112.45(b)(3)). Consistent with our intent for the microbial quality criteria in § 112.44(b) to serve as a long-term water management tool, we further clarify in § 112.45(b) that these corrective actions must be taken as soon as practicable, and no later than the following year. We expect you to apply these corrective measures as soon as it is practicable, considering various factors specific to your practices and commodities, including, for example, the timing when water testing results are obtained in relation to the current harvest of your commodity or commodities; whether you have a single or multiple commodities with different harvest cycles; and whether your commodity is of a nature such that the time intervals and/or (calculated) log reductions in § 112.45(b)(1)(i) and/or (b)(1)(ii) can be applied. However, we require you to implement such corrective measures no later than the following year. If none of the corrective measures in § 112.45(b)(1)–(3) are used, or if such measures are not effective in achieving the required criteria, you must discontinue that use of the water from that source.

(Comment 215) Several comments express concern that the burden is placed on covered farms to conduct research and identify appropriate microbial die-off or removal rate(s) that

can be applied between harvest and end of storage or during activities such as commercial washing.

(Response) As noted in the supplemental notice, at this time, we are not establishing a specific microbial die-off rate(s) between harvest and end of storage or specific microbial removal rate(s) during postharvest activities such as commercial washing because we do not have sufficient information to support the derivation of appropriate, broadly applicable microbial die-off or reduction rate(s) for these purposes. Nevertheless, we provide this option in final § 112.45(b)(1)(ii), along with revisions requiring you to use an accompanying maximum time interval or log reduction. See Comment 218. We are retaining this option so covered farms may establish and apply an adequate time interval or calculated log reduction using microbial die-off or removal rate(s) relevant to the covered produce and dependent on practices and conditions on the farm, provided the farm has adequate scientific data or information to support the conclusions. We are working with our stakeholders to facilitate research into appropriate die-off and/or removal rates for these activities, and we intend to disseminate useful scientific information, when available, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

(Comment 216) Several comments ask about the science underlying the microbial die-off rate in proposed § 112.44(c)(1) that is used to determine the time interval between last irrigation and harvest. Comments state that the established rate may not be uniformly applicable across diverse real-world conditions on farms producing different commodities across the country.

(Response) The microbial die-off rate in § 112.45(b)(1)(i) is based on our review of currently available science. As explained in the supplemental notice, we determined that a microbial reduction rate of 0.5 log per day provides a reasonable estimate of die-off under a broad range of variables including microbial characteristics, environmental conditions, crop type, and watering frequency. (See (Ref. 45) (Ref. 144) for information about the studies we reviewed, our criteria for study selection, and our conclusions.) We recognize that microbial die-off rates are dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Although our analysis led us to conclude that a rate

of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables, we understand that different microbial die-off rates may occur between last irrigation and harvest under different circumstances (Ref. 45) (Ref. 144). For example, higher microbial die-off rates may occur under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation in comparison to the die-off rates observed under cloudy, cool, and wet conditions (Ref. 123). Therefore, in final §§ 112.45(b)(1)(i)(B), 112.49(b), and 112.12, we are providing for the use of appropriate alternative microbial die-off rate(s) (as well as an accompanying maximum time intervals), provided you have adequate scientific data or information to support a conclusion that the alternative die-off rate would provide the same level of public health protection as the 0.5 log per day die-off rate in § 112.45(b)(1)(i)(A), and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act, in light of your covered produce, practices, and conditions. We expect that covered farms that rely on an alternative die-off rate under these provisions to use a rate that is supported by an equally robust and rigorous scientific analysis applicable to the region and crop for which the alternative would be used. We would expect such an alternative rate to be quantitatively demonstrated to be equivalent to the FDA-established rate under the relevant conditions, thus “providing the same level of public health protection” as the FDA-established rate and ensuring that the alternative rate would not increase the likelihood that the farm’s covered produce will be adulterated, as required under § 112.12.

(Comment 217) One comment notes the importance of end-of-season irrigation water to overall yields, and asks FDA to consider the detrimental effects of ceasing irrigation in establishing the water standards.

(Response) We recognize the importance of irrigation during produce production, and have provided options in § 112.45(b)(1) that account for microbial die-off and/or removal post irrigation, as additional means to achieve the microbial quality criteria for agricultural water that is used in a direct application method during growing of produce (other than sprouts). We also note that we have incorporated flexibility for covered farms to use an alternative microbial die-off rate in lieu of our established die-off rate, under certain specified conditions (see

§ 112.49(b)). We expect that, in most cases, these provisions will provide sufficient flexibility for covered farms to achieve our microbial quality criteria, as soon as practicable, and no later than the following year, without having to cease irrigation. See also Comment 214 regarding timing of corrective actions and other available options.

(Comment 218) Several comments state the microbial die-off and/or removal provisions in proposed § 112.44(c)(1) and (c)(2) should not be allowed to be used when agricultural water exceeds a certain level of generic *E. coli*. These comments recommend a maximum time interval between last irrigation and harvest of 4 days, applying a microbial die-off rate of 0.5 log per day. One comment provides the example that if the water quality is uncontrollable or testing results are between 410 and 41,000 CFU *E. coli*/100 mL, a time interval between last irrigation and harvest at a rate of 0.5 log per day, to a maximum of 4 days should be permitted, but that such flexibility for microbial die-off is not appropriate when water testing results indicate a level of above 41,000 CFU *E. coli*/100 mL.

(Response) As discussed in the QAR, the timing of water application can affect the potential for produce contamination. For example, water containing elevated generic *E. coli* used in overhead irrigation shortly before harvest may increase the likelihood of covered produce being contaminated at the time of harvest, but the same water could be used to establish a crop because microbes die-off over time on the surface of produce. Studies reporting decay constant(s) measured over time have concluded that microbial die-off rates are highest immediately following contamination and slow over time (Ref. 45) (Ref. 144). This phenomenon, known as “tailing,” suggests microbial die-off curves are biphasic, *i.e.*, two decay constants may be needed to accurately describe microbial die-off over time. Moreover, it suggests the initial time period immediately following a contamination event via irrigation is the most important time period in reducing the numbers of microbes (including pathogens) present on the crop.

We also reviewed available literature for a maximum time interval that is appropriate when applying a microbial die-off rate of 0.5 log per day. The studies we reviewed indicate that greater microbial die-off or decay rates occur during the early timeframe post-contamination, and although the die-off rate in these studies was established from survival data or decay rates for

bacterial studies ranging from 2–7 days, the specific timeframe for the biphasic shift in die-off was not identified (Ref. 45) (Ref. 144). Within this range identified in the literature, a maximum time interval of 4 days is reasonable because it serves as a general mid-point in time representing neither end of the range where microbial die-off was observed in these studies. A maximum time interval of four consecutive days is also consistent with recommendations by commenters. Therefore, we are adding a new limitation in § 112.45(b)(1)(i)(A) that a time interval of no more than four consecutive days may be applied between last irrigation and harvest to achieve the microbial quality criteria in § 112.44(b). In addition, we expect any scientifically-supported die-off rate that a farm applies as an alternative under § 112.45(b)(1)(i)(B) between last application and harvest; or to determine the appropriate time interval between harvest and end of storage, in accordance with § 112.45(b)(1)(ii), to be similarly characterized in a manner that addresses the likely biphasic nature of microbial die-off (*i.e.*, the two different decay constants of a rapid short-term die-off and a gradual long-term die-off). We also expect that if you develop an alternative to the microbial quality criteria in § 112.44(b) and if you intend to take advantage of the provision in § 112.45(b)(1)(i) applying die-off between last application and harvest, then you must also appropriately characterize a microbial die-off rate between last irrigation and harvest that relates to your alternative microbial quality criteria, including consideration of the likely biphasic nature of microbial die-off.

(Comment 219) One comment requests flexibility to apply the 0.5 log per day die-off rate in proposed § 112.44(c)(1) on a per hour, rather than a per day, basis.

(Response) We have determined the microbial die-off rate of 0.5 log per day between last irrigation and harvest in final § 112.45(b)(1)(i)(A) based on our review and analysis of currently available evidence. There is not enough evidence to support modifying the die-off rate that is reported in time periods of days in current literature to microbial die-off per hour. Moreover, decay constants have been found to vary within the 24 hour cycle, depending on climatic and other conditions (Ref. 145) (Ref. 146) (Ref. 147) (Ref. 148) (Ref. 149). Therefore, we do not believe it is appropriate to extrapolate the per day die-off rate to a per hour die-off rate.

(Comment 220) Some comments question the need to subject water that

is used in the growing of dry bulb onions using a direct water application method to the testing requirements in proposed § 112.45, particularly in light of the microbial die-off and removal provisions in proposed § 112.44(c)(1) and (c)(2). These comments find the testing requirements burdensome and unnecessary for water used in the growing of dry bulb onions because harvest typically occurs weeks or months after irrigation. One comment suggests a 6-day time interval between last irrigation and harvest would be sufficient to account for a “worst case scenario of 20,000 CFU generic *E. coli*/100 mL” water quality, and that dry bulb onion farms should be allowed to “opt out” of testing requirements for untreated surface water in proposed § 112.45(b), if they allow 6 days to elapse between last irrigation and harvest.

(Response) We recognize that covered farms growing dry bulb onions typically have an extended period between last irrigation and harvest and between harvest and end of storage, which should help them comply with the microbial water criteria in final § 112.44(b) for agricultural water that is used during growing of dry bulb onions using a direct application method. However, unless untreated surface water that is used during growing in a direct application method is tested, there would be no way to determine whether there is a need to apply a time interval between last irrigation and harvest and, if so, the appropriate time interval. Therefore, when required under final § 112.46, agricultural water testing and calculation of the GM and STV must be done to inform and determine the appropriate way(s) in which the water may be used. To take advantage of the die-off and/or removal options in § 112.45(b)(1), you must first characterize the water quality by testing in accordance with § 112.46(b) and calculate a GM and STV. Moreover, under § 112.45(b)(1)(i), the use of the microbial die-off rate of 0.5 log per day between last irrigation and harvest is limited to four consecutive days (see Comment 218). At a rate of 0.5 log per day and a maximum of four days, the die-off option provided in § 112.45(b)(1)(i)(A) could not, on its own, effectively achieve the microbial quality criteria for water containing 20,000 CFU generic *E. coli*/100 mL if this value represents the GM, as presented in the comment. You may instead apply an alternative microbial die-off rate under §§ 112.45(b)(1)(i)(B), 112.49(b), and 112.12. To do so, you must have adequate scientific data and

information to support your conclusions, as required in those provisions, and you must determine an accompanying appropriate maximum time interval associated with your alternative die-off rate, similar to the 4-day maximum under § 112.45(b)(1)(i)(A). Also, under § 112.45(b)(1)(ii), you may apply a microbial die-off rate between harvest and end of storage, and/or a microbial removal rate for activities such as commercial washing, that is relevant to your covered produce and dependent on practices and conditions on your farm, provided you have adequate scientific data or information to support your conclusions (see also corresponding documentation requirement in § 112.50(b)(5)). As for the die-off or removal rates in § 112.45(b)(1)(ii), you must also determine an accompanying maximum time interval or log reduction associated with these die-off rates, similar to the 4 day maximum under § 112.45(b)(1)(i)(A). See Comment 216.

While these flexible options make it less likely that a dry bulb onion farm will find that its untreated surface water cannot meet the § 112.44(b) criteria, the fact that each of these die-off or removal rates may have a maximum appropriate application limit means that they cannot be presumed to reduce the GM and STV of the most contaminated water sources to a level compliant with § 112.44(b). Testing must be conducted to determine the quality of the water and determine whether it is usable within the requirements of the rule.

(Comment 221) In the supplemental notice, we asked for comment on whether we should require farms to establish and maintain any documentation in relation to the option to apply a time interval between last irrigation and harvest. One comment recommends requiring records to be maintained on the time interval applied, how the time interval was calculated, and/or the dates of last irrigation and harvest corresponding to that time interval. The commenter also notes, however, that such records should be required only in the case where the agricultural water tested in accordance with proposed § 112.45 does not meet the microbial quality criteria established in proposed § 112.44(c).

(Response) We agree that documentation of the time interval applied, calculation of the time interval based on water testing results, and the dates of last irrigation and harvest corresponding to that time interval, must be prepared and maintained, when the provision in § 112.45(b)(1)(i) is applied to achieve the microbial quality criteria in § 112.44(b). Likewise, records

must be made and kept of the time interval or calculated log reduction applied, calculation of the time interval or log reduction based on water testing results, and the dates of harvest and end of storage or other relevant activities corresponding to that time interval or log reduction, when the provision in § 112.45(b)(1)(ii) is applied to achieve the microbial quality criteria in § 112.44(b). Such records would be required only when such a time interval or log reduction is applied, in accordance with § 112.45(b)(1), and not when no such time interval(s) is applied. We are adding this records requirement in new § 112.50(b)(6) (corresponding with our elimination of proposed § 112.161(b)), which requires you to document any actions you take in accordance with § 112.45. This new section also provides specifically that you must prepare and maintain documentation of any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), including the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities (such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing).

G. Testing of Agricultural Water (§ 112.46)

1. Testing of Agricultural Water Not Required Under Certain Conditions (§ 112.46(a))

(Comment 222) Some comments believe proposed § 112.45(a) would allow farms to draw and hold municipal water with no further requirement to test that water. These comments state that the provision, as proposed, is not sufficiently protective of the quality of water from public water system to forgo testing.

(Response) In final § 112.46(a), we are retaining proposed § 112.45(a), which establishes that there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when: (1) You receive water from a public water system, under the conditions specified in that provision (§ 112.46(a)(1)); (2) you receive water from a public water supply that furnishes water that meets the microbial quality requirement in § 112.44(a), under the conditions specified in that provision (§ 112.46(a)(2)); or you treat water in accordance with § 112.43 (§ 112.46(a)(3)).

This exception from the testing requirements that follow in § 112.46(b)

and (c) applies only when water received from a public water system (as in § 112.46(a)(1)) or a public water supply (as in § 112.46(a)(2)) is not held under your control in a way that meets the definitions of “ground water” or “surface water” before you use it as agricultural water. See the definitions of “ground water” and “surface water” in § 112.3(c). If you hold water received from a public water system or public water supply in either a ground water or a surface water capacity, the water is exposed to potential contamination in a manner similar to other ground water or surface water sources, such that it becomes a “ground water” or “surface water” source as applicable, and the testing requirements applicable to untreated ground water or untreated surface water will apply, as established in § 112.46(b) and (c).

We are also revising § 112.46(a)(1) to add a reference to the relevant EPA definition of a State approved to administer the SDWA public water supply program by adding a cross reference to the relevant definition in 40 CFR 141.2. The definition of “State” for this purpose includes, in relevant part, the agency of the State or tribal government which has jurisdiction over public water systems.

(Comment 223) One comment asks why a body of water, such as a river, would need to be tested if it meets the federal water quality standards.

(Response) The Water Quality Standards (WQS), issued under the CWA, define the goals for a waterbody by designating its uses, setting criteria to protect those uses, and establishing provisions such as anti-degradation policies to protect waterbodies from pollutants. The WQS regulation at 40 CFR part 131 describes the requirements and procedures for States and authorized tribes to develop, adopt, review, revise, and submit water quality standards. It also establishes the requirements and procedures for EPA to review, approve, disapprove, and promulgate water quality standards as authorized by section 303(c) of the CWA (33 U.S.C. 1313(c)). Water that is determined to be within the established WQS for the waterbody does not necessarily meet the agricultural water requirements in this rule, which as discussed throughout this section, are intended to prevent the introduction of known and reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. For example, many farms rely on ditches to direct water to the field, and these ditches are normally open to the environment and can cover significant distances. There are no

controls in the CWA that would account for potential contamination in these ditches.

2. Approach to Testing Untreated Surface Water (§ 112.46(b)) and Untreated Ground Water (§ 112.46(b) and (c))

(Comment 224) Several comments support the revisions we proposed in the supplemental notice to proposed § 112.45 that we had proposed in the 2013 proposed rule. These comments state the tiered approach to testing described in the supplemental notice better reflects current sources of agricultural water and farmers' practices related to use of those sources of water. These comments also find the proposed tiered approach less burdensome than the originally proposed requirements. Conversely, several other comments state the revisions to proposed § 112.45 proposed in the supplemental notice result in a testing scheme that is overly complicated, burdensome, lacks scientific justification, and does not incorporate sufficient flexibility. These comments state the proposed requirements would impose significant costs on farmers, particularly when agricultural water is derived from multiple water sources and/or when the quality of water from a source is highly variable.

(Response) In the 2013 proposed rule, we proposed requirements for specific frequencies of testing untreated surface water used for the purposes in proposed § 112.44, ranging from once every 7 days to once per month during the growing season, depending on certain specified circumstances related to the source of untreated surface water. A majority of stakeholder concerns with those proposed testing frequencies centered on the financial burden imposed on farms, in particular, under a weekly testing requirement; arguments that FDA did not provide scientific data in support of the proposed testing frequencies; and the need for a more flexible approach accounting for the variability in water quality associated with various water sources and the particular use of the water during growing, harvesting, or postharvest activities. Taking into account these comments, in the supplemental notice, we made the proposed requirements more flexible by proposing tiered approaches to testing untreated surface water (proposed § 112.45(b)) and untreated ground water (proposed § 112.45(c)).

We continue to believe our proposed tiered approaches for testing untreated surface water and untreated ground water used for certain purposes will

allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results and historically derived data; and reduce the required frequency of testing from the testing requirements of the originally proposed rule. A key objective of our requirements for water testing in relation to the microbial quality criteria in § 112.44(b), specifically, is to establish a testing approach sufficient to adequately characterize the quality of the agricultural water such that the information can be used by farms to make informed and appropriate decisions about its use and/or the need for any appropriate corrective actions, prior to such use in the future.

We explained our scientific basis, and underlying statistical analysis, for these testing frequencies in a reference memo that accompanied the supplemental notice, which we have updated for the purposes of this rule (Ref. 99). Our evaluation indicates that minimum sample sizes of 20 samples for initial survey and of 5 samples for annual survey, which we are establishing in our testing scheme for untreated surface water in § 112.46(b), are necessary to provide sufficient precision of estimation of the microbial quality profile (which includes GM and STV values for generic *E. coli*) in order to then use that information to determine and verify appropriate conditions of use of that water (Ref. 99). Similarly, for untreated ground water, we conclude that a minimum sample size of 4 samples for initial survey and of 1 sample for annual survey is necessary when the previous samples have met the microbial quality criteria under the testing scheme that we are establishing in § 112.46(b).

We have introduced flexibility into the testing requirements to minimize burden to the extent possible. For example, we provide flexibility with respect to the timing of sample collection, recognizing the timing of the use of agricultural water in a direct application method during growing varies by crop, region, season, and/or from year to year. This flexibility is intended to permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm. In addition, in new § 112.49(c) and (d), we are allowing, under certain specified conditions, the use of an alternative water testing frequency in lieu of the required minimum number of samples for initial and annual surveys under § 112.46(b)(1)(i)(A) and (b)(2)(i)(A), respectively, for testing

untreated surface water that is used during growing activities using a direct application method for produce (other than sprouts). We are also adding a corresponding provision, in new § 112.50(b)(8) to require documentation of the scientific data or information you rely on to support any such alternative to the required water testing frequencies. In addition, we have also included provisions to permit data sharing among farms as well as to permit covered farms to use data collected by third parties, under certain specified circumstances (see § 112.47(a)). We realize that the testing requirements may be particularly challenging for farms that have multiple agricultural water sources and we encourage farms to provide us with details of their specific situations so that we can consider flexible approaches to testing multiple sources.

Moreover, in final § 112.46(b), we apply the same approach to testing untreated ground water as the approach for testing untreated surface water used during growing for covered produce (other than sprouts) using a direct water application method, except that fewer tests are required at each stage for ground water as compared to surface water (see Comment 225 and Comment 232). We have combined the testing frequency provisions for untreated surface and ground water used for § 112.44(b) purposes into one provision for editorial reasons and to more clearly demonstrate the differences and similarities between the testing required for the two types of sources when the water is used for the same purpose. We note that this retains the same ground water testing frequency for these purposes as proposed in the supplemental notice as § 112.45(c).

In addition, we are revising proposed § 112.45(c) to separately address the testing of untreated ground water when used for purposes of § 112.44(a) (see final § 112.46(c)).

Similarly, in final § 112.46(c), we have retained the general approach as well as the specific frequency for testing of untreated ground water when used for purposes of § 112.44(a), as proposed in the supplemental notice in proposed § 112.45(c).

(Comment 225) One comment states that it is critical to monitor the quality of water used during growing of produce, and supports testing untreated surface water and untreated ground water used during growing at a greater frequency than the frequency we proposed, to allow earlier detection of any contamination of the water.

(Response) The requirements for testing untreated surface water and

untreated ground water used for § 112.44(b) purposes represent science-based minimum standards for the safe production and harvesting of covered produce that we have determined minimize the risk of serious adverse health consequences or death. These testing protocols will enable farms to make decisions about safe use of available water sources prior to the beginning of the next growing season, and to adjust testing frequencies based on long-term test results and historically-derived data. We specify the required testing frequencies that we conclude, based on our statistical analysis, are necessary for sufficient precision of estimation of the microbial quality profile, considering the average variability in the quality of untreated surface water and ground water sources. However, these provisions do not preclude a covered farm from testing at a greater frequency than that required under § 112.46(b)(1)(i) or 112.46(b)(2)(i), as appropriate based on your observations, experience, and practices related to your agricultural water source(s), farming operation, and commodities.

(Comment 226) One comment suggests that FDA should allow each State to develop its own testing regime for ensuring water meets the microbial quality standard in proposed § 112.44(c), subject to FDA approval. This commenter believes such an approach would allow States to tailor testing requirements to the unique circumstances farms encounter in a particular region and suited to growing conditions and variability of water sources in that region.

(Response) Under the provisions in subpart P of part 112, a State (or tribe or foreign country) may request a variance from one or more of the requirements in part 112. A competent authority in a State that considers a water testing approach that deviates from the requirements in § 112.46 to be more appropriate for covered farms within that State may submit a request for a variance, in accordance with the provisions in subpart P. The request for a variance in relation to the testing requirements may include requests for a different testing scheme for untreated surface water and/or ground water sources (in lieu of the tiered approaches we have established in § 112.46(b)), whereas the provisions for alternatives under § 112.49(c) and (d) are restricted only to the use of alternative testing frequencies in lieu of the frequencies we identified in § 112.46(b)(1)(i)(A) and (b)(2)(i)(A) for untreated surface water, and do not extend to the entire tiered

scheme set forth in § 112.46(b) more broadly.

(Comment 227) Some comments assert that the proposed testing frequency requirements in proposed § 112.45 significantly favor use of ground water over surface water, which the commenter believes may be contrary to regional efforts to prevent overdraft of aquifers.

(Response) The differences between the testing frequency requirements for untreated surface water and untreated ground water sources in § 112.46(b) are based on the difference in the expected variability in quality between these two types of sources (see Comment 225 and Comment 232). We have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. This analysis includes potential impacts related to pesticide use, chemical treatment of agricultural water, changes in ground water demand, and existing water quality standards. FDA has considered these potential impacts when making its decision on the provisions to be finalized (Ref. 150).

(Comment 228) Some comments express concern that the testing approach places burden on covered farms to test water sources, including water they receive from irrigation districts, over which they have no control. One commenter believes the responsibility should be on the government or on the irrigation districts, not the farm. Similarly, another comment points out it may not be possible for farms to correct a contamination problem when the source of contamination is not in their control. Another commenter states that if a farm is receiving water from an irrigation district, the farm may not know the water quality and cannot establish the appropriate time interval to account for microbial die-off.

(Response) Regardless of the source of water or who supplies it to the farm, a covered farm is responsible for ensuring the safe and appropriate use of that water in covered activities. Therefore, whether or not the irrigation districts provide information about the quality of water they supply to a farm, the covered farm must take measures to understand the quality of water under their control that is used as agricultural water during the growing, harvesting, packing, or

holding of covered produce, including complying with the testing requirements in § 112.46 when applicable. Test results obtained through such testing will give farms information about the quality of their water and how it may be used in compliance with the rule.

We understand that many covered farms are dependent on irrigation districts to supply water for use in farming, and some covered farms have no control over the quality of the water at the time and place at which they receive the water. We encourage irrigation districts to conduct sampling and testing around the watershed that they manage and to share the data on its water quality with farms that receive the water from that watershed. As described in the supplemental notice, for example, covered farms sourcing water from an irrigation district may consider using water testing data from the district sampling program. A covered farm considering the district sampling program data would need to determine whether the water source(s) sampled adequately represent the covered farm's agricultural water. The covered farm would also need to consider whether the district's data set includes samples collected during a time period(s) as close as practical to the covered farm's harvest time; whether the district's data set satisfies the minimum number of samples the farm is required to have under the rule; and whether the district's data were obtained using appropriate test methods, as described in subpart N of part 112 and cross-referenced in new § 112.47(b). In addition, the covered farm would need to get and keep records of the district's testing that satisfy the rule's recordkeeping requirements.

(Comment 229) Several comments ask for guidance, technical assistance, and outreach related to water testing requirements, including sampling methods and procedures, so farms know how to properly collect samples, process them for testing, and transport them in a sanitary manner. Some comments state that the GM and STV calculations and subsequent analysis necessary to test, verify, and ensure compliant use of agricultural water, are complicated, and that most farmers do not have the expertise necessary to implement these provisions.

(Response) In section XXII of this document, we discuss our plans to work with various organizations on outreach and education for effective implementation of the produce safety regulation. We agree training and outreach will be necessary to ensure covered farms understand the water testing requirements. Relevant staff will

need to be appropriately trained to properly sample, test, and make the necessary calculations to determine how best to use their water. We will consider addressing relevant issues, including appropriate water sampling methods and procedures, in the Produce Safety Regulation implementation guidance to be issued in the near term. In addition, we are exploring the development of an online tool to allow covered farms to derive their GM and STV values and appropriate time intervals between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that farms would not need to perform the necessary calculations themselves.

(Comment 230) Several comments ask for clarification on whether and how testing requirements apply in relation to water used during different stages of growing or production, particularly in reference to contact with the “harvested or harvestable portion” of the crop. For example, one comment asks whether and how proposed § 112.45(b) applies to water used in frost protection sprays, prior to any flowering or fruit production, in tree crops.

(Response) The testing requirements in § 112.46(b) require samples to be collected as close in time as practicable to, but prior to, harvest. These requirements are intended to provide a true reflection of the agricultural water that is representative of your use of the water and near the time of harvest, so the data can then be used to determine the appropriate use of that water. In § 112.3(c), we define “agricultural water” to mean water used in covered activities on covered produce, where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Moreover, we define the term “covered produce” in relevant part to refer to the harvestable or harvested part of the crop. Under these definitions, water used on a tree crop prior to any flowering or fruit production does not constitute “agricultural water” because it is not intended to, or likely to, contact covered produce (meaning the harvestable or harvested part of the crop) or food-contact surfaces.

(Comment 231) One comment expresses concern about the extent to

which imported produce would be subject to the agricultural water quality requirements, and recommends that foreign producers be required to have evidence of water testing and monitoring to ensure that they are meeting the same requirements as domestic farms.

(Response) Under the final FSVP rule (published elsewhere in this issue of the **Federal Register**), FDA is establishing requirements for importers to verify that imported food, including produce, is produced in compliance with applicable FDA food safety regulations, including this rule, or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required under these regulations in the United States. For imported produce, this will mean that importers must verify that imported produce was grown, harvested, packed, and held in accordance with the same agricultural water requirements, or equally protective measures, as domestic produce. Importers must have documentation of this verification which, in the case of produce that will not be manufactured/processed, is likely to be accomplished through an on-site audit.

(Comment 232) Several comments support the use of greater minimum testing frequencies for untreated surface water sources as compared to untreated ground water sources used for the same purposes. Conversely, several other comments state that there should be no difference between minimum testing frequencies for surface water and ground water sources. This latter set of commenters believe the testing parameters should instead be consistent across the different water sources but should still be science-based and reflect risks assessed for each operation.

(Response) We disagree with comments arguing that water from surface water and ground water sources should be tested at the same frequency. The approach we are adopting for water testing in § 112.46 is responsive to comments that requested that we establish a risk-based, flexible testing approach that accounts for variability in microbial water quality from different sources, considers the specific use of water from a particular water source, and contemplates the reduced likelihood of contamination from well-designed and adequately maintained water systems. As described in the 2013 proposed rule, surface watersheds are subject to a great number of external forces that shape their overall composition, chemistry, and microbial water quality (e.g., erosion, run-off, dust, suspended sediments). In contrast,

ground water sources typically contain microorganisms, including pathogens, much less frequently, due to the natural filtering mechanism of soil (Ref. 118). We recognize, however, that ground water, which is often believed to be more protected from contamination, can be contaminated. Ground water can be compromised and its microbial water quality degraded if wells are improperly constructed, poorly maintained, improperly located (e.g., near areas of extensive livestock production or fields where manure is applied) or if the wells are drawing water from a contaminated aquifer (Ref. 119) (Ref. 151) (Ref. 152) (Ref. 153) (Ref. 154). On the other hand, by their nature, surface waters are open systems, subject to the influence of various environmental factors that can impact the safety of the water. For example, increased precipitation levels, storm events, or run-off may result in a spike in microbial population of the water due to external inputs. We conclude that, although there exists significant potential for contamination of both ground and surface waters, surface water sources are inherently subject to a greater potential for contamination than properly designed, constructed, and well-maintained ground water sources. Therefore, although we require you to test both ground water and surface water sources used for certain purposes, where both types of sources may be used for the same purpose under § 112.44(b), we require a lesser frequency of testing for ground water than for surface water sources (see § 112.46(b)). We acknowledge that ground water sources can become contaminated, for example, if they are improperly maintained. The testing frequencies established in § 112.46 for such sources, and the requirements in § 112.42 to regularly inspect and maintain such sources, are designed to address this possibility.

It is important to note that some water that comes from underground is subject to direct influence by surface water, and therefore is not considered “ground water” for purposes of this rule. In the 2013 proposed rule, we proposed a definition of “surface water” as, “all water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances” to distinguish such water sources from other water sources that are less likely to become contaminated, i.e., “ground water” sources (see 78 FR 3504 at 3548). We are now establishing a definition of

“ground water” in § 112.3(c), and revising the definition of “surface water” in that section, to clarify the differences between the two sources for the purposes of this rule. The definition of “ground water” is “the supply of fresh water found beneath the Earth’s surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.” We are amending the definition of “surface water” to read, “All water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.” Through inclusion of the phrase, “all springs, wells, or other collectors that are directly influenced by surface water,” the definition of “surface water” includes, for example, water drawn from an underground aquifer that has been recharged with surface water (*i.e.*, an aquifer into which humans have injected surface water to replenish the aquifer). The definition of “ground water” also specifies that “[g]round water does not include any water that meets the definition of surface water.” Thus, where a ground water source is directly influenced by surface water, it no longer meets the definition of “ground water” and must be considered to be surface water for the purposes of this rule. “Directly influenced by surface water” includes direct influences that are significant, such as a consistent inflow of surface water. The term “collectors” in the definition of “surface water” means sources of accumulated water or vessels that collect and hold accumulated water such that it may be subject to external influence. See also discussion under Comment 184.

The specific frequencies for testing that we have established in § 112.46 are intervals that are reflective of the varying potential for changes in water quality between ground water sources and surface water sources. Our analysis suggests that a minimum number of samples required in “average” surface water sources would be 20 samples, assuming a standard deviation of 0.4 (of log abundance of *E. coli*). If you have a discrete surface water source that is minimally impacted by external forces, such as run-off, such that there is less variation in its microbial quality than an average surface water source, you may be able to test the water at frequency lower than that required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A). To account for such circumstances, we are providing in § 112.49(c) and (d) for the use of an

alternative testing frequency (in lieu of those required in § 112.46(b)(1)(i)(A) or § 112.45(b)(2)(i)(A)), under the conditions specified in § 112.12. On the other hand, because ground water sources (as we have defined “ground water” in § 112.3(c)) are generally less variable, the required testing frequency for ground water in the rule is lower than for surface water when both types of sources may be used for the same purpose (see § 112.46(b)), and no alternative option for different testing frequencies is available for ground water sources.

(Comment 233) Several comments state the importance of making sure that water tests are conducted properly by certified and accredited labs. Some comments ask FDA to establish standards and procedures for third-party laboratories that perform the tests.

(Response) We are currently working on a proposed rule to implement section 202 of FSMA (section 422 of the FD&C Act), which addresses “Laboratory Accreditation for Analyses of Foods.” Neither model laboratory standards nor laboratory accreditation are within the scope of the produce safety regulation in part 112.

Water testing required under this rule must be conducted using certain methods in accordance with § 112.151, as required under § 112.47(b). In addition, we are specifying in 112.47(b) that agricultural water samples must be aseptically collected. Aseptic sampling, often used for product and environmental samples, is a sampling technique used to assure that the microbial load of a sample is not affected by the sampling method and/or the sample collector does not contaminate the source from which the sample is collected. The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling (Ref. 155) (Ref. 156) (Ref. 157). Collecting and delivering samples to the laboratory using an aseptic technique also helps assure the microbiological findings accurately reflect the agricultural water at the time of sampling.

3. Timing of Collection of Water Samples for Testing Required Under § 112.46(b) and (c)

(Comment 234) Some comments request clarification on the meaning of the phrases, “as close to harvest as practical,” “during growing activities,” and “as it is used”, which we used in proposed § 112.45(b) and/or § 112.45(c). Some comments point out the time period for harvesting varies across regions and ranges from a few days to several months or year round. Other

comments support the provision as proposed, and state that it allows the time frame to be determined by the farmer based on the wide variation in growing seasons, overlap of growing seasons for multiple crops, and likelihood of pathogen die-off prior to harvest.

(Response) For testing of untreated surface water or untreated ground water used during growing activities using a direct water application method, the initial and annual survey samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest (see § 112.46(b)(1)(ii) and § 112.46(b)(2)(ii)). We recognize the timing of the use of agricultural water using a direct application method varies by crop, region, season, and/or from year to year. By revising the rule to use the term “representative of your use of the water” in lieu of “as it is used,” we intend to clarify that agricultural water should be collected for analysis around the time of harvest so that samples will be representative of the water that is applied during the end of the growing season. Samples collected from the source water when it is not being applied to the crop would not fulfill this requirement. We intend the wording “collected as close in time as practicable to, but prior to, harvest” to permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm. The agricultural water applied prior to harvest must be targeted for sampling, recognizing that in some circumstances such applications may not be preplanned (*e.g.*, application of crop protection water due to early frost or unusually hot, dry weather). Further, sample collection should be designed to represent events that can reasonably be expected to both impact water quality (*e.g.*, rainfall wildlife and domesticated animal movement through upstream water systems) and occur during the end of the growing season. We expect covered farms to determine the appropriate time for sampling to meet the requirements that samples be collected during a time period(s) as close as practicable to harvest, while recognizing that samples of agricultural water taken more than a few weeks prior to harvest are less representative of the agricultural water applied at the end of growing when the risk of produce contamination is greater. We anticipate seasonal trends in microbial water quality that can be captured in the long-term microbial water quality profile. In addition, we do not consider multiple samples collected in a single day to

provide adequate variation as the distribution estimates resulting from such a sampling plan would defeat the purpose of the microbial water quality profile. We also do not consider samples collected after the final harvest of the crop (for a single crop farm) to be representative of the agricultural water applied to that crop.

In addition, we intend the wording “representative of your use of the water” and the requirement that samples must be “collected as close in time as practicable to, but prior to, harvest” to ensure that, when testing water used for growing activities of produce (other than sprouts) using a direct application method, the samples for initial and annual surveys are collected prior to harvest and at a time that can be reasonably expected to represent the quality of the water when it is being applied to the crop. Collection before harvest is necessary in order for the samples and the microbial water quality profile to represent the water used for the purposes in § 112.44(b). Collection close to harvest is necessary because there are certain seasonal variations in water quality that may be relevant to the microbial water quality profile, such as harvesting during a time of heavy, seasonal rains or harvesting of commodities at the end of the summer when water temperatures may be elevated compared to the beginning of the summer. The microbial water quality profile is intended to capture long-term trends related to quality of water as it is used close to harvest, and sample collection must be done with the understanding that recurring patterns of water quality variations are often seen on an annual basis. See also a discussion of the definition of “direct water application method” in section IX.B of this document.

On the other hand, for untreated ground water used for purposes of § 112.44(a), considering the nature of different uses spanning across different covered activities specified in that provision, we require that samples be taken at least four times either during the growing season or over a period of one year, as applicable, using a minimum total of four samples collected to be representative of the intended use(s) (see § 112.46(c)). See Comment 229.

4. Clarification of Terms Used in § 112.46

(Comment 235) Some comments oppose the use of the term “water quality profile,” stating the concept is not clearly explained and/or not necessary.

(Response) As used in this rule, “microbial water quality profile” generally refers to the set of data that provides information about the microbial quality of water from a specific water source, based on which a covered farm can determine whether the water meets the microbial quality criteria in § 112.44(b) and make a decision regarding corrective measures, as necessary, under § 112.45(b). The microbial water quality profile consists of two numerical values of generic *E. coli* in the water: The GM and the STV. The GM and STV values are initially calculated using data obtained in an initial survey and updated annually thereafter. The GM and STV values are initially derived based on the initial survey data set (described in § 112.46(b)(1)), which consists of a minimum total of 20 samples for untreated surface water sources (taken over at least 2 and no more than 4 years) and 4 samples for untreated ground water sources (taken during the growing season or over a period of one year). The GM and STV values are then revised annually based on annual survey data (described in § 112.46(b)(2)). For untreated surface water sources this entails taking at least 5 new samples, and for untreated ground water this entails taking at least one new sample. The new samples are then combined with your most recent data from within the previous 4 years, to make up a rolling dataset of 20 samples for untreated surface water and 4 samples for untreated ground water, and the GM and STV values are recalculated using this updated data set to update the microbial water quality profile.

(Comment 236) Some comments request clarification on the meaning of “statistical threshold value.”

(Response) The “statistical threshold value” is a value that approximates a specified percentile of a distribution, which depends upon the inherent variability of the observations in a sample set as well as their central tendency. For purposes of the testing requirements in § 112.46(b) and (d), STV is a value that is derived as a model-based calculation based on the lognormal distribution and approximates the 90th percentile of the water quality distribution. For clarity, we are specifying in § 112.44(b) that “STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution.” See also our discussion in the supplemental notice at 79 FR 58434 at 58444 for additional information. We note that we are exploring the development of an on-line tool that you

can use to derive STVs and certain other values (such as GM values and appropriate time intervals (in days) between last irrigation and harvest using the 0.5 log per day die-off rate) based on input of sample data, such that a farmer would not need to perform the necessary calculations themselves.

(Comment 237) Several comments request clarification on the meaning of the term “water source,” as it relates to the water testing requirements in proposed § 112.45(b), (c), and (d). One comment recommends that FDA broadly define “water source” as “any reasonable portion of a watershed where a sanitation survey identifies no reasonably foreseeable point or nonpoint source of microbial discharge between agricultural water and withdrawal points.” Another comment provides an example of an open irrigation ditch and questions whether water samples would be required for each irrigation district, at each pump site or water box, for each block or branch of the irrigation system, or for each sprinkler head. This commenter also asks whether a farm using multiple sources of water for irrigation would need to conduct a baseline survey of 20 samples over two years for each source. Comments ask whether a single source can be used for multiple commodities or to irrigate noncontiguous fields. Another comment notes testing agricultural water stored in holding containers (such as barrels) would be impractical and expensive.

(Response) We consider each agricultural water source in your operation to be a discrete body of water that is representative of the microbial quality of agricultural water from that source used in your growing, harvesting, packing, or holding activities. For example, if you have a surface water impoundment on your farm that stores water to be used as agricultural water, but you also source water from a river that you use for the same purpose, you would need to consider these two be two different water sources, as each delivers water that is distinctly different in origin and likely to differ in overall composition and characteristics. Or if, for example, you source some water directly from a properly constructed well on your property, and you also draw water from the same source and hold it in a holding pond on your property that is open to environmental influences before you use it, you would need consider the well and the holding pond to be two separate water sources (the well would be a ground water source, and the holding pond would be a surface water source). Where water testing requirements apply, they apply

to each water source individually. There is no difference in testing requirements based on whether the water is used for multiple commodities, or applied over non-contiguous fields. We realize that the testing requirements may be particularly challenging for farms that have multiple agricultural water sources and we encourage farms to provide us with details of their specific situations so that we can consider flexible approaches to testing multiple sources.

Section 112.42(a) requires you to inspect your water distribution systems to the extent that they are under your control, including considering different factors identified in (a)(1) through (a)(5). Therefore, for example, provided you have inspected your water distribution systems in compliance with § 112.42 and you have determined there is no additional exposure to potential contamination along your distribution system from your ground water to the sprinkler heads, collecting water samples from the ground water would sufficiently represent your water source such that you would not need to additionally collect water samples at the sprinkler head(s). This rule is not prescriptive about the exact point of collection of water samples when testing is required, but it requires that all water samples must be representative of your use of the water (see § 112.46(b) and (c)).

5. Minimum Number of Samples for Initial Survey (§ 112.46(b)(1)(i)(A)) and/or Annual Survey (§ 112.46(b)(2)(i)(A)) Related To Testing of Untreated Surface Water Used in a Direct Water Application Method During Growing Activities

(Comment 238) Some comments oppose the proposed minimum number of samples required for the proposed baseline and annual surveys for untreated surface water used in a direct water application method during growing activities for covered produce other than sprouts. These comments ask that we align the testing frequency requirements with the guidelines in USDA GAPs, which according to these comments recommend testing three water samples during the growing season.

(Response) The testing frequency we proposed, and are now finalizing in § 112.46(b) for untreated surface water used for § 112.44(b) purposes, is based on the minimum number of samples needed to do the relevant calculations to characterize the untreated surface water source used as agricultural water for purposes of § 112.44(b), given certain expectations about the variability of that source. For untreated surface water

sources, where measurements of \log_{10} abundance of generic *E. coli* are expected to exhibit an average (population) standard deviation of 0.4, our evaluation indicates that when water quality is stable, neither deteriorating nor improving over time, a sample size of 20 for initial or for a moving window of most recent observations from initial and/or annual surveys would provide sufficient precision of estimation of the microbial water quality profile (GM and STV of indicator bacteria) to determine appropriate conditions of use. In the absence of detailed information concerning how frequently changes occur in water quality of surface water sources, and what patterns and magnitude of changes are most likely, it is not possible to determine a best or optimal frequency by which prior data should be replaced by more current survey data within a moving window of observations collected over multiple years. However, based on an assessment of the magnitude of bias in estimates of \log_{10} GM and \log_{10} STV for hypothetical changes in population \log_{10} GM, a minimum sample size of 5 for annual surveys, being 25 percent of the minimum of 20 samples found to be sufficient to determine appropriate conditions of use, provides a reasonable degree of compromise between the competing objectives of having estimates of the microbial water quality profile sensitive to sudden and substantive changes in water quality and minimizing the number of samples collected annually when water quality is relatively stable and unchanging (Ref. 99). Therefore, we are establishing the minimum testing frequencies as 20 samples for the initial survey required under § 112.46(b)(1)(i) and 5 samples for the annual survey required under § 112.46(b)(2)(i). To provide flexibility and account for sources of water that have less variability in their quality than that assumed in our calculations, we are providing for the use of an alternative testing frequency in lieu of the required minimum number of samples, in § 112.49(c) and (d), provided the conditions in § 112.12 are met. With respect to comments about USDA's GAP guidelines, we plan to work with USDA as they update their GAPs audit program to align with the requirements of the produce safety regulation.

(Comment 239) Several comments state that the proposed minimum number of 20 samples for the proposed baseline survey, under proposed § 112.45(b)(1)(ii), is excessive, too stringent, and/or does not take into consideration critical site-specific

variables of surface waters. Comments also point out that the 20-sample minimum requirement is a statistical construct, and argue that it was not selected as an indicator of food safety, arguing that the time and location of sampling are far more important than the number of samples. Others contend that 20 samples over two years would be burdensome or impracticable for certain commodities or in certain regions. For example, one comment states that the proposed frequency is not practicable in the mid-Atlantic States, where the commenter notes overhead irrigation is often used fewer than ten times per year, depending on the crop. This commenter also points out strawberry farms often only apply overhead irrigation as frost control one to three times per season, and crops are often rotated and farms may change water sources every three to four years. Similarly, another comment argues that the proposed 20-sample minimum would be impracticable for certain crops, such as cherries and berries, which have a harvest period of approximately 20 days. Another comment recommends that baseline characterization should be done once a month during the growing season with a minimum of three times per season, but that the required testing frequency should never be greater than the frequency of irrigation. Still other comments that suggest aligning the frequency for baseline characterization for untreated surface water with that for untreated ground water, recommend requiring testing at least four times during the growing season or over a period of 1 year, using a minimum total of four samples. These comments argue that four tests for untreated surface water, particularly when based on effective sample collection (e.g., time of day, depth, and at high or low flow of water), provide an appropriate range for farms to use in establishing the profile of their water quality.

(Response) As previously explained, a sample size of 20 for the initial survey for untreated surface water used in a direct application method is the minimum necessary to provide sufficient precision of estimation of the microbial water quality profile to determine and verify appropriate conditions of use of the water based on certain expectations about the average variability of \log_{10} *E. coli* abundance (Ref. 99). Therefore, we are retaining the requirement for a minimum sample size of 20 samples in § 112.46(b)(1)(i)(A). However, we acknowledge the concerns commenters raised about the impracticability of collecting 20 samples

in 2 years, as the water is used during growing activities using a direct water application method and collected as close in time as practicable to, but prior to, harvest, particularly for certain commodities or irrigation practices where the time period of direct application of agricultural water is short or variable. The minimum 20 samples for the initial survey are required to be collected over a minimum (not maximum) of 2 years such that, in the circumstances where direct application periods are short, you may collect your samples over more than 2 years. We believe a minimum period of 2 years is necessary to provide an adequate representation of the microbial quality of agricultural water to enable informed decisions about its use in a direct application method. However, we are also adding a requirement that the 20 samples for the initial survey must be collected within a time period not greater than 4 years. This limitation on the use of older data is intended to ensure that the data used adequately represent the current microbial quality of your untreated water source. Therefore, you may collect your water samples for the initial survey over a period of four years to make up the minimum sample size of 20 samples to then establish your microbial water quality profile. We expect that farms will use this option to collect initial survey samples over more than 2 years and up to 4 years in circumstances with short timeframes for direct application of agricultural water, for example.

(Comment 240) One comment recommends the necessary number of samples for the proposed baseline survey should be based on a study of available historical data on quality of that water source.

(Response) As previously explained, we conclude a minimum sample size of 20 samples is necessary for the initial survey, assuming a standard deviation of 0.4 (of log abundance of *E. coli*). If you have evidence the microbial quality of your untreated surface water source is less variable than that assumed in our calculations, including based on your historical data (provided such data are representative of the current quality of your water and were gathered within the previous four years), you may be able to use a testing frequency that is lower than that required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A). To account for such circumstances, we are providing for the use of an alternative testing frequency in lieu of the required minimum number of samples (see §§ 112.49(c) and (d) and 112.12).

(Comment 241) Some comments state the proposed minimum 20 samples for baseline survey for each untreated surface water source would be economically burdensome, especially for small farms, with no appreciable increase to produce safety. These comments also contend that reducing the testing frequency (and thereby reducing the significant burden on small farmers) would be consistent with the public health goals of the rule.

(Response) See our response to Comment 235 where we explain our rationale for the minimum testing frequencies we are establishing in § 112.46(b)(1)(i)(A) for the initial survey. We intend to work with stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule. Moreover, we are providing for extended compliance periods of an additional 2 years each for covered activities involving covered produce (except sprouts), which results in compliance periods of 6 years for very small farms, 5 years for small farms, and 4 years for all other farms for compliance with certain water provisions, § 112.46(b) among them (except § 112.46(a) and (b)(1) with respect to untreated surface water sources) as explained in response to Comment 240 and in section XIII.K of this document. (See also section XXIV for compliance dates for covered activities involving sprouts, which are subject to all of part 112 including subpart M). We also have included certain size-based provisions, including a coverage threshold and a qualified exemption described in §§ 112.4 and 112.5.

(Comment 242) Several comments oppose the minimum sample size of five samples for the annual survey, under proposed § 112.45(b)(2)(i), stating that such a frequency of testing is unnecessary, burdensome, and not scientifically determined. These comments suggest different acceptable minimum samples sizes ranging from three samples annually (along with a request to align with USDA GAPs guidelines) to one sample annually.

(Response) See our response to Comment 238 where we explain our rationale for the minimum testing frequency we are establishing for the annual survey in § 112.46(b)(2)(i)(A) and our intent to work with USDA to update their GAPs audit program to align with the requirements of the produce safety regulation.

6. Use of Historical Data for Testing Untreated Surface Water Used in a Direct Water Application Method During Growing Activities (§ 112.46(b))

(Comment 243) Some comments note farms currently conduct water testing (including, for example, consistent with relevant industry guidelines) and maintain these historical data, and ask that these farms be allowed to use such data in their baseline survey to establish the water quality profile. Comments also request FDA to clarify that farms would be able to start collecting samples immediately on publication of the final produce safety rule to allow sufficient time to conduct the proposed baseline survey.

(Response) To develop the microbial water quality profile required under § 112.46(b)(1) for untreated surface water used in growing covered produce other than sprouts using a direct water application method, covered farms are required to conduct an initial survey over a minimum period of 2 years and not greater than 4 years, using a minimum total of 20 samples. We do not expect farms to incur additional sampling costs to satisfy the initial survey requirement in § 112.46(b)(1), if they already possess sufficient microbial water quality data (consisting of the minimum required number of samples) collected in the manner required under § 112.46(b). Under these circumstances, a farm is permitted to use available historical microbial water quality data, from the previous four years, to make up the minimum 20 samples to calculate the current microbial water quality profile. Moreover, covered farms will have an additional 2 years, *i.e.*, a total of 4 to 6 years, depending on farm size, from the effective date of this rule for compliance with the water testing provisions in § 112.46, except § 112.46(a) and (b)(1) with respect to untreated surface water, for covered activities involving covered produce (except sprouts).

We exclude § 112.46(b)(1), with respect to untreated surface water only, from the 2-year extended compliance period provided for the remainder of § 112.46 because, in order to comply with the microbial quality criteria in 112.44(b), farms must have developed a microbial water quality profile based on the initial survey conducted over a minimum of 2 years and not greater than 4 years. Accordingly, to develop the microbial water quality profile prior to the point at which they must comply with all of the requirements of subpart E, covered farms must begin water sampling and subsequent testing not later than 4 years after issuance of this

rule for very small farms; not later than 3 years after issuance of this rule for small farms; and not later than 2 years after issuance of this rule for all other farms. If they choose to, a farm that is not small or very small can begin water sampling and subsequent testing as early as when this rule is published, and expect to use those test results to comply with the rule by the compliance date. Initiating water sampling upon publication of this rule will allow those covered farms to collect 5 samples per year over the next four years, sufficient to make up the minimum 20 samples necessary to develop the microbial water quality profile required under § 112.46(b) at the point at which they must comply with all of the requirements of subpart E. On the other hand, if these covered farms initiate water sampling two years after issuance of this rule, the farms will need to collect 10 samples per year over the next two years to make up the minimum 20 samples necessary to develop the microbial water quality profile. In either instance, the covered farms will have sufficient time to develop a microbial water quality profile and determine the appropriate way(s) in which to use water from that source based on that profile, in accordance with § 112.45(b)(1) through (b)(3). Covered farms that are small and very small may decide not to begin testing upon issuance of this rule with the expectation of using those test results at their compliance date because they are not required to have established the microbial water quality profile under § 112.46(b) until 5 and 6 years, respectively, after the effective date of this rule and because farms must use data that are no more than 4 years old to establish their microbial water quality profile. We are not similarly excluding § 112.46(b)(1) with respect to untreated ground water from the extended compliance period because the amount of time needed for the initial survey for such sources is significantly shorter (compare § 112.46(b)(1)(i)(A) and (B)).

Note that the exclusion of § 112.46(b)(1) with respect to untreated surface water from the extended compliance period does not mean that covered farms must bring untreated surface water used for § 112.44(b) purposes into compliance with that microbial quality requirement within the 2–4 year compliance period (depending on farm size) applicable to the remaining provisions of this rule. Rather the exclusion is intended to ensure that covered farms will begin collecting and testing samples and obtain data to develop the microbial

water quality profile necessary to then comply with the remainder of the water requirements, for which the extended compliance period of 4 to 6 years (depending on farm size) applies.

We are also excluding § 112.46(a) from the extended compliance period because this provision provides an important exception to the testing requirements in § 112.46(b)(1) and is referenced therein. Section 112.47 is also subject to the shorter compliance period because it establishes requirements that are relevant to testing requirements when they become applicable.

We are not similarly providing extended compliance periods for these specified water requirements, in the case of covered activities involving sprouts, as discussed in section XVIII.J of this document. Therefore, covered farms must comply with all of the applicable requirements of part 112, including subpart E, for all covered activities involving sprouts, within one to three years of the effective date of the rule, depending on the size of the farm. See also section XXIV for additional information.

7. Updating the Microbial Water Quality Profile Annually for Water Used in a Direct Water Application Method During Growing Activities (§ 112.46(b)(2))

In the supplemental notice, we acknowledged that there are certain limitations to our proposed tiered approach, particularly regarding whether and how annual verification data may be used to identify the need for changes to water use practices in the current season and/or the need for a new water quality profile. For example, we asked if there is a threshold based on magnitude of deviation indicated in an annual survey that would suggest that the existing water quality profile is no longer representative of the current water quality.

(Comment 244) Some comments disagree that water quality profiles should be re-characterized every ten years, as would have been required under proposed § 112.45(b)(1)(iii)(A), and, instead, recommend applying a rolling set of samples such that the water quality profile is updated on an ongoing basis. Similarly, one other comment recommends eliminating the concept of a baseline water quality profile followed by an annual verification survey, in favor of a rolling geometric mean coupled with appropriate guidance on steps to take when a test exceeds a threshold limit; however, this commenter did not further specify what such threshold

limit should be. One comment states that a single high test result should be followed-up by retesting to confirm the previous finding and rule out a potential false positive. Another comment finds it unclear whether and when the water quality profile would need to be re-characterized based on annual survey test results.

(Response) We are making several revisions to our proposed baseline and annual survey provisions to simplify the requirements related to developing a new or updated microbial water quality profile, while retaining the advantages of the tiered approach proposed in the supplemental notice. We are also combining the testing provisions for untreated surface water and untreated ground water sources used for direct water application during growing covered produce other than sprouts into the same provision (§ 112.46(b)).

We are revising our tiered approach to testing by, first, eliminating (1) the proposed requirement to develop a new water quality profile at least once every 10 years (proposed § 112.45(b)(1)(iii)(A)); and (2) the proposed requirement that, if the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile (proposed § 112.45(b)(2)(ii)).

Second, in lieu of the eliminated provisions, we are adding these revised requirements in final § 112.46(b)(2): (1) Following the development of the microbial water quality profile based on an initial survey, you must test water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year (for untreated surface water) or one sample per year (for untreated ground water). These samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest (§ 112.46(b)(2)(i) and (ii)); and (2) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from prior years, but within the previous 4 years, to make up a rolling data set of at least 20 samples (for untreated surface water) or 4 samples (for untreated ground water) (§ 112.46(b)(2)(iii)); and (3) You must modify your water use, as appropriate, based on the revised GM and STV

values in your updated water quality profile, in accordance with § 112.45(b)(1) through (3) (§ 112.46(b)(2)(iv)), as soon as practicable, and no later than the following year.

This revised approach, which relies on an annually updated microbial water quality profile comprised of rolling GM and STV values, has several advantages compared to the approach proposed in the supplemental notice. It maintains the advantages of the tiered approach proposed in the supplemental notice compared to the originally proposed approach in the 2013 proposed rule in that it reduces the required frequency of testing compared to the originally proposed requirements. It also maintains the flexibility of the tiered approach by allowing farms to make decisions about safe use of available water sources as soon as practical, but no later than the following year, as well as adjusting testing frequencies based on long-term test results. In addition, unlike the approach in the 2013 proposed rule, use of GM with accompanying STV values eliminates the need for a single sample maximum threshold, while accounting for variability of water quality and occasional high sample results that could highlight potential risk associated with use of the water. Moreover, the revised approach established in § 112.46(b) eliminates the need for specific thresholds based on annual verification survey data to determine whether and when a new microbial water quality profile is needed (using, for example for untreated surface water sources, previous years' 15 samples versus a complete new set of 20 samples).

Under this revised approach, codified in § 112.46(b), covered farms must develop an updated microbial water quality profile, consisting of revised GM and STV values based on each year's annual survey of a minimum of 5 samples or 1 sample (for untreated surface water, or untreated ground water, respectively) plus the data of the most recent 15 samples or 3 samples (for untreated surface water, or untreated ground water, respectively) collected within the previous 4 years to make up the minimum 20 samples or 4 samples (for untreated surface water, or untreated ground water, respectively) necessary to establish the GM and STV values. Under this approach, the microbial water quality profile is continually updated on an annual basis so that changes in the water quality can be identified to inform any necessary modifications to practices. You must make those modifications to practices as

soon as practical, and no later than the following year. If you are aware, based on your GM and STV, that you need to make modifications in your water use practices and it is practicable for you to make those modifications for the crop in the field at the time you receive your test results, at your next harvest if you have multiple harvests of a crop, or during the next growing season if you have multiple growing seasons within a calendar year, you must do so. If none of these timeframes are practicable or applicable to your operation, you must make the modifications to your water use practices no later than the following year.

This approach also alleviates the complexity around determining when to re-characterize the microbial water quality profile. For example, if a single crop farm with a single surface water source calculates the GM of 20 untreated surface water samples at the end of the growing season in year 3 to be 126 CFU generic *E. coli*/100 mL and the STV of 20 samples to be 300 CFU generic *E. coli*/100 mL, and then determines the updated GM at the end of the growing season in year 4 to be 200 CFU generic *E. coli*/100 mL and his STV to be 450 CFU generic *E. coli*/100 mL, the farm can adjust its practices for year 5, such as to include a 1 day die-off interval, reflecting the change in the water quality profile. In year 5, the farm finds the GM to be 230 CFU generic *E. coli*/100 mL, and STV to be 460 CFU generic *E. coli*/100 mL. No further mitigation strategy (beyond the 1 day die-off interval) is required in this scenario from the previous year, because the farm's existing practices reflect the required mitigation strategies to achieve the microbial water quality criteria in § 112.44(b). While the GM and STV do not match exactly those from the previous year, the farm recognizes that its mitigation strategies are still sufficient to meet the § 112.44(b) criteria, and so does not have to make changes to its current water use. We believe that annually-updated, rolling GM and STV calculations address commenters' concerns about false positives or single high test results, by allowing any high data to be incorporated into the long-term profile.

As another example, a diversified farm growing multiple crops per year using a surface water source for direct water application measures the GM at the end of the growing season for the first crop of the season in year 3 to be 150 CFU generic *E. coli*/100 mL and the STV to be 400 CFU generic *E. coli*/100 mL of agricultural water. The STV achieves the microbial water quality criteria, but the GM exceeds the criteria

of 126 CFU generic *E. coli*/100 mL. The farm calculates the values for the microbial water quality profile prior to the harvest of the second crop of the year, and is therefore able to adjust the growing practices for the harvest of this crop to provide 1 day of microbial die-off between last irrigation and harvest to achieve the specified GM of the microbial water quality criteria.

The GM and STV are sensitive to extremes among individual sample measurements and a sufficiently high level (spike) in even one sample can elevate the GM (and/or STV) over the microbial quality criteria in § 112.44(b). For example, a grower calculates his/her microbial water quality profile and find that the GM is 118 CFU generic *E. coli* per 100 mL, and the STV is 140 CFU generic *E. coli* per 100 mL. In the next year the grower collects five new samples as part of the annual survey and the sample results include 95, 147, 96, 6,000 and 137 CFU generic *E. coli* per 100 mL. These values are rolled into the previous year's microbial water quality profile, and it now includes the latest five samples. The updated microbial water quality profile has a GM of 143 CFU generic *E. coli* per 100 mL, and STV of 448 generic *E. coli* per 100 mL. The grower uses this information to apply a one-day die-off period between last irrigation and harvest, as soon as practicable, but no later than the following year. This sensitivity is one of the reasons we believe that the rolling GM and STV calculations are the appropriate tool for determining microbial water quality while protecting public health. We realize that farms have concerns about single high samples and we encourage farms to treat each sample as a marker in the variability of the water source to identify trends over long periods of time. This approach will help covered farms understand how their water sources may vary in the long term.

Even though we are finalizing a rolling GM and STV measurement so covered farms can develop a microbial water quality profile over time, we are also retaining the requirement, in § 112.46(b)(3), that if you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed. To develop a new microbial water quality profile, you must calculate new

GM and STV values, using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of at least 20 samples or 4 samples (for untreated surface water, or untreated ground water, respectively). You must then modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b) (see § 112.46(b)(3)).

8. Testing Highly Variable Untreated Surface Water Sources

(Comment 245) In the supplemental notice, we requested comment on whether, for a highly variable water source (*e.g.*, a moving water body), we should require more than a five-sample annual verification survey. Some comments oppose increasing the sampling frequency, stating that most, if not all, surface water sources would qualify as a “moving water body.” In addition, comments argue if a water source does not consistently achieve the proposed GM and STV standard because of uncontrolled variability, an increased frequency of testing would not achieve compliance. These comments suggest, in such instances, the farm should acknowledge the uncontrolled variability and implement proposed mitigation measures, rather than test more frequently.

(Response) We are not establishing water testing requirements specific to highly variable untreated surface water sources. Rather, under our revised approach established in § 112.46(b), such water sources would be subject to the same testing requirements as all other untreated surface water used during growing of covered produce (other than sprouts) using a direct water application method. We have incorporated flexibility in the requirements in § 112.46(b) to allow farms to independently determine, in compliance with §§ 112.49(c) and (d) and 112.12, the appropriate number of samples required to characterize an untreated surface water source based on their knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination. The untreated surface water testing requirements are used to inform the appropriate use of the water source, by accounting for the variability of the source. Therefore, you must first characterize the microbial water quality of the water source by testing in accordance with § 112.46(b) and developing a microbial water quality profile. If the GM or STV do not meet the microbial quality criteria in § 112.44(b), then you must consider and

implement the options provided in § 112.45(b)(1) through (b)(3), as appropriate for your commodity and practices and conditions on your farm.

9. Follow-Up Actions Based on Water Testing Results or Other Information (§§ 112.45 and 112.46)

(Comment 246) Some comments state that FDA did not clearly outline the actions a covered farm must take under the tiered testing approach for untreated surface water. For example, comments ask for clarification about the steps a farm must take if the annual test results indicate a change in microbial water quality and do not confirm the baseline water quality profile. Some comments also request clarification of necessary actions if the test results are not available prior to harvest and additional storage die-off rates and/or appropriate microbial removal rates have not been developed. Some comments also point out the proposed provisions do not provide an exception for circumstances where a high positive finding is later corrected and confirmed to be within the established water quality profile.

(Response) With the revisions we have made to § 112.46(b), you will have a rolling microbial water quality profile consisting of 20 samples for untreated surface water sources (*e.g.*, 5 samples from your annual survey and the most recent 15 samples, taken within the last 4 years) or 4 samples for untreated ground water sources (*e.g.*, 1 annual sample and the most recent 3 from within the last 4 years). From this data set, you will update the GM and STV values each year. If the GM and STV do not meet the microbial quality criteria in § 112.44(b), you must take actions in accordance with § 112.45(b). See also discussion in Comment 214 regarding taking action at your next harvest or in the next growing season, if more immediate changes are not practicable.

We appreciate the concerns of commenters seeking additional information and clarification on follow-up corrective measures that are required under the different provisions, including in response to results of testing required in § 112.46 and/or in response to your knowledge or determination that water is not safe or of adequate sanitary quality and/or does not meet the microbial quality criteria in § 112.44. We discuss some examples in the paragraphs that follow.

Example 1: Knowledge of Upstream Change in Conditions—A concentrated animal feeding operation (CAFO) is established upstream and is discharging untreated wastewater into your water source. In this example, a farmer uses water from a stream for direct water application method

irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. The farm now learns that a CAFO has started operation upstream from the farm and within a close distance and is regularly discharging untreated wastewater into its water source. The farm has reason to believe that its microbial water quality profile no longer represents the quality of the water from the stream. This is because, under the circumstances, the addition of the CAFO upstream and its regular discharge of untreated wastewater is a significant change in nearby land use that is reasonably likely to adversely affect the quality of the water source. Thus, under § 112.46(b)(3), the farm must develop a new microbial water quality profile reflective of the time period at which the farm believes the microbial water quality profile changed. In this case, the farm’s new microbial water quality profile must reflect only data from after the time the CAFO began operation upstream. The farm must take new samples of the water, combined with as many test results as it already has from its previous data set from samples taken after the CAFO began operations, to make up a data set of at least 20 samples, and calculate new GM and STV (the new water quality profile) from that data set. Then the farm must modify its water use based on the new GM and STV values in its new microbial water quality profile in accordance with § 112.45(b).

Example 2: Knowledge of Likely Contamination Event—Dead deer in stream. In this example, as in Example 1, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a microbial water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. During the growing season, the farm finds deceased and decaying deer in the area of the stream under the farm’s control, upstream from where the farm draws its water and at a close distance. The farm now has reason to believe that its agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 because the water is reasonably likely to contain human pathogens transferred by the dead and decaying deer. Therefore, under § 112.45(a), the farm must immediately discontinue using the water for irrigation until it completes one of the actions described in § 112.45(a). The approach that the farm is most likely to take (as most likely the most feasible option) is to re-inspect the entire affected agricultural water system to the extent it is under the farm’s control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective (§ 112.45(a)(1)). In this case, that would entail, at a minimum: re-inspecting the entire water system potentially affected by the dead deer to the extent it is under the farm’s control to identify any relevant

conditions (such as additional dead deer, including carcass materials that may have contaminated the farm's water distribution system if applicable); removing the dead deer and any related hazards identified during the re-inspection; cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the deer); and visually verifying that all carcass materials have been removed. Once the farm has taken all of the appropriate steps in light of its specific circumstances, it may resume using the water for direct water application irrigation of its covered produce.

Example 3: Exceedance of no detectable generic *E. coli* criterion in § 112.44(a) in water used for hand-washing and rinsing produce during and after harvest. In this example, a farmer uses water drawn directly from a properly protected well that qualifies as an untreated ground water source for hand-washing and rinsing produce during and after harvest. The farm has tested the well over the years and is using the water from the well in compliance with the relevant provisions of the rule (in this example, the farm has never detected generic *E. coli* in the well water before). This year, the farm conducts its annual test of the well water, taking a sample that is representative of the intended use (in this case, taken during the time the farm is using the water for hand-washing and produce rinsing), and detectable generic *E. coli* is found, thus exceeding the required criterion in § 112.44(a). Under § 112.45(a), the farm must immediately discontinue using the water for hand-washing and produce rinsing and may not reuse it for those purposes until it completes one of the actions described in § 112.45(a). The farm's choices are to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective (§ 112.45(a)(1)), or to treat the water in accordance with § 112.43 (§ 112.45(a)(2)). The farm may, of course, also choose to use a different water source that does meet the microbial quality criterion in § 112.44(a) for hand-washing and rinsing of produce either permanently or while it pursues these corrective actions. The farm may not use untreated surface water for these purposes (see § 112.44(a)). If the circumstances allow the farm to use § 112.45(a)(1) to correct the problem (for example, if a fixable problem is identified with respect to the farm's affected water distribution system that the farm is able to adequately correct in compliance with that provision), a required aspect of compliance with this provision under the circumstances is to re-test the water to adequately ensure that it now meets the microbial quality criterion in § 112.44(a) (see § 112.45(a)(1)). Making necessary changes to address the identified conditions (as required by § 112.45(a)(1)) also includes steps such as cleaning affected food contact surfaces, for example. Moreover, under § 112.46(c), the farm must also test the well at least four

times per growing season or year in the next year because of the test result that failed to meet the microbial quality criterion in § 112.44(a). If all four tests in the next year meet the criterion, the farm may switch back to testing once per year.

Example 4: Exceedance of GM/STV generic *E. coli* criteria in § 112.44(b). In this example, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. In past years, the GM and STV calculated using the farm's test results have been within the bounds of the microbial water quality criteria of § 112.44(b) (so no time intervals based on microbial die-off, or log reductions based on microbial removal rates have been applied). This year, however, the calculation of the GM and STV values for the updated microbial water quality profile (calculated, in this case, after the harvest has been completed and the water is no longer being used for direct water application method irrigation) exceed the microbial quality criteria. In this case, the covered farm must take actions, as appropriate, based on the revised GM and STV values in the updated microbial water quality profile, in accordance with § 112.45(b)(1) through (3) as soon as practicable, and no later than the following year. The farm's practices related to that water use can be modified through applying an adequate time interval (in days) between last irrigation and harvest in accordance with § 112.45(b)(1)(i); or applying a time interval (in days) between harvest and end of storage, or applying a calculated log reduction during activities such as commercial washing, provided the farm has adequate supporting scientific data and information in accordance with § 112.45(b)(1)(ii). If these mitigation options are not selected or cannot be appropriately applied to achieve the microbial water quality criteria, the farm may consider the options in § 112.45(b)(2) or (b)(3), *i.e.*, the farm must either re-inspect the entire affected agricultural water system to the extent it is under the farm's control and take other steps, including make necessary changes and retesting the water to determine if the changes were effective and the water now meets the criteria; or treat the water in accordance with § 112.43. If none of the above mitigation options are selected and appropriately applied to achieve the microbial water quality criteria, the farm must discontinue using water from that source for direct water application method irrigation of covered produce no later than one year from the time that the farm determined that the water did not meet the required criteria.

There may be circumstances that allow the farm to use § 112.45(b)(2) to correct the problem. For example, the farm might reasonably determine, under the circumstances, that the change in microbial water quality was due to non-recurring point-source contamination that can be adequately corrected in

compliance with this provision. An example of such a finding would be visible damage to a water dam on the farm's property (and under the farm's control) upstream from where the farm draws its water, where the dam serves to reduce water flow by holding back water from a stream that would otherwise converge with the stream water the farm uses. The farm might reasonably conclude, under these circumstances, that the damage to the dam is a correctable, non-recurring point-source of contamination. If the farm is able to stop the leak and repair the damaged dam, the farm may use § 112.45(b)(2) as a mitigation option. In such cases, a required aspect of compliance with this provision under the circumstances is to re-test the water after the correction has been made to adequately ensure that the water meets the microbial quality criteria in § 112.44(b) (see § 112.45(b)(2)). Under § 112.45(b), the farm in this example has up to a year before it must discontinue use of the water for direct application method irrigation of covered produce, and post-correction sampling should be conducted and analyzed within such time if the farm wishes to continue using the water for this purpose without interruption. We note that to meet the requirements of § 112.46(b)(2) for the annual survey, samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. However, we also encourage farms in such situations to voluntarily conduct additional sampling earlier (such as immediately post-correction, even if not close in time to harvest) as may be appropriate.

In rare situations such as that described in this example, the farm need not include in its rolling dataset of 20 samples for calculation of the GM and STV the set of 5 samples that caused the exceedance, leading it to re-inspect, find, and correct the non-recurring point source contamination. In this rare situation the data set should be made up only of samples that are not reasonably likely to have been affected by the non-recurring point-source contamination. With respect to calculations for the microbial water quality profile, we encourage farms in such situations to take more than the minimum 5 samples in the following year(s), because doing so would make it unnecessary to include data older than 4 years in the microbial water quality profile. However, because the circumstances in which you need not include the samples that caused the exceedance in your microbial water

quality profile are likely to be rare (*i.e.*, we consider that such situations most likely only involve non-recurring point-source contamination that can be immediately eliminated), we intend to exercise enforcement discretion with respect to the 4 year limitation in § 112.46(b)(2)(iii) in such situations. This would allow the farm in this example to make up its microbial water quality profile in the following year using its new annual survey data, combined with its most recent initial or annual survey data (not including the samples that caused the exceedance), to make up a rolling data set of 20 samples.

(Comment 247) One comment argues the proposed water testing approach fails to respond to significant changes in water quality in a timely manner. Similarly, another comment points out the proposed approach for testing untreated surface water reflects a retrospective testing scheme, where results of water testing may not be available in time to take actions on the harvested produce because the harvested produce may already be in commerce by the time the analysis is completed and the farm receives the results.

(Response) The goal of our framework for testing of agricultural water that is used for direct water application during growing activities for covered produce other than sprouts is to establish a microbial water quality profile to help covered farms characterize their water sources, understand the variability of those sources, and make appropriate long-term decisions about the use of that water for the specific purpose of direct water application during growing. As explained in response to Comment 180, our framework for the microbial quality criteria for water used in direct water application coupled with our decision to test for generic *E. coli* as an indicator organism means that exceeding the microbial water quality criteria in § 112.44(b) does not result in a determination that, based on this testing in and of itself, the produce is adulterated. Therefore, the follow-up actions listed in § 112.45(b) that must be taken when the microbial water quality criteria in § 112.44(b) are not met involve longer-term decisions (rather than the immediate decisions required under § 112.45(a)) about the use of that water as soon as practicable (considering crop in the field, next harvest, or next growing season), and no later than the following year. Given the logistical realities of sampling and testing close to harvest, there may not be time for a farm to adjust water use practices for the current year's crop because they may not receive test results

in sufficient time to take actions related to that crop (for example, test results may not be received until after the crop is out of the field and into distribution). However, the point of this testing is to develop a long-term strategy to ensure that covered farms understand the quality of their water, pay attention to changes (such as the establishment of a CAFO upstream) that may affect water quality, and make appropriate decisions going forward about use of that water. Regardless, if the farm has reason to believe that its agricultural water is contaminated such that it would render the produce adulterated under section 402 of the FD&C Act (*e.g.*, a finding of a pathogen in dump tank water), the farm must take appropriate actions to ensure that affected food does not enter commerce.

Under our framework where the microbial quality criteria in § 112.44(b) and the corresponding testing scheme in § 112.46(b) serve as a long-term strategy to help covered farms to understand the quality of their water sources and plan the appropriate use of water from those sources accordingly, and in light of the options for corrective measures in § 112.45(b)(1) through (b)(3), a requirement to immediately implement corrective actions on the current crop during growing or harvested crop solely based on the results of § 112.46(b) is not warranted. Rather, we conclude the general requirement in §§ 112.41 and corresponding 112.45(a) sufficiently address those circumstances and necessary immediate actions when water is not safe or of adequate sanitary quality for its intended use.

H. Sharing of Water Testing Data (§ 112.47(a))

(Comment 248) One comment requests that FDA provide for the establishment of water quality profiles for common water sources affecting various farms in a specific geographic area or region.

(Response) Section 112.47(a)(2) explicitly allows data sharing under certain circumstances. However, we do not expect that it will typically be possible to develop water quality profiles as described under § 112.46(b) on a regional basis for large water sources such as rivers. As provided in § 112.47(a)(2), you may use data collected by a third party or parties only if the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of the rule are met. As explained in the supplemental notice (79 FR 58434 at 58455), a water source sampled by a third party adequately

represents your water source if the third party takes its samples from the same water source you use (*e.g.*, the same river), and there is no reasonably identifiable source of likely microbiological contamination (*e.g.*, an untreated sewage discharge point, a source of significant amounts of untreated animal feces such as a livestock farm) between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, under this provision, testing data may only be shared if there is no reasonably identifiable source of likely microbiological contamination between the sampling site(s) and the farm(s) involved. For a regional water source such as a river, we expect that in most cases there will be reasonably identifiable source(s) of likely microbiological contamination at various points along the river that will prevent all users of the river from sharing the same data under this provision. Some users of a river may be able to share data under this provision, but only if there are no reasonably identifiable source(s) of likely microbiological contamination between their sampling point(s) and draw point(s) and all other requirements of the rule are met.

(Comment 249) One comment recommends that FDA work with EPA and other agencies to develop and share water testing data with relevant parties.

(Response) To the extent this commenter is referring to water from a Public Water System, as defined under EPA's Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, we note that under § 112.46(a)(1), there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when you receive water from such a system and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement.

(Comment 250) Referring to leased lands where an owner may lease a field or a portion of the land each year to different farms, one comment recommends that, in such cases, the current tenant farmer should be able to use the previous tenant farm's water sampling results to establish the water quality profile when one is required under proposed § 112.45(b), rather than having to conduct a new baseline survey.

(Response) Under § 112.47(a)(2), you may use test data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the rule are met. A water source sampled by a third party adequately represents your water source if the third party takes its samples from the same water source you use (e.g., the same canal, stream, or reservoir) and there is no reasonably identifiable source of likely microbiological contamination between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, if a farmer of leased land has access to previous years' water testing data that meets the requirements of § 112.47(a)(2), the farmer may use such data to satisfy relevant testing requirements under § 112.46, including those required under § 112.46(b). On the other hand, if a farmer of a leased land does not have access to previous years' water testing data, or the farmer has access to such data but those data do not meet the requirements of § 112.47(a)(2), the farm will need to perform its own testing to develop the initial microbial water quality profile.

I. Agricultural Water Used During Harvest, Packing, and Holding Activities (§ 112.48)

(Comment 251) Some comments state that it would be impossible to maintain a potable water standard for postharvest water at all times. Comments also state that FDA should include a cost-effective recommendation for visual monitoring, and clearer criteria for how farms should deal with organic build-up in water and when to change the water. Some of these comments also maintain that reliance on visual inspection in place of other testing mechanisms may not be safe.

(Response) Section 112.48(b) requires you to visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for build-up of organic material (such as soil and plant debris). We are including this monitoring requirement to highlight conditions that require action, such as a water change in a dump tank, and take appropriate measures, as necessary. The specific method and criteria for monitoring to maintain water quality will need to be operation-specific and, therefore, we recommend that you consider

establishing protocols specific to your harvesting, packing, or holding activity. We note that this requirement is not the only requirement applicable to agricultural water used for these purposes. Section 112.44(a) establishes a microbial quality criterion for such water and prohibits using untreated surface water for such purposes. We consider the § 112.44(a) criterion to apply to the water as it is being added to a dump tank, flume, or wash tank. Section 112.45(a) establishes steps that a farm must take when the water does not meet the § 112.44(a) microbial criterion. In addition, § 112.46(a) establishes the circumstances in which water used for the purposes listed in § 112.44(a) is not required to be tested, and § 112.46(c) requires testing untreated ground water used for these purposes. Thus, this rule does not rely on visual inspection in place of testing water quality as suggested by some comments. Where we have determined that a testing requirement is appropriate (i.e., for untreated ground water used for these purposes), we have established such a requirement.

(Comment 252) One comment suggests requiring disinfection treatment of re-circulated water used during and after harvest. By contrast, another comment states that disinfection of re-circulated water in case of dump tanks is unnecessary and impractical.

(Response) Section 112.48(a) requires you to manage the water used during harvest, packing, and holding activities for covered produce as necessary, including by establishing and following water-change schedules for re-circulated water to maintain the safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce). In addition, under § 112.44(a), agricultural water applied in any manner that directly contacts covered produce during or after harvest activities is required to meet the zero detectable generic *E. coli* in 100 mL microbial quality criterion. This requirement applies to the water as it is being added to a dump tank, flume, or wash tank (see Comment 251). Recognizing the wide-range of handling procedures, washing line set-ups, and commodity-specific practices where agricultural water directly contacts covered produce during or after harvest activities, we are not requiring treatment of re-circulated water. Instead, we have provided flexibility for farms to

implement measures appropriate to their practices to comply with § 112.48(a), which may include disinfection treatment during re-circulation. See also Comment 196.

(Comment 253) Some comments express a need for commodity-specific research to tailor requirements for the use of water during harvest, packing, and holding activities to specific covered produce commodities. Some commenters also believe that, although maintaining a positive temperature differential between the produce and wash water could be a good practice, it may not be practicable based on current industry practices. In addition, some commenters do not believe applying a water temperature differential has been demonstrated to minimize the risk of infiltration of microorganisms.

(Response) As described in the 2013 proposed rule, water temperature can influence processes leading to infiltration of microorganisms into many types of produce. In the QAR, too, we noted that infiltration of water containing pathogens into produce has been demonstrated in apples (Ref. 158), oranges (Ref. 159), tomatoes (Ref. 160) (Ref. 161), and mangoes (Ref. 162), and was suggested to play a role in a 1999 *Salmonella* outbreak associated with mangoes (Ref. 163). In the development of the 2013 proposed rule, we considered proposing a specific temperature differential between water and product core temperature (e.g., water must be at least 10 °F warmer than core), and tentatively concluded that there is insufficient scientific evidence supporting the application of such a specific temperature differential requirement across all covered produce. Instead, we proposed and now finalize § 112.48(c), which requires that you must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance. Thus, the requirement is tailored to apply only to appropriate commodities and practices, and only as needed to minimize the potential for infiltration of pathogens.

Although research suggests that water temperature can influence the infiltration of microorganisms into various types of produce, including apples, oranges, mangoes and tomatoes, other studies demonstrate that infiltration can occur without a temperature differential (Ref. 159) (Ref. 164). For example, it was demonstrated that internalization of *Salmonella* into tomatoes via their stem scar can occur

even under a zero temperature differential, and temperature differentials up to 10 °F have no effect on the internalization frequency and have limited impact on *Salmonella* spp. cell populations internalized in tomatoes. In addition, factors such as tomato variety and the time delay between tomato stem removal and water immersion have a significant impact on the frequency and population of internalized *Salmonella* spp. in tomatoes (Ref. 164). We did not receive data or information in response to the 2013 proposed rule that would support a requirement for a specific temperature differential to be maintained in agricultural water used during harvest, packing, and holding activities across all covered produce.

J. Records Related to Agricultural Water (§ 112.50)

(Comment 254) In response to the 2013 proposed rule, several comments support the recordkeeping requirements of proposed § 112.50, and state that effective water management includes recordkeeping that is sufficient to confirm that agricultural water is safe throughout the growing season. Comments also agree that farms must establish and keep records relating to the findings of the inspection of the agricultural water system; the results of any analytical tests conducted to determine whether water is safe and of adequate sanitary quality for its intended use; and scientific data relied on to support the adequacy of methods used to treat agricultural water. One comment also agrees with the proposed requirement to maintain annual documentation from a public water system, if applicable. Another comment suggests that FDA should require documentation of any corrective actions that farms employ to address problems identified with their water system and to verify that those corrective actions were effective.

(Response) We conclude that certain records are necessary for you to ensure your own compliance with the requirements in this rule for use of agricultural water, and so that FDA can verify your compliance with the relevant requirements of subpart E. We agree that documentation of corrective actions is necessary to verify effectiveness of the corrective actions and compliance with the relevant requirements. In proposed § 112.161(b), we proposed a general provision

applicable to records required under subparts C, E, F, L, and M of part 112 that you must establish and keep documentation of actions you take when a standard in any of these subparts is not met. For clarification, we are eliminating proposed § 112.161(b) and, instead, adding that requirement within the records provisions of two relevant subparts, subparts E and M. In subpart E as edited, under new § 112.50(b)(6), you must establish and keep documentation of actions you take in accordance with § 112.45. For example, if you determine that water you use for a purpose listed in § 112.44(a) does not meet the microbial quality criterion established in that section, § 112.45(a) provides that you must take certain steps as a result. This § 112.50(b)(6) requires that you establish and keep documentation of the steps taken to satisfy § 112.45(a). In addition, in this section we are also establishing specific requirements for documentation of time intervals or calculated log reductions applied in accordance with § 112.45(b)(1).

We are also adding new § 112.50(b)(9) to require that you retain documentation of any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a). Under § 112.151(b)(1), you may use any scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity to satisfy the water testing requirements under § 112.46. In addition, under § 112.151(b)(2), if you use an alternative indicator of fecal contamination in accordance with § 112.49(a), you must use a scientifically valid method to test for the indicator. We conclude such records are necessary for us to verify and for you to ensure that appropriate methods are used for testing agricultural water. This provision is consistent with proposed § 112.150(b)(5), which we have retained in this rule and which requires similar records regarding alternative analytical methods used when conducting testing required under subpart M for sprouts. We are also combining two proposed records requirements related to water testing results (proposed § 112.50(b)(2) and (5)) into one requirement in final § 112.50(b)(2).

(Comment 255) A comment requests clarification on the type of record that will sufficiently verify that the inspection of each water source and

identification of potential hazards has been conducted as required in proposed § 112.42.

(Response) Under § 112.50(b)(1), you are required to establish and keep records of your agricultural water system inspection findings under § 112.42(a). Other than as provided generally for records required under this rule in subpart O, we are not further specifying the manner or format in which you prepare the record(s) to satisfy this recordkeeping requirement. We note that under § 112.161(a)(1), all records required under this part must include, as applicable, the name and location of your farm, actual values and observations obtained during monitoring, an adequate description of covered produce applicable to the record, the location of a growing area or other area applicable to the record, and the date and time of the activity documented. Under § 112.161(a)(2), records must be created at the time an activity is performed or observed, under § 112.161(a)(3) they must be accurate, legible, and indelible, and under § 112.161(a)(4) they must be dated, and signed or initialed by the person who performed the activity documented. Covered farms may prepare and maintain documentation of their inspections and associated findings in a manner that is appropriate for the farm's operation provided that the records contain all necessary information and satisfy subpart O. Under § 112.163(a), you are not required to duplicate any existing records if those records contain all of the required information and satisfy the requirements of this rule. Similarly, if you have records containing some but not all of the required information, § 112.163 provides you the flexibility to keep any additional information required either separately or combined with your existing records, even where the formats for each record may not be the same.

K. Compliance Periods Related to Agricultural Water

For covered activities involving covered produce (except sprouts subject to subpart M), the compliance dates for water quality requirements in § 112.44 and certain related provisions are two years beyond the compliance date for the rest of the final rule applicable to the covered farm based on its size. See Table 12.

TABLE 12—COMPLIANCE DATES FOR REQUIREMENTS IN SUBPART E FOR COVERED ACTIVITIES INVOLVING COVERED PRODUCE (EXCEPT SPROUTS SUBJECT TO SUBPART M)

[See also Table 30]

Compliance dates of 2–4 years applicable to the farm based on its size	Extended compliance date of additional 2 years beyond the compliance date based on size of farm
§ 112.41	§ 112.44.
§ 112.42	§ 112.45(a) with respect to § 112.44(a) criterion.
§ 112.43	§ 112.45(b).
§ 112.45(a) with respect to safe and adequate standard	§ 112.46(b)(2) and (b)(3)§ 112.46(c).
§ 112.46(a)	§ 112.46(b)(1) with respect to untreated ground water.
§ 112.46(b)(1) with respect to untreated surface water.	
§ 112.47.	
§ 112.48.	
§ 112.49.	
§ 112.50.	

Note that although most of § 112.46 is subject to the extended compliance periods, § 112.46(a) is not, and § 112.46(b)(1) with respect to untreated surface water is not. Therefore, covered farms must initiate actions in compliance with § 112.46(a) and, with respect to untreated surface water, § 112.46(b)(1) under the regular compliance periods applicable to the remaining sections of this rule. Similarly, § 112.47 is subject to the shorter compliance period because it establishes requirements that are relevant to testing requirements when they become applicable. See our response to Comment 243 for an explanation for treating § 112.46(b)(1) with respect to untreated surface water differently from the remaining water testing requirements for purposes of compliance. We recognize that farms may need additional time to prepare for implementation of the water quality testing, monitoring, and related record-keeping provisions. This additional 2-year compliance period for water quality requirements is also expected to permit farms to consider alternatives to the microbial quality criteria in § 112.44(b), the microbial die-off rate in § 112.45(b)(1)(i), or the testing frequencies in § 112.46(b)(1)(i)(A) and § 112.46(b)(2)(i)(A), and develop adequate scientific data or information necessary to support a conclusion that the alternative would provide the same level of public health protection as the relevant requirement, and would not increase the likelihood that the covered produce will be adulterated under section 402 of the FD&C Act, in light of the farm's covered produce, practices,

and conditions. Therefore, for covered activities involving covered produce (except sprouts subject to subpart M), the extended compliance dates for certain water quality testing, monitoring, and related recordkeeping requirements identified in column 2 of Table 12 are six years from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms.

We are not similarly providing extended compliance periods for these specific water requirements, in the case of covered activities involving sprouts, as discussed in section XVIII.J of this document. Therefore, covered farms must comply with all of the applicable requirements of part 112, including subpart E, for all covered activities involving sprouts subject to subpart M, within one to three years of the effective date of the rule, depending on size of the farm. See also section XXIV.A of this document for additional information.

XIV. Subpart F—Comments on Biological Soil Amendments of Animal Origin and Human Waste

In subpart F of proposed part 112, we proposed minimum standards directed to treated and untreated biological soil amendments of animal origin and human waste that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonable necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is

not adulterated under section 402 of the FD&C Act. In the 2013 proposed rule and the supplemental notice, we asked for comment on our proposed provisions, including our decision not to establish requirements for chemical or physical soil amendments, or biological soil amendments that are not of animal origin; the appropriateness of treatment options considered for treated soil amendments; the appropriateness of the microbial standards selected and potential alternatives; and the proposed waiting periods between application and harvest (“application intervals”). In the supplemental notice, we withdrew our proposal for an application interval for untreated biological soil amendments of animal origin (including raw manure) and deferred our decision on an appropriate minimum application interval until such time as necessary for us to pursue certain steps, including a risk assessment and research to supplement the science on an appropriate interval.

In this section of this document, we discuss comments we received on the standards directed to biological soil amendments of animal origin and human waste in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the new and amended proposed provisions in the supplemental notice.

We are finalizing these provisions with revisions (see Table 13). We discuss these changes in this section. There are also revisions relevant to subpart F in the Definitions section in § 112.3, which are described in section IX of this document.

TABLE 13—DESCRIPTION OF REVISIONS TO SUBPART F

Final provision	Description of revisions
§ 112.51	<ul style="list-style-type: none"> —Revision to (a) and (b)(1) clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, and to replace reference to § 112.44(a) with clarifying text. —Revision to (b)(5) to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin. —See Table 14 for additional information.
§ 112.52	<ul style="list-style-type: none"> —Revision to (a) to add other soil amendments and to clarify that drip fertigation with agricultural teas that are biological soil amendments of animal origin is permitted in compliance with other requirements of this rule. —Revision to (c) to replace “that has become” with “that you know or reasonably believe may have become.” —See Table 15 for additional information.
§ 112.53	<ul style="list-style-type: none"> —No change
§ 112.54	<ul style="list-style-type: none"> —Revision to (a) and (b) to add biological processes and replace “demonstrated” with “validated.” —Rearrangement to combine relevant provisions of proposed (c) into revised (b). —Renumbering of proposed (c)(1) to (b)(1) and proposed (c)(2) to (b)(2) as a conforming change to combining (b) and (c). —Elimination of proposed (c)(3) as not necessary. —Revision to descriptions of static composting (in (b)(1)) and turned composting (in (b)(2)) to further clarify the processes. —See Table 17 for additional information.
§ 112.55	<ul style="list-style-type: none"> —Revision to (a)(1) to add liquid sampling. —Revision to (a)(2) and (a)(3) to add liquid sampling and indicate that it is a ‘non-detect’ standard. —Revision to (b) to add liquid sampling and indicate that the <i>Salmonella</i> method is a ‘non-detect’ standard. —See Table 18 for additional information.
§ 112.56	<ul style="list-style-type: none"> —Revision to (a) to delete “except as provided in paragraph (b) of this section.” —Revision to combine proposed (a)(3) and proposed (a)(4) as renumbered (a)(2), corresponding to revised § 112.54(b). —Renumbering of proposed (a)(2) as (a)(3). —See Table 19 for additional information.
§ 112.60	<ul style="list-style-type: none"> —Revision to (b)(1) to eliminate proposed (b)(1)(ii) and as a conforming change to renumber (b)(1)(iii) to (b)(1)(ii) and to require such documentation at least annually. —Elimination of (b)(3) as a conforming change since proposed § 112.54(c)(3) has been deleted. —See Table 20 for additional information.

A. General Comments

(Comment 256) Many comments state that biological soil amendments of animal origin can contain pathogenic bacteria that can cause foodborne illness in humans and therefore special precautions must be taken in their use. Some comments further cite certain provisions within subpart F that address the need for such special precautions and state that they were in alignment with current GAPs, some marketing orders, certain industry standards (in particular the mushroom industry standards), and that they are currently being followed by segments of the industry. These commenters generally agree with FDA’s approach.

Conversely, many comments take exception to our coverage of biological soil amendments and our approach to doing so, particularly the original proposal to require a 9-month application interval for untreated biological soil amendments of animal origin, including raw manure. Some comments state that mandatory requirements for biological soil amendments of animal origin are not needed, or should be in guidance rather than a regulation.

(Response) FDA continues to conclude that biological soil amendments of animal origin are an

important route of contamination on farm and, therefore, we do not believe it would be sufficient merely to make recommendations related to biological soil amendments of animal origin in guidance. We have finalized our QAR and it supports this conclusion. With regard to comments on the application interval for untreated biological soil amendments of animal origin, including raw manure, which was proposed in the 2013 proposed rule and withdrawn in the supplemental notice, see Comment 257.

(Comment 257) Many commenters suggest that provisions within subpart F should be written to align with NOP standards. Some comments expressed concern that the provisions of subpart F would cause farms to use specific methods of agriculture, including use of synthetic fertilizers, which would eliminate a farm’s ability to become certified organic. Some comments state that organic farming provides a benefit in protecting the public health from consequences associated with the use of harmful chemical pesticides, herbicides, and synthetic fertilizers, and already includes a food safety component and has an excellent track record on food safety. Other comments suggest FDA adopt NOP standards because farms are already accustomed to implementing

them. Further, other comments recommended that FDA and USDA collaborate to align their respective regulations to be maximally protective of the public health from both foodborne illness and environmental health perspectives.

(Response) We do not agree that the provisions of subpart F are in conflict with NOP standards or would require farms to use synthetic amendments such that they could not achieve organic certification. The provisions of subpart F allow use of both treated and untreated biological soil amendments of animal origin, as long as they are applied in accordance with § 112.56. The provisions of § 112.54 allow for biological (including composting), chemical, and physical treatment processes, or combinations thereof, for producing treated biological soil amendments of animal origin, as long as they meet the microbial standards in § 112.55. We do not believe it would be appropriate to broadly adopt USDA’s NOP standards for biological soil amendments of animal origin because they were established for purposes of organic certification and not for produce safety. However, we do agree that inter-agency collaboration to align goals and approaches, in order to minimize individual requirements placed on the

industry, is beneficial. FDA has worked, and will continue to work, with USDA to ensure our programs do not have conflicting or duplicative measures.

With regard to the application interval for use of untreated biological soil amendments of animal origin, including raw manure, in response to our original proposal we received many comments taking issue with our proposed 9-month interval. In response to these comments, we indicated in the supplemental notice (79 FR 58434 at 58460–58461) that we were deferring action on an application interval until we pursued certain steps including a risk assessment and research to supplement the science on an appropriate interval. We anticipate that these efforts will take 5 to 10 years to complete. Following the completion of the risk assessment and research work, we expect to: (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment; (2) consider such new data and information to develop tentative scientific conclusions; (3) provide an opportunity for public comment on our tentative decisions; and (4) consider public input to finalize the provision(s) establishing an appropriate minimum application interval(s).

(Comment 258) Several comments agree with our decision in the supplemental notice to pursue a risk assessment and research prior to establishing an application interval for untreated biological soil amendments of animal origin, including raw manure. However, other comments state that 5–10 years would be too long to wait for the public health benefits of setting such an application interval, that there is science demonstrating that a 120-day interval would be an appropriately protective interim standard while FDA pursues its risk assessment and research, that many in the agricultural community are already applying a 120-day interval, and that FDA should establish a 120-day application interval for raw manure as an “interim” standard for the intervening 5–10 years while FDA pursues its risk assessment and research agenda and additional rulemaking. Conversely, some comments state it is not appropriate for FDA to establish an application interval based on the NOP interval (90/120 days depending on the crop), because the NOP standards require incorporating manure into the soil after application and were established for the purpose of maintaining organic integrity, and not for produce safety.

Some other comments relating to application intervals include a suggestion that we subject only liquid

manures to a 9-month application interval based on an asserted greater risk presented by liquid manure as compared to non-liquid manure, a suggestion that we count the time period when soil is frozen toward any application interval, and a request that we conduct research to determine the impact of hard freezes on survivorship of pathogens in northern climates.

(Response) As explained in the supplemental notice (79 FR 58434 at 58460–58461), FDA withdrew its proposal for an application interval for untreated biological soil amendments of animal origin, including raw manure, and indicated that it would establish such an interval after pursuing a risk assessment and research agenda to supplement the science regarding an appropriate interval. Because FDA withdrew its proposal for such an application interval, we do not have a proposal to finalize at this time. To establish an application interval for untreated biological soil amendments of animal origin, FDA will need to undertake notice-and-comment rulemaking consistent with the Administrative Procedure Act (5 U.S.C. 553). We recognize that we could provide public health protection by applying an application interval for untreated biological soil amendments of animal origin while we pursue our risk assessment and research, and the familiarity of the farm community with the NOP 90/120-day interval. We also recognize that FDA stated in the supplemental notice that it would pursue its risk assessment and research agenda before proposing to establish such an application interval, and that some comments oppose establishing an interval by regulation before completion of that agenda. FDA is considering appropriate next steps. However, we will not establish an application interval for untreated biological soil amendments of animal origin without giving the public a chance to provide comment on a proposed interval.

As noted in the supplemental notice, we continue to believe that a quantitative application interval standard, established in part 112, is necessary to minimize the likelihood of contamination of produce resulting from the use of untreated biological soil amendments of animal origin, including raw manure, in a manner that contacts covered produce. We acknowledged in the supplemental notice that many farms currently employ the NOP standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and we recognize that such farms will likely continue their current practice to use this standard in organic crop

production, in the absence of an FDA regulation that establishes a food safety standard for minimum application intervals associated with the use of untreated biological soil amendments of animal origin such as raw manure. Given that the scientific literature demonstrates that the probability of pathogen survival decreases as the length of time between application of untreated biological soil amendments of animal origin and harvest increases, and that more rapid die-off occurs during the months immediately following application (e.g., three to four months) as compared to subsequent months (followed by prolonged survival of pathogens at low levels), we believe adherence to the NOP standard to be a prudent step toward minimizing the likelihood of contamination while the above described risk assessment and research program is ongoing. At this time, we do not intend to take exception to the continuation of this practice in the interim period.

(Comment 259) One comment recommends only stabilized compost that has not been subjected to cross-contamination and re-growth of pathogens be allowed for use on agricultural lands designated for production of ready-to-eat foods.

(Response) FDA agrees that stabilized compost (or any treated biological soil amendment of animal origin) must be handled, conveyed, and stored in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin (§ 112.52(b)) and that it should be considered untreated if it has become contaminated (§ 112.52(c)). However, we do not agree that only stabilized compost should be allowed to be used during the growing of covered produce (or more broadly as suggested by the comment). As described in Comment 277 there are several different types of biological soil amendments of animal origin that are appropriate for use on land used to grow covered produce, and this rule does not restrict use of other types of soil amendments not subject to subpart F (such as chemical and physical soil amendments and biological soil amendments that are not of animal origin). All such soil amendments may be used in the growing of covered produce, provided that all biological soil amendments of animal origin and human waste are used in accordance with the requirements in subpart F.

(Comment 260) A commenter requests only mammalian and avian species be included in the definition of “biological soil amendments of animal origin” and

therefore subject to the requirements of subpart F.

(Response) Animals other than mammalian and avian species, such as fish, amphibians, and reptiles, are known to carry human pathogens (*e.g.*, Salmonella) (Ref. 165) (Ref. 166) (Ref. 167) and fecal contamination by such animals is a concern. The comment did not provide information to support the request that only certain species be covered. FDA concludes that the risks posed by biological soil amendments from all animal sources should be addressed through inclusion in the term “biological soil amendments of animal origin” and resulting requirements under subpart F of this rule.

(Comment 261) Some comments state that food safety on a farm is related to the microbial soil ecology, and that biological diversity adds to soil health and protects the environment, while “sterile” soils lack this healthy fertility. Some comments also suggest healthy soils are essential to food safety, can boost the nutrient content of food, and contribute to long-term food security by ensuring land is viable for diverse, long-term production systems. Comments request that we explore ways to enhance the safety of covered produce while promoting biological diversity in soil ecology.

(Response) FDA agrees that soil health, environmental stewardship, and reducing the risk of food becoming contaminated with pathogens are all important and are not mutually exclusive. We intend to work with stakeholders to address co-management of produce safety and the environment.

(Comment 262) Comments focusing on environmental concerns associated with chemical fertilizer use requested that FDA revise the proposed produce safety rule to remove any incentives it may create for using chemical fertilizers as a replacement for biological soil amendments of animal origin.

(Response) As discussed in the 2013 proposed rule (78 FR 3504 at 3576), animal waste is likely to contain human pathogens. Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death, and we are still not aware of any situation in which chemical or physical soil amendments, such as elemental fertilizers, soil stabilizers, or others typically made of mined or synthetic materials, have served as sources of microbial contamination. Therefore, neither chemical nor physical soil amendments are a focus of this rule. Instead, we focus on biological soil

amendments of animal origin and human waste, which present a reasonable likelihood of harboring human enteric pathogens. We do not believe our focus on biological soil amendments of animal origin incentivizes the use of chemical fertilizers. However, we did consider the effect of farms switching to chemical fertilizers in the EIS and concluded that a switch away from biological soil amendments of animal origin to chemical fertilizers could cause moderate adverse environmental impacts to soils, but not to a significant level because such effects are reversible and may be mitigated through other practices that are growing in popularity such as green manuring, no-till practices, and use of cover crops. FDA expects that the cumulative effects nationwide related to soil health and biological soil amendments of animal origin will not be significant. See discussion in Chapter 5.5 of the EIS (Ref. 126).

(Comment 263) One comment suggested that biological soil amendments that do not contain animal waste, such as yard trimmings from a municipal source, residential, or public properties, have the potential to be contaminated with domestic and wild animal feces and pose a risk to public health. The commenter therefore suggests FDA include requirements for complete composting before allowing use of any “green waste” (meaning biological soil amendments not of animal origin). Another comment noted a study (Ref. 168) that concluded the presence or absence of manure is not a suitable predictor of the pathogen load of a stabilized compost, suggesting that “green waste” should not be treated as less risky than biological soil amendments of animal origin. Conversely, other comments agreed with FDA’s tentative conclusion that biological soil amendments that do not contain animal or human waste products are low-risk products, suggesting that the tentative conclusion to exclude biological soil amendments not of animal origin from the requirements of the rule is sensible. These commenters believed that restrictions on the use of biological soil amendments that are not of animal origin, as defined in this subpart, would be unnecessary due to an extremely low likelihood of contamination from these soil amendments.

(Response) FDA appreciates the comments indicating that there is some risk associated with biological soil amendments not of animal origin (or “green waste”). First, we note that the definitions of “yard trimmings” and

“pre-consumer vegetative waste” in § 112.3(c) stipulates that these are purely vegetative materials. To the extent that vegetative waste is known to include animal feces, it would not meet the definitions of “yard trimmings” or “pre-consumer vegetative waste,” and a soil amendment made from such material would instead be a biological soil amendment of animal origin included in the scope of the provisions of subpart F. However, we recognize that even in purely vegetative material such as that described in the definition of “yard trimmings” or “pre-consumer vegetative waste,” there is the potential for unknown and unavoidable contamination with animal waste. We have concluded that the likelihood of contaminating produce with pathogens by use of biological soil amendments that are not known to contain, and not likely to contain significant animal waste or human waste (*e.g.*, yard trimmings, pre-consumer vegetative waste) is low, and therefore they are not subject to the requirements of this rule.

With regard to the comment that highlighted a paper on the presence of pathogens of public health concern in purely vegetative material, we agree that no biological soil amendment is without risk. However, we conclude that the relative risks are greatest with untreated biological soil amendments of animal origin due to the highly likely presence of human pathogens in such materials, and that is where we are choosing to focus our regulatory efforts. We note that there is currently not a great deal of research on pathogen presence in biological soil amendments not containing animal material. We will continue to follow the science pertaining to this issue and will consider appropriate next steps should there be additional evidence that this is an area of public health concern.

Finally, we note that § 112.52(a) requires that a biological soil amendment of animal origin be handled, conveyed, and stored in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems. We are revising this provision to include a requirement that biological soil amendments be handled, conveyed and stored such that they do not contaminate other soil amendments. In addition, if you know that a soil amendment that had originally not contained animal material has been in contact with, or otherwise contaminated by, a biological soil amendment of animal origin, you should consider the

possibility that, depending on the circumstances, the soil amendment may meet the definition of a biological soil amendment of animal origin and therefore be subject to the requirements of subpart F.

(Comment 264) Some comments suggest that the provisions in subpart F would disallow farmers from utilizing manure produced on their own farms as part of a “closed-loop” or “zero-input” sustainability program, or that farms would be disallowed from having compost curing and storage on site.

(Response) The provisions of subpart F do not prohibit farms from using manure produced on the farm, including manure produced as part of a sustainability program, nor does it prohibit farms from curing or storing compost on site. Covered farms must conduct relevant activities in accordance with the provisions of subpart F.

(Comment 265) One comment requests clarification on whether “table waste” would be an example of a biological soil amendment of animal origin. In addition, other comments request clarification on what is included in the category “table waste,” and express concern that this may also include food preparation waste such as raw meat. Some comments state stabilized compost derived from “table waste” or “post-consumer food waste,” and stabilized compost derived from manure represent different types and levels of risk and should be examined separately.

(Response) FDA proposed to define, and is now finalizing its definition of “table waste” as “any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer” (§ 112.3(c)). Table waste is explicitly included within the definition of “biological soil amendment of animal origin” in § 112.3(c), making it subject to the requirements in subpart F of this rule. As discussed in the 2013 proposed rule (78 FR 3504 at 3548–9), the definition of “table waste” is intended to distinguish post-consumer food waste from pre-consumer vegetative waste. Also as discussed in the 2013 proposed rule (78 FR 3504 at 3574), post-consumer food waste, or table waste (such as plate scrapings), has a greater likelihood of being contaminated, or being contaminated at higher populations, with human pathogens of public health significance due to its unknown content (e.g., animal products, vegetable products, etc.) and its greater

likelihood of containing human fluids or waste (e.g., spittle, vomitus, etc.). On the other hand, food preparation waste that is solely of plant origin may be considered “pre-consumer vegetative waste” (and therefore not subject to the requirements in subpart F) if it meets the terms of that definition (§ 112.3(c)). Notably, we are defining “pre-consumer vegetative waste” in part to require that these materials may not have come in contact with animal products, byproducts or manure or with an end-user (consumer). We are also excluding table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, and any waste generated by restaurants. Any material of animal origin (such as meat) that is added to a soil amendment, regardless of whether it has been served to or come in contact with a consumer, renders that soil amendment a biological soil amendment of animal origin subject to the requirements of subpart F. We acknowledge that a variety of feedstocks may be used to produce treated biological soil amendments of animal origin, including stabilized compost, and that feedstocks differ with respect to their inherent risk. Therefore, in subpart F we chose to establish requirements for the end product of treatment (i.e., the stabilized compost) rather than the feedstock. If a feedstock is treated to meet the standards of §§ 112.54 and 112.55, we conclude that the end product may be used in accordance with requirements for treated biological soil amendments of animal origin rather than untreated biological soil amendments of animal origin in § 112.56. We note that, depending on the level of treatment received, the end products present differing levels of risk reflected in the different application requirements established in § 112.56.

(Comment 266) One comment requests FDA not subject manure from grass-fed animals to the requirements of subpart F. The comment states manure from grass-fed animals does not contain harmful levels of *E. coli* and other noxious bacteria.

(Response) FDA is not providing an exemption from subpart F for manure from grass-fed animals used as a soil amendment. We are not aware of evidence to support the assertion made by the commenter and the comment did not provide any such data or other information.

(Comment 267) Some comments recommend FDA specifically exempt tree nuts from the biological soil amendment requirements in the rule. These comments state that certain types of tree nuts never touch the ground and

most tree nut farms use non-biological soil amendments.

(Response) If a covered farm does not use biological soil amendments of animal origin, then the provisions of subpart F are not applicable to that covered farm. In addition, the requirements we are establishing in § 112.56 allow use of both treated and untreated biological soil amendments of animal origin in situations where there is no contact between the covered produce and the soil amendment. Thus, we do not believe it is necessary or appropriate to exempt tree nuts from this subpart, as suggested by the comment.

(Comment 268) Some comments stated that raw manure is preferable to stabilized compost because raw manure has greater nitrogen content. These comments indicated that farms that switch from raw manure to stabilized compost will need to use additional stabilized compost to make up the loss in nitrogen content. These comments expressed concern that such changes would interfere with nutrient management programs and increase nutrient runoff into waterways.

(Response) As we noted in the supplemental notice, we recognize that some loss of nitrogen during the composting process is likely (Ref. 169) and that adjustments to fertility management will be necessary when shifting to use of stabilized compost. However, we continue to believe that use of stabilized compost is preferable to use of raw manure for growing covered produce because of the higher likelihood of pathogens associated with raw manure. With regard to concerns about nutrient management programs and runoff, we note that stabilized compost has stabilized forms of nitrogen, which are less susceptible to leaching or runoff than unstabilized forms (Ref. 170) (Ref. 171). At the same time, stabilized compost also retains many other key values of raw manure, including serving as a supply of carbon to support diverse and abundant soil microbial communities, which serve important functions in nutrient cycling, conditioning of soil physical and chemical properties, and in some cases crop protection from phytopathogenic diseases (Ref. 171) (Ref. 172) (Ref. 173). Concerns about runoff from biological soil amendments of animal origin are also addressed in the final EIS (Ref. 126).

(Comment 269) One comment points out that the ability to safely and responsibly handle waste from animal livestock production and processing, primarily swine and poultry operations, is critical to the agricultural economy.

The comment further states swine and poultry waste is applied primarily to crops such as corn or soybeans, or in forestry plantations.

(Response) Nothing in this rule prevents the use of waste from animal livestock production and processing as biological soil amendments of animal origin, provided that the amendments are produced and used in accordance with the relevant provisions of subpart F. We also note that dent- or flint-corn and soybeans are excluded from the definition of “produce” in this rule because they are grains (§ 112.3(c)) and are therefore not subject to this rule. Sweet corn is exempt from the rule because it is on the list of produce that FDA has determined is “rarely consumed raw” in § 112.2(a)(1). Further, lumber is also not “produce” for purposes of this rule and forestry plantations producing lumber are therefore not subject to this rule.

1. Use of Agricultural Teas

(Comment 270) Many comments recommend agricultural teas should be regulated using the same standards as stabilized compost. Specifically, some comments suggest that agricultural tea used as a soil amendment in direct soil application with covered produce poses a significant risk, and that such teas are often produced on-farm, with little emphasis on minimizing the presence of pathogens. Several other comments discuss agricultural tea as having unique food safety risks and request that FDA address agricultural teas separately within § 112.56. These comments ask FDA to establish reasonable, scientifically based minimum application intervals for use of agricultural teas as soil amendments and to require that they be applied in a manner that has minimal potential for contact with covered produce during and after application. On the other hand, some comments argue that agricultural teas prepared from stabilized compost in accordance with NOP standards do not carry any food safety risks and therefore should have no application interval requirements. One such comment provides two literature citations to argue that pathogens such as *E. coli* and *Salmonella*, are poor at surviving on plants and are quickly overruled by normal, plant colonizing bacteria. The comment argues that more significant risks are posed by anaerobically prepared manure or non-NOP compliant agricultural teas, which the comment argues should be banned from use as soil amendments.

(Response) FDA agrees that agricultural teas that are biological soil

amendments of animal origin (see Comment 271) should be regulated similarly to other biological soil amendments of animal origin, with appropriate attention given to their unique qualities, and we believe we have done so in this rule. Under § 112.51, the components of an agricultural tea (of animal origin) must be processed to the same standards as other biological soil amendments of animal origin to be classified as a treated biological soil amendment of animal origin, with the addition of specific requirements for the quality of the water used to produce the tea (see §§ 112.51(a) and (b)(1)) and the heightened risk presented by the use of agricultural tea additives (see § 112.51(b)(5)). We consider that, in connection with the provisions of § 112.51 just described, the treatment processes described in § 112.54 and the microbial standards of § 112.55 are adequate for all biological soil amendments of animal origin, including agricultural teas (of animal origin), and it is not necessary to also include a separate section in § 112.56 regarding agricultural teas (of animal origin). We have addressed the unique risks of agricultural teas (of animal origin) by limiting in § 112.51 the circumstances under which they may be considered “treated.” Thus, agricultural teas (of animal origin) made with untreated surface water, or water that has detectable generic *E. coli* in 100 mL of water; and agricultural teas (of animal origin) that contain agricultural tea additives are considered “untreated” and must be applied in accordance with § 112.56(1)(i) or (ii). In addition, like all other biological soil amendments of animal origin, agricultural teas (of animal origin) must be considered untreated and applied in accordance with § 112.56(1)(i) or (ii) if they fall within any of the categories in § 112.51(b) (for example, if the biological materials of animal origin used to make the tea are not processed to completion in accordance with the requirements of § 112.54, or if they have been contaminated after treatment).

The comment asserting the safety of agricultural teas produced from stabilized compost following NOP standards did not provide data or information supporting that assertion. However, we note that under §§ 112.56(a)(2) or (a)(3), biological soil amendments of animal origin that are agricultural teas prepared from properly handled stabilized compost (*i.e.*, biological materials of animal origin are processed to completion in accordance with § 112.54 to meet relevant microbial

standards in § 112.55; made with water satisfying the requirements of § 112.51(a); and not otherwise considered “untreated” under § 112.51(b)) have an application interval of zero days, and application method restrictions that vary based only on the level of treatment provided by the processing. Under § 112.56(a)(1), other biological soil amendments of animal origin that are agricultural teas and that are considered “untreated” under § 112.51(b) must be applied in a manner that does not contact covered produce at application and minimizes potential for contact after application, or in a manner that does not contact covered produce during or after application. See Comment 257 regarding our plans relating to a minimum application interval for untreated biological soil amendments of animal origin applied in a manner that contacts covered produce.

With regard to the comment about anaerobic preparation, FDA does not consider that there is enough evidence in the literature to link the method of agricultural tea production (actively aerated or anaerobic brewing) to a difference in *E. coli* risk. Most enteric bacterial pathogens (such as *E. coli* and *Salmonella* spp.) are classified as facultative anaerobic organisms; these organisms will grow faster and out-compete other organisms at a faster rate in an aerobic environment, as compared to an anaerobic environment, provided the same amount of nutrients and conditions for growth are present in both environments. It is a common misperception that these pathogens thrive better in an anaerobic environment than in an aerobic one (Ref. 174). The scientific literature points to agricultural tea additives, and not brewing method, as the main factor associated with human pathogen growth in agricultural teas (Ref. 174).

(Comment 271) Several comments state that agricultural teas are not typically considered to be agricultural water; are applied sporadically, sometimes very close to harvest; and are used in conjunction with plants, other microbes, nutrients, and the soil to suppress disease, improve soil structure, maintain nutrients, and increase water holding capacity. These comments recommend that FDA clarify that the water used to make agricultural tea, or the resulting agricultural tea, does not need to meet the requirements for “agricultural water” in subpart E.

(Response) In § 112.3(c) of this rule, we are revising the definition of “agricultural tea” to include an explicit statement that “[a]gricultural teas are soil amendments for purposes of this rule.” We recognize that agricultural

teas may be applied in some cases for purposes in addition to those specified in our definition of “soil amendment,” that is, “to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water.” However, we understand that even when such additional purposes exist, agricultural teas are generally used for the purposes described in the definition of “soil amendment” in this rule. In addition, we believe that the appropriate requirements to apply to agricultural teas made with materials of animal origin are those we have established in subpart F of this rule for biological soil amendments of animal origin, and not the requirements in subpart E that apply to agricultural water. We are removing the reference to agricultural tea in subpart E of this rule, in proposed § 112.44(a)(3), because it was confusing. Water used to make an agricultural tea must not be untreated surface water, and must meet the same microbial criteria as that set forth in § 112.44(a) for the resulting agricultural tea to be considered “treated” under § 112.51 in subpart F. Whether a biological soil amendment of animal origin is “treated” or “untreated” under § 112.51 affects the application restrictions that apply to its use in § 112.56. However, we do not intend to require that agricultural teas, or the water used to make them, meet other requirements in subpart E for agricultural water. Thus, we are deleting the reference to agricultural teas in subpart E, making the revision discussed previously to the definition of “agricultural tea,” and revising to § 112.51(a) and (b)(1) to clarify this. As revised, § 112.51(a) provides that “a biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.” As revised, § 112.51(b)(1) provides that “a biological soil amendment of animal origin is untreated if it has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is

untreated surface water, or the water used to make the tea has detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.”

We also note that to the extent agricultural teas are being used as pesticides, FIFRA provides for federal regulation of their distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. The term “pesticide chemical” is also defined in section 201(q) of the FD&C Act. Food bearing or containing a pesticide chemical residue is adulterated under 402(a)(2)(B) unless a tolerance is in effect and the quantity of the residue is within the limits of the tolerance, or an exemption from the requirement of a tolerance is in effect (see section 408(a) of the FD&C Act). EPA has established tolerances, and exemptions from the requirement of a tolerance, in 40 CFR part 180, subparts C and D, respectively. For more information, see <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#laws> and <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> (Ref. 127) (Ref. 174a)

(Comment 272) One comment states that the 2013 proposed rule does not distinguish between “compost extracts” and “compost teas.” Compost extracts as described by the commenter are simply water infusions of compost, without any “compost tea additive” (what we have termed “agricultural tea additive”). The comment states that compost extracts without “compost tea additives” should have no greater restrictions than the compost that was used to make the tea.

(Response) As discussed in response to Comment 270, this rule regulates agricultural teas that are biological soil amendments of animal origin similarly to other biological soil amendments of animal origin, with appropriate attention given to their unique qualities, including whether they contain agricultural tea additives as we have defined that term in § 112.3(c). Further, this rule does distinguish between agricultural teas, as we have defined that term in § 112.3(c), and other extracts. FDA defines “agricultural tea” to mean “a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are

held for longer than one hour before application. Agricultural teas are soil amendments for purposes of this rule.” An agricultural tea (of animal origin) must be used in accordance with the provisions of § 112.56 in accordance with its status as a ‘treated’ or ‘untreated’ biological soil amendment of animal origin. In response to Comment 270, we describe how those requirements differ for agricultural teas that are biological soil amendments of animal origin as compared to other biological soil amendments of animal origin. A water extract of biological materials of animal origin that is not an agricultural tea (such as extracts that are held (*i.e.*, “steeped”) for less than one hour before application) may still be a biological soil amendment of animal origin if it fits that definition, in which case it is subject to the requirements for biological soil amendments of animal origin in subpart F.

(Comment 273) One comment argues that the rule places restrictions on agricultural teas made from biological materials not of animal origin that are not reasonable, given the proposed exclusion of other biological soil amendments of non-animal origin from the coverage of subpart F.

(Response) We based our proposed definition of “agricultural tea” in part on a similar definition of “compost tea” used by the NOSB (78 FR 3545). We did not limit this definition to teas made from biological materials of animal origin because we intended to describe the wide range of agricultural teas used in the production of produce in this definition. However, we agree that, consistent with the scope of this rulemaking, agricultural teas made entirely from vegetative material are excluded from the requirements of subpart F that apply to biological soil amendments of animal origin. This is achieved not through the scope of the definition of “agricultural tea,” but by the fact that the requirements in subpart F refer in all relevant locations to biological soil amendments of animal origin, thus requiring that there be some component of animal origin in the biological soil amendment feedstock (or, in the case of § 112.53, human waste). To improve clarity, we are amending the three appearances of the term “agricultural tea” in § 112.51 to specify that the biological materials used to make the tea include materials of animal origin.

B. Determining the Status of a Biological Soil Amendment of Animal Origin (§ 112.51)

In proposed § 112.51, we proposed to establish requirements for determining

the status of a biological soil amendment of animal origin as being treated or untreated, for use in covered

activities. In Table 14, we describe the codified provisions of § 112.51 and any changes we made to those provisions in

the final rule. Comments specific to § 112.51 follow the table.

TABLE 14—DESCRIPTION OF REVISIONS TO § 112.51

Proposed provision	Proposed language	Final revisions, if any
§ 112.51(a)	A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the requirements of § 112.44(a).	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, and to replace reference to § 112.44(a) with clarifying text.
§ 112.51(b)(1)	A biological soil amendment of animal origin is untreated if: (1) It has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of § 112.44(a).	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, and to replace reference to § 112.44(a) with clarifying text.
§ 112.51(b)(2)	A biological soil amendment of animal origin is untreated if: (2) It has become contaminated after treatment.	No change.
§ 112.51(b)(3)	A biological soil amendment of animal origin is untreated if: (3) It has been recombined with an untreated biological soil amendment of animal origin.	No change.
§ 112.51(b)(4)	A biological soil amendment of animal origin is untreated if: (4) It is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness.	No change.
§ 112.51(b)(5)	A biological soil amendment of animal origin is untreated if: (5) It is an agricultural tea that contains an agricultural tea additive.	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin.

(Comment 274) A comment recommends that FDA make a distinction between raw animal manures and other animal-based fertilizers such as bone, feather, and blood meal, which are commercially processed.

(Response) FDA’s approach does distinguish between “treated” and “untreated” biological soil amendments of animal origin. The distinction is established in § 112.51 and is made based upon the components, processing, handling, and other information about the soil amendment, and not the particular type of animal component that was the feedstock (starting material). Application restrictions for treated and untreated biological soil amendments of animal origin are described in § 112.56.

(Comment 275) One comment generally agrees with our regulatory descriptions in § 112.51(b) of biological soil amendments of animal origin that are untreated, but asked us to modify § 112.51(b)(4) so that if any discrete component of a soil amendment is untreated, the entirety is considered untreated. The comment argues that whether any untreated component part renders the entirety “untreated” should not depend on whether the farm knows

or has reason to believe that the untreated component is contaminated.

(Response) FDA agrees that if any discrete component of a soil amendment is untreated, the entirety is considered untreated. However, such situations are addressed in § 112.51(b)(1) (not processed to completion), (b)(2) (contaminated after treatment), and (b)(3) (recombined with an untreated biological soil amendment of animal origin). The comment misunderstands § 112.51(b)(4), which refers to a situation in which, for example, you find out that your feedstock (or a portion of it) was contaminated with a pathogen, or associated with foodborne illness. In such cases, FDA concludes that you should be required to consider the biological soil amendment to be untreated for purposes of subpart F, including the application restrictions in § 112.56. If there is reason to think that materials used in a biological soil amendment of animal origin are actually contaminated or associated with foodborne illness, there is a need to apply the most stringent controls to such materials, even if they have undergone a treatment process meeting the requirements of §§ 112.54 and 112.55.

(Comment 276) One comment disagrees with FDA’s decision to treat

agricultural teas (of animal origin) that contain additives as “untreated” because FDA cited only one study by Ingram and Millner (Ref. 174). This comment cites a reference (Ref. 175) which, according to the commenter, showed that while the addition of molasses as an agricultural tea additive at 1 percent enhanced growth of *Salmonella* and *E. coli* O157:H7 in an agricultural tea, the addition of 0.2 percent molasses did not. Further, the comment argues that the addition of carrot juice as an agricultural tea additive was shown to inhibit the growth of nonpathogenic *E. coli* in swine manure compost extract (Ref. 176). This comment contends that FDA should focus on factors other than the addition of additives to determine requirements for agricultural teas.

(Response) FDA recognizes that many agricultural tea production practices include the addition of nutrient additives (such as molasses) during the steeping process, a practice designed to rapidly increase the indigenous heterotrophic microbiological populations extracted from the biological feedstock. The two studies mentioned in the comment do, however, provide scientific evidence to support FDA’s conclusion that even when stabilized compost or other biological

materials of animal origin used as feedstock for an agricultural tea meet the microbial standards of § 112.55(a) or the microbial standard of § 112.55(b), when an agricultural tea additive is used, it can result in a final product that contains human pathogens capable of causing serious adverse health consequences or death (Ref. 174) (Ref. 175) if used as a soil amendment in growing covered produce without restriction. In these same studies, when agricultural teas were produced using the same compost feedstocks without the addition of agricultural tea additives, pathogens were undetectable in the final product.

The scientific body of evidence is inconclusive as to what component or components (e.g., soluble carbon content) in agricultural tea additives may be contributing to the propagation of human pathogens during the production of agricultural teas, so it is difficult for FDA to ascertain the significance between 0.2 percent (vol:vol) molasses that did not support growth in the Duffy et al. 2004 study and 0.5 percent (vol:vol) of Soil Soup Additive (contains molasses) in the Ingram study that supported pathogen growth. It should be noted that Kannangara (2006) noticed a population increase in generic *E. coli* during aerated agricultural tea production amended with only 0.01 percent molasses, but did document a reduction (but not elimination) of generic *E. coli* in response to the addition of carrot juice extract used as an agricultural tea additive. We continue to believe the preponderance of evidence supports the conclusion that the use of an agricultural tea additive will increase the likelihood of pathogen growth in an agricultural tea (of animal origin). However, FDA supports innovation and

encourages development and scientific evaluation of agricultural tea additives that can reliably suppress the growth of, or eliminate, foodborne pathogens in agricultural tea. Should consistently safe production and use of agricultural tea additives become established, we will consider appropriate next steps, including possibly revisiting these requirements.

(Comment 277) Several comments disagree with the proposed distinctions related to treated and untreated biological soil amendments. These commenters believe that, as proposed, various types of biological soil amendments of animal origin (such as static compost, vermicompost, compost teas with additives such as molasses or sea kelp, and compost that is produced outside of the proposed time and temperature requirements) would be treated as raw manure even though, in the view of these commenters, such biological soil amendments may not pose the same risks as raw manure.

(Response) We disagree that our requirements would result in all the listed biological soil amendments of animal origin being subject to the same requirements as raw manure. Section 112.51 distinguishes between ‘treated’ and ‘untreated’ biological soil amendments of animal origin, and § 112.56 describes the application restrictions that apply to biological soil amendments of animal origin depending on whether they are treated or untreated (and if treated, depending on which level of treatment they received). The provisions of § 112.51 refer to the treatment processes of § 112.54, which in turn refers to the microbial standard provisions of § 112.55. We have revised the text throughout § 112.54 to refer to ‘biological process[es],’ and we use ‘composting’ as an example of a

biological process. Thus, under the revised options for treatment processes in § 112.54, this rule classifies the end products of any scientifically valid controlled biological processes that have been validated to satisfy the microbial standard in § 112.55(a) or (b) as ‘‘treated’’ biological soil amendments of animal origin (provided there is no other reason to consider them untreated under § 112.51(b), such as contamination after treatment). Therefore, stabilized compost produced by static composting processes, end products of vermicomposting processes, or stabilized compost produced through time/temperature combinations other than those described in § 112.54(c)(1) and (2) may be considered ‘‘treated’’ provided that they meet the requirements of § 112.54, including satisfying one of the microbial standards in § 112.55. On the other hand, raw manure must be regarded as ‘‘untreated’’ under § 112.51. An agricultural tea made with biological materials of animal origin that contains an agricultural tea additive (such as molasses or sea kelp) is considered ‘‘untreated’’ under § 112.51(b)(5) due to the heightened risk presented by the use of such additives (see also Comment 44), and is therefore in the same category as raw manure with regard to application restrictions in § 112.56.

C. Handling, Conveying, and Storing Biological Soil Amendments of Animal Origin (§ 112.52)

As proposed, § 112.52 would establish requirements for handling, conveying and storing soil amendments of animal origin. In Table 15, we describe the codified provisions of § 112.52 and any changes we made to those provisions in the final rule. Comments specific to § 112.52 follow the table.

TABLE 15—DESCRIPTION OF REVISIONS TO § 112.52

Proposed provision	Proposed language	Final revisions, if any
§ 112.52(a)	You must handle, convey, and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems.	Revised to add other soil amendments and to clarify that drip fertigation with agricultural teas that are biological soil amendments of animal origin is permitted in compliance with other requirements of this rule.
§ 112.52(b)	You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.	No change.
§ 112.52(c)	You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated.	Revised.

(Comment 278) One comment states that many farms store animal manure purchased from animal production facilities for several months before application. The comment maintains that this practice can threaten produce safety through potential contamination of water and air, just like animal manure stored on adjacent animal production facilities.

(Response) FDA agrees that stored animal manure can be a source of contamination. Section 112.52(a) requires biological soil amendments of animal origin to be handled, conveyed, and stored in a manner and location such that they do not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments.

(Comment 279) One comment interprets § 112.52(a) as forbidding drip “fertigation” with biological soil amendments of animal origin, even if the material is not reasonably likely to contact covered produce. The commenter requests that FDA clarify the provision by adopting the following edit: “. . . such that it does not become a potential source of contamination to . . . water distribution systems, if such contamination may reasonably be likely

to result in contamination of covered produce.”

(Response) We did not intend for § 112.52(a) to forbid drip fertigation with biological soil amendments of animal origin. Biological soil amendments of animal origin may be used in water distribution systems in accordance with § 112.56 and their status as “treated” or “untreated” and, if “treated”, to what standard. If “untreated” or “treated” to the standard in § 112.55(b), then the biological soil amendment of animal origin must not contact covered produce at application and contact later must be minimized. If the biological soil amendment of animal origin is “treated” to the standard in § 112.55(a), then there are no restrictions on use. We are revising § 112.52(a) to add a statement that agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(Comment 280) One comment is concerned that the proposed language of § 112.52(c) does not specify the basis for the knowledge or suspicion that a soil amendment has become contaminated. The commenter recommends FDA make the following change to § 112.52(c) (additions underlined): “(c) You must handle, convey, and store any biological

soil amendment of animal origin that you know *or have reason to believe may have become contaminated* as if it was untreated.”

(Response) FDA is making this change. FDA agrees that you should be required to regard as “untreated” under § 112.51 any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated, and not only biological soil amendments of animal origin that have actually become contaminated. This revision makes clear that covered farms must regard biological soil amendments of animal origin as untreated as soon as they have information giving them reason to believe contamination of the biological soil amendment may have occurred.

D. Prohibitions Regarding Use of Human Waste (§ 112.53)

In § 112.53 we proposed to prohibit the use of human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. In Table 16, we describe the codified provisions of § 112.53 and any changes we made to those provisions in the final rule. Comments specific to § 112.53 follow the table.

TABLE 16—DESCRIPTION OF REVISIONS TO § 112.53

Proposed provision	Proposed language	Final revisions, if any
§ 112.53	You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.	No change.

(Comment 281) Some comments express concern that FDA’s proposed rule allowed the use of untreated human waste and biosolids for the production of covered produce, even if users were following the EPA requirements in 40 CFR part 503, subpart D, or equivalent regulatory requirements. Comments express particular concern that the rule would allow foreign producers to use human waste as a soil amendment, even though their use may not meet EPA standards, and some comments noted that farms in some countries have historically used human waste in growing produce. Many commenters request that FDA prohibit the use of human waste in the production of covered produce. Conversely, at least one comment requests that FDA allow for the use and application of human waste in the growing of covered produce.

(Response) Section 112.53 clearly states that the use of human waste is prohibited for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. In consultation with EPA, FDA has concluded that adherence to 40 CFR part 503 remains an appropriate approach to the use of biosolids for the growing of covered produce. We continue to believe that these requirements are appropriately protective of public health.

With regard to concerns about ensuring that the provisions are followed for imported produce, we note that § 112.53 refers to “equivalent regulatory requirements” to provide for the possibility that other competent authorities have established such requirements in other jurisdictions. In addition, please see the response to

Comment 50 regarding the provisions of the FSVP regulation. We also note that the use of human waste for food production has been addressed by the Codex (Ref. 22). FDA plans to conduct outreach activities regarding the produce safety rule to help farms understand how to comply (see section XXII for additional information).

(Comment 282) Several comments object to referencing the requirements in 40 CFR part 503. A few comments argue that part 503 is out of date. One comment points to a National Academy of Sciences review of part 503, and argues that the requirements for using human waste for growing covered produce should be strengthened in accordance with this NAS report, and should use current risk assessment methods. One comment questions the validity of the application intervals in part 503 and expresses concerns about

the environmental implications of applying biosolids to agricultural land. (Response) FDA, in consultation with EPA, has determined that 40 CFR part 503 remains the most appropriate approach to safe use of sewage sludge biosolids on land involved in the production of covered produce. We point out that the NAS 2002 report (Ref. 177) noted that there is “. . . no documented evidence to indicate that part 503 has failed to protect public health”; that EPA responded to the NAS review with a 14-point action plan, which it is carrying out; and that under section 405(d)(2)(C) of the CWA, EPA is required to publish a biennial review of part 503 (Ref. 178). FDA concludes that the provisions of 40 CFR part 503 are appropriate standards for protecting public health with respect to the use of sewage sludge biosolids in growing covered produce. (Comment 283) A comment requests that source separated human urine be classified separately from sewage sludge biosolids, thus allowing it to be used in

growing covered produce. The comment maintains that human urine is sterile, contains bioavailable nutrients, and is an otherwise wasted resource that could be important to agriculture and is used in other countries as a fertilizer. (Response) Urine is not covered by 40 CFR part 503 and, therefore, as human waste, § 112.53 prohibits its use in growing covered produce. The commenter did not provide data or information from which we could conclude that source separated human urine should be allowed to be used in growing covered produce, and therefore we are not making this change. (Comment 284) One comment argues that even if human sewage has been adequately treated to be free of pathogens, it would still be susceptible to recontamination. This comment suggests that recontamination should be explicitly addressed in this rule. (Response) FDA’s requirement is that sewage sludge biosolids be used in accordance with 40 CFR part 503. Under those requirements if sewage sludge

biosolids that met the standards to be Class A biosolids have human waste added to them, they become Class B biosolids and need to be used in accordance with the requirements for Class B biosolids. However, whether they are Class A or Class B sewage sludge biosolids, they may be used in accordance with 40 CFR part 503. Therefore, we do not believe that recontamination needs to be explicitly addressed in our rule because it is already addressed in 40 CFR part 503 in the various standards that apply to sewage sludge biosolids. *E. Treatment Processes (§ 112.54)* Section § 112.54 describes acceptable processes for the treatment of biological soil amendments of animal origin to be used for growing covered produce. In Table 17, we describe the codified provisions of § 112.54 and any changes we made to those provisions in the final rule. Comments specific to § 112.54 follow the table.

TABLE 17—DESCRIPTION OF REVISIONS TO § 112.54

Proposed provision	Proposed language	Final revisions, if any
§ 112.54	Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, providing that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 122.56:	No change.
§ 112.54(a)	A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy the microbial standard in § 112.55(a) for <i>L. monocytogenes</i> , <i>Salmonella</i> spp., and <i>E. coli</i> O157:H7;	Revised to add biological processes and replace “demonstrated” with “validated.”
§ 112.54(b)	A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> and fecal coliforms; or	Revised to add biological processes and replace “demonstrated” with “validated.”
§ 112.54(c)	A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> and fecal coliforms. Scientifically valid controlled composting processes include:	First sentence eliminated because biological processes meeting the § 112.55(b) standard are now included in revised § 112.54(b). Second sentence is now part of § 112.54(b) and has been revised to refer again to the microbial standard in § 112.55(b).
§ 112.54(c)(1)	Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation;	Renumbered to § 112.54(b)(1) as a conforming change to the combination of § 112.54(b) and (c); clarified that “3 days” is consecutive; and deleted “which includes proper insulation” as it is covered by adequate curing.
§ 112.54(c)(2)	Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or	Renumbered to § 112.54(b)(2) as a conforming change to the combination of § 112.54(b) and (c); revised to state that “15 days” does not have to be consecutive; deleted “which includes proper insulation” as it is covered by adequate curing; and deleted “or” at end because § 112.54(c)(3) is deleted.
§ 112.54(c)(3)	Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative has been demonstrated to satisfy the microbial standard in § 112.55(b).	Eliminated as not necessary. All scientifically valid, controlled biological treatment processes, including composting, that meet the microbial standards of § 112.55 are allowable under revised § 112.54(a) and (b), making the allowance for alternative processes unnecessary.

(Comment 285) Some comments states that the rule inappropriately treats use of physically and chemically treated soil amendments as less risky than soil amendments treated by composting. One comment proposes an alternative approach to regulating stabilized compost, including an additional process to be added for stabilized compost that 1) meets the time and temperature requirements specified in § 112.54(b)(1) and (b)(2); and 2) has been demonstrated to satisfy the microbial standard in § 112.55(a).

(Response) FDA agrees that flexibility needs to be added to the provisions of § 112.54 to broaden the allowable methods for producing stabilized compost that may be regarded as “treated” under § 112.51 and also to allow farms to regard as “treated” biological soil amendments of animal origin processed using biological processes other than composting, such as vermicomposting, provided that such processes meet the microbial standards in either § 112.55(a) or (b). We also recognize that the structure of proposed § 112.54 should be revised to better reflect the application requirements in § 112.56, which we proposed to change in our supplemental notice without making conforming changes to § 112.54. Thus, we are adding options for biological treatment processes (including, but not limited to, composting) in § 112.54(a); and collapsing § 112.54(b) and (c) to allow for a “scientifically valid, controlled biological (e.g., composting), chemical, or physical process, or combinations thereof, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms.” Importantly, because these changes retain the requirements that all such treatment processes be demonstrated to satisfy either the microbial standards in § 112.55(a) or (b), we believe these changes address the comments, make these provisions as flexible as possible for farms, and provide sufficient public health protection.

(Comment 286) A comment recommends that subpart F, in reference to biological soil amendment treatment processes, change the term “scientifically valid” to “scientifically validated.” The comment recommends this revision to clarify the need for validation of the treatment method(s) used to treat biological soil amendments of animal origin to meet the microbial standards of § 112.55. The comment notes that the need for validation is discussed in the preamble, but contends that it should also be explicitly stated in

the codified so that there is no confusion.

(Response) We do not agree that we should replace the term “scientifically valid” in this subpart with the term “scientifically validated,” as these terms have different meanings. However, a biological soil amendment of animal origin does not meet the definition of “treated” per this subpart unless the treatment process is scientifically valid and controlled and has been demonstrated (i.e., validated) to meet the applicable microbial standards of § 112.55. A treatment process that has been demonstrated to satisfy the microbial standards of § 112.55 has been validated to meet those microbial standards. Therefore, because this comment suggested that there may be some confusion on this, we are revising §§ 112.54(a) and (b) to replace the word “demonstrated” with the word “validated.” We note that consistent with language in other regulations (see the PCHF regulation and 21 CFR part 111), we use the term “scientifically valid” in this rule to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research.

(Comment 287) A comment requests that FDA add the following language to § 112.54 “. . . provided that the resulting biological soil amendments meet the microbial standards for the treatment processes as stated in § 112.55 and are applied in accordance with the applicable requirements of § 112.56...”

(Response) It is not necessary to add this language to the introductory text of § 112.54 as the requirements to meet the microbial standards in § 112.55(a) or (b) are contained within the provisions of § 112.54(a)–(b). To add the language as suggested by the comment would be duplicative.

(Comment 288) Comments request that, in order to ensure that whatever scientifically valid controlled process is chosen by a farm (or their supplier) to comply with proposed § 112.54 has been effectively followed, FDA add a required “condition-specific” verification as a requirement in the language of the regulation, which would include appropriate microbial testing using scientifically valid sampling techniques that include timing and location parameters, to establish that the appropriate microbial results stated in the proposed § 112.55 have been achieved.

(Response) FDA is not making this change. As discussed in the 2013 proposed rule (78 FR 3504 at 3578), FDA is not requiring microbial testing of

treated biological soil amendments of animal origin to ensure that they meet the relevant microbial standards. Rather, we have provided the microbial standards against which treatment processes must be validated. Proper validation to show that a process satisfies the microbial standards of § 112.55 needs to include specific process variables, and the person applying the treatment process will need to monitor the physical parameters of the process (e.g., the temperature of a compost pile) to ensure they meet the conditions under which the process was validated. See also our response to Comment 286.

(Comment 289) One comment suggests there may be a higher risk of microbial contamination and a greater threat to public health associated with the use of commercial compost than with compost made on-farm.

(Response) FDA is not aware of a greater threat to public health from the use of commercial compost than compost made on individual farms. The comment did not provide additional information in support of this assertion.

(Comment 290) One comment urges FDA to issue a regulation specifically for the use of manure from animal production facilities. The comment states that FDA should require animal production facilities that sell or give manure to produce farms to take specific steps to minimize contamination, including by harmful pathogens, in their animal waste.

(Response) FDA declines this request. While we recognize the risk presented by the use of manure in growing of covered produce, manure comes from many sources, including from produce farms on which it is used. We believe that it is appropriate to focus this rule’s requirements regarding biological soil amendments of animal origin on the operations that are using those materials in the growing of covered produce to minimize the risk presented by such uses.

(Comment 291) Several comments request clarification on whether FDA requires testing of individual feedstocks used to prepare an agricultural tea, at intervals during the brewing process, or the final agricultural tea product, with attention to the fact that by the time the tea is applied, the test will no longer be representative of the original sample. One comment notes that if an agricultural tea is prepared from a stabilized compost feedstock that meets the microbiological standard of § 112.55(b), then the remaining populations of these microorganisms have the potential to experience rapid population growth. The commenter also notes that the microbiological criterion

set in § 112.55 are based on a dry weight (MPN/gram) basis, which would not be representative of an agricultural tea, in which the solid fraction is mostly removed prior to application.

(Response) Like other biological soil amendments of animal origin, FDA is not requiring that agricultural teas (of animal origin) be tested. Rather, for an agricultural tea (of animal origin) to be considered “treated” for the purposes of § 112.51, the components used to make the tea be treated via a process described in § 112.54 (a) or (b) to meet the microbial standards of § 112.55(a) or (b). If a scientifically valid controlled process has been followed, there is no need to test the tea to consider it “treated.” Agricultural teas (of animal origin) that are not treated to such standards, or that contain agricultural tea additives or are made with water not meeting the requirements in § 112.51(a), must be considered “untreated” for purposes of § 112.51. With regard to the potential rapid growth of pathogens in agricultural teas that meet the microbial standards of § 112.55, we note that agricultural teas cannot contain agricultural tea additives if they are to be considered “treated” for purposes of § 112.51, which are the primary contributing factor to rapid growth of microflora in teas (Ref. 174). Finally, we agree that the proposed microbial standards in § 112.55 were established on a dry weight basis, which would not be appropriate for agricultural teas. Therefore, we have modified § 112.55 to add a liquid weight basis for sampling (for use in validation).

(Comment 292) At least one comment suggests that stabilized compost be regulated according to a two-tier approach, whereby a farm could use a zero day application interval if the stabilized compost meets stringent criteria, but would have a 45-day interval for stabilized compost meeting general safety standards and being used on certain covered crops.

(Response) FDA originally proposed a two-tiered strategy for the application interval for use of compost (78 FR 3504). However, in the supplemental notice, FDA proposed that all stabilized compost would have a zero day application interval (see discussion in 79 FR 58434). We are finalizing the provision in § 112.56 for a zero-day interval for stabilized compost. Depending on the microbial standards that the stabilized compost meets (§ 112.55(a) or (b)), the allowable application methods differ (compare § 112.56(a)(3) and (a)(2)).

(Comment 293) A comment requests that FDA focus on compost maturity at the time of field application and

requested that FDA provide a specific definition of “curing” along with guidance that would help farms ensure adequate pathogen reduction in stabilized compost, prior to field application. Several other comments also support requiring a curing stage in composting for purposes of considering a biological soil amendment of animal origin to be “treated,” stating that heating manure during the composting process uniformly and to a sufficient temperature through one phase of microbial activity is only part of the pathogen-control process. Other comments indicate that curing must be done in a manner that prevents cross-contamination and which may include proper insulation. Some comments express confusion about insulation, including the type (some comments suggested the use of a plastic tarp) and the timing of insulation (many comments suggested compost needs to be turned many times during the compost curing process). These comments suggest such use of insulation would be neither economically feasible nor operationally practical. Another commenter suggests that the specific requirements for use of insulating material on compost piles during the curing process are impractical for small-farm methods of composting. Some comments indicate that the proposed requirement for insulated curing of compost in § 112.54 (b)(1) and (b)(2) (originally proposed as § 112.54(c)(1) and (c)(2)) is overly burdensome and not necessary for all approaches to the composting process.

(Response) Curing is an important part of any type of composting process (*i.e.*, static or turned), and reduces pathogens if performed in an adequate manner. The definition of “composting” in § 112.3(c) reflects that curing is an integral part of the process: “Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.” Curing involves the complete decomposition of cellulose and lignin in feedstock such that it cannot be further broken down by microbial metabolism. Curing may or may not need to include insulation to be adequate to reduce pathogens to a specified level, depending on environmental conditions. For example, insulation may be needed to ensure that compost temperatures do not drop too fast;

proper curing involves a gradual temperature decline. Thus, we are clarifying the definition of “curing” by adding a statement that “[c]uring may or may not involve insulation, depending on environmental conditions.” When there is a need to protect compost from external temperature changes, a plastic tarp would typically not be expected to provide effective insulation. Materials such as a layer of straw, hay, or stabilized compost are effective for use in insulation.

We also acknowledge that, for static composting, insulation may also be used during the first stage of composting as well as during the curing stage. We have made a change to the definition of “static composting” to reflect this (see Comment 107) such that the definition reads, in relevant part, “[s]tatic composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning.

As noted previously, curing may or may not involve insulation. We are removing the requirements for proper insulation in § 112.54(b)(1) and (b)(2) because these provisions are examples of scientifically valid controlled biological (*e.g.*, composting) processes that meet the microbial standard in § 112.55(b). We agree that insulation may not be necessary to meet the microbial standard of § 112.55(b) under all circumstances and so we have removed the reference to insulation in § 112.54(b)(1) and (b)(2). However, those employing the static and turned composting processes described in § 112.54(b)(1) and (b)(2) will need to make a determination whether insulation is needed as part of the curing phase to achieve stabilized compost.

(Comment 294) A comment requests clarification regarding whether animal manure, or another biological soil amendment of animal origin, that is passively composted (that is, simply left in place without turning or monitoring) for nine months or more, would be considered “untreated” or “treated” for purposes of § 112.51 and associated application restrictions in § 112.56. The commenter suggests that it would be reasonable to consider manure to be “treated” if it has been aged for a period equal to the proposed application interval for untreated biological soil amendments of animal origin.

(Response) Processes that meet the requirements of § 112.54 must be scientifically valid, controlled processes that have been validated to meet the

microbial standards in either § 112.55(a) or (b). We are not aware of any data or information supporting a conclusion that “passive composting” as described by the commenter (stockpiling or aging manure) meets the microbial standards in either § 112.55(a) or (b).

(Comment 295) One comment asks for a revision to the example process provided for “turned composting” in § 112.54(b)(2) (originally proposed as § 112.54(c)(2)) to read, “Composting that maintains a minimum average temperature of 131 °F (55 °C) or higher for 15 days or longer and is followed by adequate curing, storage and handling practices. During the period when the compost is maintained at 131 °F (55 °C) or higher, there shall be a minimum of five turnings of the windrow with a minimum of 3 days between turnings. The 15 or more days at or above 131 °F (55 °C) do not have to be continuous.”

(Response) We believe it would be appropriate to make some, but not all, of the changes to the example process for “turned composting” in § 112.54(b)(2) suggested by the commenter. The distinctions between our language and that suggested by the comment are: (1) The commenter’s additional mention of storage and handling; (2) the commenter’s suggestion of requiring a minimum of 3 days between turnings; and (3) the commenter’s suggestion that the 15 days need not be continuous.

With respect to storage and handling, the rule already covers these topics sufficiently in § 112.52, and those requirements apply equally to all processes used under the rule, including those described in § 112.54(b)(2).

With respect to the commenter’s suggestion of requiring a minimum of 3 days between turnings, we are not aware of science sufficient to support a conclusion that this is required to meet the microbial standard in § 112.55(b). Every compost pile has a unique size, shape and feedstock composition, all of which affects how the pile will generate and maintain heat. For example, many compost windrows will reach 55 °C relatively quickly, at which time the operator will begin monitoring the ‘degree days’ above this temperature toward meeting the fifteen days of exposure to 55 °C per § 112.54(b)(2). To continue this ‘thermophilic phase’ of the process, the operator will typically manage both oxygen and influx of new nutrient materials (via turning), and in some situations even moisture, to maintain the 55 °C temperature for a total of 15 days to rely on the option in § 112.54(b)(2). Turning the piles also serves the purpose of maximizing the exposure of as much of the compost

material as possible to the elevated temperatures. To ensure that as much of the compost as possible is exposed to the 55 °C temperature, to rely on the option in § 112.54(b)(2), we are requiring a minimum of 5 turnings but we are not specifying a timeframe for the turns. The timing will be driven by the size, shape and feedstock composition. It is our understanding that, in order to maintain a compost temperature of at least 55 °C for the required 15 days, the operator will likely need to turn the windrow approximately three times per week (within the first two weeks) and then decrease the frequency to once or twice per week for the following month(s) as the compost matures.

As discussed in response to Comment 293, § 112.54(b)(1) and (b)(2) provide two example processes that farms may use to satisfy the microbial standard in § 112.55(b), but these are not the only means of achieving adequate composting to meet the microbial standard in § 112.55(b). Thus, we do not discourage farms from using processes that allow a minimum of 3 days between turnings if those processes are validated to meet the microbial standards in § 112.55(a) or (b), but we are not revising our example process in § 112.54(b)(2) because we do not believe it is necessary.

With respect to the commenter’s suggestion that the 15 days need not be continuous, we agree that the 15 days at 55 °C need not be continuous and, given the nature of turned composting, it is unlikely that they would be continuous (Ref. 179). We are revising § 112.54(b)(2) to indicate that the 15 days at 55 °C need not be consecutive. For clarity, we are also revising § 112.54(b)(1) to indicate that the 3 days at 55 °C is consecutive. For static aerated composting, 3 consecutive days at or above 55 °C ensures that the microbial standard in § 112.55(b) is achieved, considering the expected die-off rates of various classes of thermophilic and thermotolerant pathogens (Ref. 180).

(Comment 296) One comment asks for confirmation that covered produce grown using biological soil amendments of animal origin containing pathogens at or below the microbial standards set forth in § 112.55(a) and (b) are considered “safe.”

(Response) In this regulation, FDA is establishing those standards that we conclude minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that are reasonably necessary to prevent the introduction of hazards into produce, and to provide reasonable assurances that process is not

adulterated under section 402 of the FD&C Act. We do not expect that compliance with these standards will eliminate all occurrences of hazards in covered produce.

(Comment 297) One comment recommends that rather than focusing on process standards, which the commenter criticizes as ambiguous, the rule should instead require that stabilized compost be tested for indicator microbial species to determine appropriate application restrictions.

(Response) FDA disagrees. We have established an approach where we define “treated” and “untreated” biological soil amendments of animal origin through the application of a scientifically valid, controlled process (described in § 112.54) that has been validated to satisfy the microbial standards of either § 112.55(a) or (b). We do not agree that such process standards are ambiguous. See discussions in Comment 286 and Comment 288. Moreover, we conclude that our approach is more protective of public health than relying on lot testing for indicator species. Appropriate indicator species in biological soil amendments of animal origin may be difficult to identify, and routine pathogen testing is not an effective indicator of the presence or absence of pathogens. In addition, such testing could require multiple target organisms, which could be very costly.

(Comment 298) Some comments request that accepted treatment processes be backed by scientific evidence that they will protect public health.

(Response) As discussed in the 2013 proposed rule (78 FR 3580–1), the microbial standards set out in § 112.55 are protective of public health. Treatments for biological soil amendments of animal origin must be scientifically valid, controlled processes that have been validated to satisfy the relevant microbial standard in § 112.55(a) or (b). In § 112.54(b)(1) and (b)(2) we have described processes for static and turned composting that have been previously validated to meet the standard in § 112.55(b) for Salmonella and fecal coliforms when done properly.

(Comment 299) Some comments request that FDA require suppliers to provide a guarantee to purchasers that a biological soil amendment the supplier claims is not of animal origin indeed not include any components of animal origin.

(Response) FDA declines to require provision of such guarantees. Soil amendments that do not contain components of animal origin are not subject to the requirements in subpart F.

This rule does not require covered farms to receive such guarantees to use soil amendments that are not of animal origin other than as provided by subpart F. However, covered farms are responsible for their compliance with the rule, and we do not discourage farms from requesting such guarantees

from their suppliers, which seems likely to be a prudent practice.

F. Microbial Standards Applicable to the Treatment Processes in § 112.54 (§ 112.55)

Section 112.55 establishes microbial standards applicable to the treatment

processes in § 112.54. In Table 18, we describe the codified provisions of § 112.55 and any changes we made to those provisions in the final rule. Comments specific to § 112.55 follow the table.

TABLE 18—DESCRIPTION OF REVISIONS TO § 112.55

Proposed provision	Proposed language	Final revisions, if any
§ 112.55	The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.	No change.
§ 112.55(a)	For <i>L. monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7, the relevant standards [are those in (a)(1)–(a)(3)] or;	No change.
§ 112.55(a)(1)	<i>L. monocytogenes</i> . . . Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion.	Revised to add liquid sampling.
§ 112.55(a)(2)	<i>Salmonella</i> species . . . Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis).	Revised to add liquid sampling and indicate that it is a ‘non-detect’ standard.
§ 112.55(a)(3)	<i>E. coli</i> O157:H7 . . . Less than 0.3 MPN per 1 gram analytical portion.	Revised to add liquid sampling and indicate that it is a ‘non-detect’ standard.
§ 112.55(b)	Less than three MPN <i>Salmonella</i> species per four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).	Revised to add liquid sampling and indicate that the <i>Salmonella</i> method is a ‘non-detect’ standard.

(Comment 300) One comment suggests that should FDA consider end-use risk in establishing final microbial standards for treated biological soil amendments of animal origin. The comment pointed to Austrian ÖNORM standards for compost, which differ by end-use categories.

(Response) We believe we have appropriately considered end-use risk in establishing the microbial standards for treated biological soil amendments of animal origin. First, we note that this rule does not apply to end uses such as home gardening or growing crops other than covered produce. The end uses to which the requirements of subpart F apply are more limited than those in the Austrian standards noted in the comment. Second, we conclude that all treated biological soil amendments of animal origin must meet the standards in § 112.55(a) or (b), and those that meet the standards of § 112.55(b) must also be applied in accordance with the restrictions in § 112.56(a)(2). We also conclude that untreated biological soil amendments of animal origin must be applied in accordance with the restrictions in § 112.56(a)(1). See Comment 257 regarding our plans for application intervals for such biological soil amendments of animal origin.

(Comment 301) Some comments indicate a belief that the standards in

proposed § 112.55 are metrics for required microbial testing. The comments suggest the use of guidance documents, which can be more easily updated, in lieu of incorporating metrics in the provisions of the rule.

(Response) FDA is not requiring microbial testing of treated biological soil amendments of animal origin to ensure that they meet the relevant microbial standards. Rather, we have provided the microbial standards against which treatment processes must be validated. Proper validation to show that a process satisfies the microbial standards of § 112.55 needs to include specific process variables, and the person applying the treatment process will need to monitor the physical parameters of the process (e.g., the temperature of a compost pile) to ensure they meet the conditions under which the process was validated. See also our response to Comment 286. In §§ 112.54(b)(1) and (b)(2) we have also described processes for static and turned composting that have been previously validated to meet the standard in § 112.55(b) for *Salmonella* and fecal coliforms when done properly.

(Comment 302) One comment recommends FDA change the microbial standards for *Salmonella* spp. and *E. coli* O157:H7 in § 112.55(a) to

“negative” or less than detectable limit (<1/30 grams).

(Response) The microbial standards as proposed in § 112.55(a) represented “less than the detectable limit” for each pathogen, though only § 112.55(a)(1) was phrased as “not detected using a method that can detect . . .” We are revising the standards in §§ 112.55(a)(2) and (a)(3) and the *Salmonella* standard in 112.55(b) to provide a parallel structure. As revised, § 112.55(a)(2), (a)(3), and (b) read as set forth in the regulatory text of this rule.

G. Application Requirements and Minimum Application Intervals (§ 112.56)

Section 112.56 establishes application restrictions based on whether biological soil amendments of animal origin are treated or untreated; and for those biological soil amendments of animal origin that are treated, based on the level of treatment they received (with reference to the microbial standards in § 112.55). In Table 19, we describe the proposed codified provisions of § 112.56 (considering the 2013 proposed rule and the supplemental notice, taken together) and any changes we made to those provisions in the final rule. Comments specific to § 112.56 follow the tables.

TABLE 19—DESCRIPTION OF REVISIONS TO § 112.56(A)

Proposed provision	Proposed language	Final revisions, if any
§ 112.56(a)	Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph [table follows containing (1)–(4)].	Deleted “Except as provided in paragraph (b) of this section” as a conforming change to the deletion of (b) (made in the supplemental notice). Revised (a)(1)–(4) to (a)(1)–(3).

Proposed § 112.56(a)(1)–(4) was published at 78 FR 3504, January 16, 2013.

Final § 112.56(a)(1)–(3) is set forth in the regulatory text of this rule.

The revisions in final § 112.56(a)(1)–(3) consist of conforming amendments to match changes made in § 112.54 (including biological processes in both § 112.54(a) and (b), and collapsing § 112.54(b) and (c)); and to renumber proposed (a)(2) as (a)(3).

(Comment 303) Several comments request that FDA clarify the meanings of “does not contact,” and “minimizes contact.” Some comments suggest that the phrase “In a manner that does not contact covered produce during or after application” might be read to require that there is absolutely no possibility of contact of the soil amendment with the covered produce, and one comment suggested that such a requirement could never be met in light of the variety of activities performed on farms and the potential that dust from fields may contact covered produce. Another comment seeks clarification on whether the harvestable portion of underground crops would be considered to come into contact with the biological soil amendments of animal origin used on the soil.

(Response) FDA intends “does not contact” in § 112.56 to mean there is no intended or likely contact between the biological soil amendment of animal origin and covered produce during the relevant time period. For example, when an amendment is applied beneath a high tree crop that is not intentionally dropped to the ground for harvest, there would be no intended or likely contact either during or after application. We do not agree with the comment suggesting that a “does not contact” requirement could never realistically be met. We realize that there is always a chance that

some soil amendment could be present in dust such that it settles on covered produce; however, we do not believe at this time that this type of potential contact is significant enough to be considered intended or likely for purposes of § 112.56. However, we intend to include consideration of wind-blown contamination in our upcoming risk assessment on untreated biological soil amendments of animal origin (See discussion under Comment 257).

FDA intends “minimizes contact” to mean there is no intended contact between the biological soil amendment of animal origin and covered produce during the relevant time period, but some unintentional contact is likely due to incidental or environmental action. For example, a farm choosing to side-dress a leafy green crop with a soil amendment in the alley between crop rows could apply the amendment in a manner that does not contact the covered produce at application. However, it would be likely that some portion of the amendment would migrate to the area where the crop is located. This post-application contact would not be intended, but it is likely. Conversely, if the farm were to apply the soil amendment in the previous example not in the alley between crop rows but instead in a broadcast manner, it could be reasonably expected that there would be widespread contact between the amendment and the harvestable portion of the leafy greens both during and after application, and that such contact is both intentional and likely.

A root crop grown in soil that has been amended with biological soil amendments of animal origin is both intended and likely to be in contact with those soil amendments both during and after application.

We will consider addressing this topic further in our forthcoming implementation guidance.

(Comment 304) Some comments state that use of raw manure should be subject to additional application restrictions beyond those in § 112.56(a)(1)(i) and (a)(1)(ii) because there is risk even if the manure is applied in such a way that there is no intended or likely contact with covered produce, noting that there will always be opportunities for indirect contact from forces such as wind and dust. These comments provide several references to support their conclusion that raw manure poses a significant risk to covered produce.

(Response) As discussed in response to Comment 257, FDA is pursuing a risk assessment and research agenda to supplement the science on an appropriate application-to-harvest interval for raw manure. FDA will consider the information provided by these comments during future risk assessment and research efforts. We agree that raw manure can be an important route of contamination for covered produce and encourage farms to consider use of stabilized compost as an alternative to raw manure.

H. Records Related to Biological Soil Amendments of Animal Origin (§ 112.60)

Section 112.60 requires that you establish and keep records for subpart F in accordance with the requirements of subpart O of this part and that you establish and keep certain records. In Table 20, we describe the codified provisions of § 112.60 and any changes we made to those provisions in the final rule. Comments specific to § 112.60 follow the table.

TABLE 20—DESCRIPTION OF REVISIONS TO § 112.60

Proposed provision	Proposed language	Final revisions, if any
§ 112.60(a)	You must establish and keep records required under this subpart F in accordance with the requirements of subpart O of this part.	No change.

TABLE 20—DESCRIPTION OF REVISIONS TO § 112.60—Continued

Proposed provision	Proposed language	Final revisions, if any
§ 112.60(b)	For any biological soil amendment of animal origin you use, you must establish and keep the following records:	No change.
§ 112.60(b)(1)	For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that: <ul style="list-style-type: none"> (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; (ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and (iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin 	Revision to eliminate proposed (1)(ii) and as a conforming change to renumber (1)(iii) to (1)(ii) and to require such documentation at least annually.
§ 112.60(b)(2)	For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved.	No change.
§ 112.60(b)(3)	Scientific data or information you rely on to support a process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3).	Elimination of § 112.60(b)(3) as a conforming change since § 112.54(c)(3) has been deleted.

(Comment 305) One comment requests clarification on what compost suppliers should document to ensure covered farms could rely on such documentation to satisfy the rule and on documentation needed when using alternative composting procedures. Another comment asks us to clarify the requirements for records related to process verification in composting.

(Response) With regard to documentation that a farm receives from a third party, such as a stabilized compost supplier, we have revised the proposed requirements. We are sensitive to requests that we minimize the burden of testing. Therefore, we are eliminating proposed § 112.60(b)(1)(ii) that would have required documentation of testing of treated biological soil amendments of animal origin received from third parties to verify that the treatment process satisfies the applicable microbial standard in § 112.55 and the results of the periodic testing. We consider such periodic verification testing to be a best practice, but we conclude it is not necessary to mandate that farms maintain documentation of such testing performed by their suppliers. We are requiring in § 112.60(b)(1)(i) that, with respect to treated biological soil amendments of animal origin received from a third party, covered farms must maintain documentation demonstrating that the process used to treat the biological soil

amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring. Parameters will be process specific and may include, for example, time/temperature, moisture content, and pH. We are also renumbering proposed § 112.60(b)(1)(iii) to § 112.60(b)(1)(ii) and maintaining the requirement, as proposed, that with respect to treated biological soil amendments of animal origin received from a third party, covered farms must maintain documentation that the biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

Regarding documentation that a farm producing its own treated biological soil amendment of animal origin must have, in accordance with § 112.60(b)(2) a farm must have documentation that process controls (for example, time, temperature and turnings) were achieved. As a conforming change to the elimination of § 112.54(c)(3), we are eliminating proposed § 112.60(b)(3) which would have required records documenting the scientific data or information relied on to support any alternative composting process used to treat biological soil amendments of animal origin in accordance with § 112.54(c)(3).

(Comment 306) Several comments agree with FDA's decision to require certain documentation for any treated biological soil amendment of animal origin received from a third party. These comments stated this was consistent with established industry programs. Other commenters suggest that requiring certificates of conformance will be economically burdensome to compost suppliers, and requested clarification on how often such documentation would need to be obtained from a supplier.

(Response) FDA agrees that documentation, meeting the requirements in § 112.60(b)(1) should be required for a treated biological soil amendment of animal origin that you receive from a third party. Note that FDA proposes "such as a Certificate of Conformance" in the codified language only to serve as one possible example of adequate documentation. Any form of documentation is acceptable provided that it includes the information required in § 112.60(b)(1); it need not be named a "Certificate of Conformance." We disagree with the comment suggesting that such documentation is economically burdensome as we understand that such documentation is already frequently provided and is consistent with industry standards. Documentation must be obtained from third-party suppliers at least annually. We are adding the annual requirement to the codified in § 112.60(b)(1).

(Comment 307) Some comments suggest that, in order to best protect consumers from the risk of pathogens, FDA should require adequate recordkeeping for application intervals for all biological soil amendments of animal origin, whether treated or untreated, and without regard to whether produce contacts the soil.

(Response) FDA agrees that robust recordkeeping is a best practice. However, FDA disagrees that it is reasonably necessary to require covered farms to maintain records of dates of application and harvest when they use biological soil amendments of animal origin that have a required application interval of zero days as described in § 112.56, which at this time includes all biological soil amendments of animal origin. Should FDA establish application intervals greater than zero days for any uses of biological soil amendments of animal origin at a later date, we will also establish appropriate recordkeeping requirements related to those intervals. See Comment 257 regarding our plans on this topic.

(Comment 308) One comment states that FDA should require farms to document the particular fields on which biological soil amendments of animal origin received from a supplier are applied. This comment states that such a requirement could help facilitate traceback investigations if problems are identified, and may help limit the scope of a recall or product withdrawal.

(Response) While we agree that this information could be useful in some very limited circumstances, we do not agree that it is reasonably necessary to establish such a requirement to minimize the risk of serious adverse health consequences or death, to prevent the introduction of hazards into or onto produce, or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We will consider addressing this topic in guidance.

I. Other Comments

(Comment 309) Several comments address our request regarding how to

classify spent mushroom mulch (growth media already used in the production of mushrooms for subsequent use as a biological soil amendment of animal origin in the growing of other covered produce). Some comments argue that spent mushroom mulch should not be defined as a biological soil amendment of animal origin regardless of the contents of its feedstock because it is processed with a steam treatment after the mushrooms are harvested and it originally met the microbial standards of § 112.55(a) prior to use in growing mushrooms. These comments argue that spent mushroom mulch should have no restrictions on its use. On the other hand, many comments agree with FDA's tentative conclusion that if the spent mushroom mulch has been subject to a treatment process which met the microbial standard in § 112.55(a), it would still be considered a "treated" biological soil amendment after use for growing mushrooms and therefore available for use as "treated" in growing any covered produce commodity without any intervening treatment unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness.

(Response) FDA disagrees with the commenters that argued that spent mushroom mulches or other spent growth media should not be defined as biological soil amendments of animal origin, when it was defined as such before it was used. We conclude that if a substrate such as spent mushroom mulch previously met the requirements to be considered a "treated" biological soil amendment of animal origin under § 112.51, then it retains that status after use as a growth media, unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness.

XV. Subpart I—Comments on Domesticated and Wild Animals

In subpart I of proposed part 112, we proposed science-based minimum standards that are directed to

domesticated and wild animals. As proposed, subpart I included standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. We requested comment on all provisions in subpart I, including specifically on the scope of the subpart's proposed applicability, including the meaning of the phrase "under the circumstances" and our tentative conclusion that crops that grow completely underground would not be subject to the proposed requirements of subpart I. We also requested comment on the interactions of the proposed provisions of subpart I with the NOP.

In addition, in the supplemental notice, taking into account comments on the 2013 proposed rule, we proposed § 112.84 to state that part 112 does not authorize or require covered farms to take certain actions. We asked for comment on our current thinking, including on proposed § 112.84 (79 FR 58434 at 58463–58464).

We solicited additional comments on the potential impact of the proposed produce safety rule on wildlife and animal habitat. We considered these comments in our EIS (see section XXVII of this document. In this section of this document we discuss comments we received on the standards directed to wild or feral animals and domesticated animals, in the 2013 proposed rule, but that we did not address in the supplemental notice. We discuss comments received on proposed § 112.84 in the supplemental notice in section III.E of this document.

We are finalizing these provisions with revisions (see Table 21). We discuss these changes in this section. We are finalizing the other provisions of subpart I without change.

TABLE 21—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART I

Proposed provision (as proposed in the 2013 proposed rule and amended in the supplemental notice)	Final provision	Description of revisions
§ 112.81	§ 112.81	—Revision to § 112.81(b) to state that subpart I does not apply to fish used in aquaculture operations.

TABLE 21—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART I—Continued

Proposed provision (as proposed in the 2013 proposed rule and amended in the supple- mental notice)	Final provision	Description of revisions
§ 112.82	§ 112.83	<ul style="list-style-type: none"> —Revision to combine and unify requirements related to grazing and working animals and animal intrusion. —Revision to require farms to assess relevant areas and take certain steps to prevent covered produce that is reasonably likely to be contaminated when, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce. —Revision to clarify that § 112.83 applies during the growing season, in contrast to the related § 112.112, which applies during and immediately prior to harvest. —Revisions to further clarify what type of evidence of potential contamination requires a covered farm to take action under § 112.83 (observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), and what kind of action is required (evaluate whether the covered produce can be harvested and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard).
§ 112.83 § 112.84	§ 112.84	—No change.

A. Subpart I and Prevention of Contamination

(Comment 310) Some comments suggest that FDA should address contamination of produce from domesticated and wild animals through postharvest processing or treatment (including steps such as washing) rather than requiring measures to prevent contamination of covered produce with fecal material.

(Response) We disagree that postharvest processing or treatments provide viable options for addressing the potential for contamination of covered produce by domesticated or wild animals. Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from this rule with certain documentation under § 112.2(b). In addition, produce that is rarely consumed raw (*i.e.*, it is typically cooked before consumption) is not subject to this rule under § 112.2(a). Thus, by definition, covered produce is produce that is not likely to receive a postharvest processing or a treatment step that will adequately reduce the presence of microorganisms of public health concern. As discussed in the 2013 proposed rule, studies have concluded that wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 181) (Ref. 182) (Ref. 183). In addition, bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is

not readily washed off (Ref. 184) (Ref. 185). Thus, our rule takes an approach consistent with the requirement in section 419(c)(1)(A) that this regulation set forth the procedures, processes, and practices the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables.

B. Limited Scope of Applicability of Subpart I (§ 112.81)

(Comment 311) Several comments support limiting the applicability of subpart I to outdoor areas and partially-enclosed buildings, and not to fully-enclosed buildings. In contrast, some comments express concerns about intrusion by pests in both fully- and partially-enclosed buildings, and suggest that the scope of subpart I be expanded to include fully-enclosed buildings for this reason. One commenter believes we exempted activities that take place in fully enclosed buildings from subpart I on the basis that mammals and other carriers of human pathogens are less likely to come into contact with produce that is grown in controlled areas.

(Response) We are maintaining the limitation on applicability of subpart I to outdoor areas and partially-enclosed buildings, as proposed. We are not expanding the applicability of subpart I to fully-enclosed buildings. We identified mammals (such as cows, dogs, swine, and deer) as examples, and not to suggest that these are the only animals that can be a potential source of contamination of covered produce. We acknowledge that domesticated animals and intrusion by pests can be potential

hazards for covered activities that take place in fully-enclosed buildings, and we are establishing requirements addressing these hazards in subpart L of part 112. Specifically, measures directed at domesticated animals in a fully-enclosed building are described under § 112.127, and requirements regarding pest control in both fully-enclosed and partially-enclosed buildings are described under § 112.128. We have also revised § 112.181(b) to reflect that subpart I does not apply to fish used in aquaculture operations (See Comment 17).

(Comment 312) One comment disagrees with our tentative conclusion that there would not be a reasonable probability of contamination by animals when covered produce grows completely underground, and that therefore such produce would not be subject to the requirements in subpart I. This comment stated that different scenarios of animal interaction with produce operations entail different levels of risk, and that it may not be appropriate to harvest covered produce grown underground in areas where there is a prolonged, high concentration of animals known to be vectors of key human pathogens, and suggested that the provisions of subpart I should apply under such circumstances.

(Response) We agree that there may be situations in which even produce that grows completely underground should not be harvested as a result of wild animal activity, *e.g.*, if the produce is visibly contaminated with animal excreta. We are revising both § 112.112 and § 112.83 to make explicit when and how these provisions apply and how they differ from each other, clarifying

that § 112.112 applies immediately prior to and during harvest, while § 112.83 applies during the growing season. The requirement in § 112.112 of subpart K requires covered farms to take all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of all covered produce to be harvested, regardless of the harvest method used. This requirement (§ 112.112) applies even to covered produce grown completely underground and FDA concludes that it is sufficient to address the majority of potential scenarios in which animals may contaminate covered produce grown completely underground.

For example, section 112.112 requires farms to take steps to identify and not harvest covered carrots that are reasonably likely to be contaminated, including carrots that are visibly contaminated with animal excreta. At a minimum, with respect to animal excreta, this requires a covered farm to conduct a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. Underground produce that is not visible prior to harvest must be visually assessed during harvest to comply with this requirement. If, during your assessment of the growing area or of the covered carrots, you see evidence of animal excreta on or surrounding a carrot, you must not harvest that carrot; and you must not harvest an area of carrots if animal excreta that is present in the growing area would be likely to contaminate carrots or food-contact surfaces of harvest equipment. By contrast, the requirements in subpart I include assessing relevant areas for evidence of potential contamination of covered produce as needed during the growing season, with required follow-up actions to be taken during the growing season if evidence of potential contamination is found (§ 112.83). FDA concludes it is not necessary to apply the additional requirements in subpart I to covered produce that grows completely underground because the growth habit of such commodities means that there will not be a reasonable probability of contamination of such commodities by animals as a

general matter. We acknowledge that there is a rare and limited range of potential scenarios in which animals may contaminate covered produce grown completely underground during the growing season but where no evidence of such contamination would be visible immediately prior to or during harvest of that produce. For example, it is theoretically possible that pigs may root in a field of carrots, exposing those carrots to potential contamination from the pigs' excreta, and weather events may remove the evidence of the pigs' activity prior to harvest. However, we do not think this rare and limited scenario presents a reasonable probability of contamination during the growing season as a general matter that warrants application of the additional requirements in § 112.83 during the growing season. Our QAR, too, suggests limited concerns of contamination of such underground produce from animals during the growing of these produce. Given the limited chance that animals will contaminate covered produce that grows completely underground in a manner not visible at harvest such that appropriate measures may be taken at that time, we do not think it is necessary to require covered farms to take the measures required in subpart I with respect to such produce. We emphasize, however, that covered produce commodities that grow completely underground will be subject to the rest of this rule, as applicable, including § 112.112. We note that even covered produce grown completely underground is reasonably vulnerable to contamination with known or reasonably foreseeable hazards during and after harvest, as harvesting exposes such produce to contamination through various pathways. Thus, we conclude that it is warranted to apply § 112.112 even to covered produce grown completely underground. We also emphasize that covered produce commodities that do not grow completely underground (for example, spinach or tomatoes) are subject to the requirements of subpart I.

(Comment 313) One comment asserts that occasional animal intrusions should not represent a threat for the harvest of apples, in particular, given that the fruit is located above the ground while it grows and is typically hand-harvested, suggesting that such produce should not be subject to subpart I.

(Response) We cannot draw a categorical conclusion with regard to the applicability of subpart I to all tree crops that grow high above the ground and are hand-harvested. Animal intrusion is outside the farm's control,

and may include intrusion by significant quantities of birds that may, in some circumstances, be reasonably likely to contaminate such crops. There may be circumstances in which subpart I does not apply to such crops, and there will likely be circumstances in which subpart I does apply to such crops. That determination must be based on the farm's specific circumstances.

C. Grazing and Working Animals (§ 112.83)

(Comment 314) Some comments request that FDA clarify what would be considered an adequate waiting period under proposed § 112.82(a) and request that FDA specify a minimum waiting period between grazing of animals in a field and harvest of covered produce from that field. Some comments suggest that FDA should not require a waiting period between grazing and harvesting, or that certain commodities should not be subject to such a requirement. Several comments express concern about the ability of farmers who employ diversified crop-livestock farming systems that integrate or rotate livestock farming and produce growing to comply with proposed § 112.82(a). Several comments express concerns with FDA's statement in the 2013 proposed rule that we would not expect it to be necessary for an adequate waiting period between grazing and harvest to exceed 9 months, which was the application interval we proposed for use of raw manure as a soil amendment in originally proposed § 112.56(a)(1)(i). In contrast, other commenters recommend that FDA require a waiting period of nine months. One comment asks whether a visual evaluation of the presence of fecal material, as required in certain situations under § 112.83 relating to wildlife, could be used to satisfy the requirements of proposed § 112.82(b) for working animals. Several comments noted the importance of working animals to farm operations and expressed concerns about how farmers who rely on working animals would comply with proposed § 112.82(b). For example, some comments suggest that § 112.82(b) may limit the use of working animals such as horses used for tilling and harvest activities and transporting produce, stating that it would be difficult to maintain a designated path completely segregated from growing produce to be used by draft animals such as working horses. Some comments express concerns about whether proposed § 112.82(b) would prevent covered farms from using dogs, cats, or chickens to deter pests in growing areas; or prevent farms from

using guard dogs to keep other animals out of fields.

(Response) We are removing § 112.82 from the rule and replacing it with revised requirements related to grazing and working animals in § 112.83, discussed further in the paragraphs that follow. FDA continues to believe that an adequate waiting period between grazing and harvest is an important consideration when, under the circumstances, there is a reasonable probability that grazing animals will contaminate covered produce. As discussed in the 2013 proposed rule and our QAR, domesticated animals can be a source of human pathogens. Some human pathogens of public health concern (*e.g.*, *E. coli* O157:H7) that have been associated with produce-related foodborne outbreaks are zoonotic. Moreover, domesticated animals, due to their close proximity and interaction with humans, are generally more likely to harbor zoonotic pathogens than are wild animals (Ref. 186). The likelihood of contaminating produce with human pathogens from excreta from grazing animals is determined by numerous factors, including, but not limited to, the species of the animal and its association with human or domesticated animal activity or waste, the number of animals per unit area of land, agro-ecological conditions, the type of commodity and the time period between animal grazing in fields and the harvest of produce (Ref. 187) (Ref. 188) (Ref. 189) (Ref. 190) (Ref. 191).

However, currently available science does not allow us to identify a specific minimum time period between grazing and harvesting that is generally applicable across various commodities and farming practices. Rather, the appropriate minimum time period between grazing and harvesting would need to be determined based on the specific factors applicable to the conditions and practices associated with growing and harvesting the commodity. We are eliminating the proposed requirement for an adequate waiting period between grazing and harvesting in proposed § 112.82(a). However, we encourage covered farms to voluntarily consider applying such waiting periods, as appropriate for the farm's commodities and operations. We will consider providing guidance on this practice in the future, as needed.

In response to comments suggesting that the assessment strategy in proposed § 112.83 was a reasonable approach not only to the risk of animal intrusion, but also to the risk posed by working animals, we evaluated applying that strategy more broadly to grazing animals, working animals, and animal

intrusion. We have concluded that such an approach was reasonable, scientifically sound, and simpler than establishing different requirements based on different types of animal activity. Therefore, we are removing the proposed requirements for a waiting period between grazing and harvesting in relation to grazing animals (proposed § 112.82(a)) and measures to prevent introduction of hazards from working animals into or onto covered produce (proposed § 112.82(b)), and we are adopting an approach that unifies the requirements addressing the potential for contamination from grazing animals, working animals, and animal intrusion. Under revised § 112.83, we are requiring that you take the same steps if, under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce (§ 112.83(a)). In such cases, you must assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience) (§ 112.83(b)(1)). If you find evidence of potential contamination during that assessment (such as observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112, and you must take measures reasonably necessary during growing to assist you later during harvest when under § 112.112 you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§ 112.83(b)(2)).

Assessing the growing areas as needed during the growing season will enable you to identify instances when covered produce cannot be harvested for safe consumption, such as produce that was directly exposed to animal excreta or that may be cross-contaminated during harvest (*e.g.*, contamination of covered produce by contact with a food-contact surface that contacted animal excreta). Depending on the quantity of animals, extent of animal excreta, or extent of crop destruction, the affected growing areas may be localized (for example, a specific area of the field where you allowed grazing) or more widespread. We expect that, in cases of grazing and working animals, in particular, it is more likely that affected areas will be localized because grazing or working

animals are expected to be present intermittently and in known areas of the field. Once you identify produce, or an area of produce, that cannot be harvested in accordance with § 112.112, § 112.83(b)(2) requires you to take measures reasonably necessary during growing to assist you later during harvest in complying with the requirements of § 112.112. For example, if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time of harvest, such as if a significant rain event washes away fecal deposits.

FDA recognizes the longstanding collocation of animals and plant food production in agriculture. This rule does not prohibit the use of grazing or working animals on covered farms. We believe this approach addresses concerns regarding the feasibility of compliance with the rule for farms that rely on grazing animals (such as integrated or diversified farms with crop-livestock rotation systems) and farms that rely on working animals for various purposes, including horses, dogs, cats, and chickens. Under revised § 112.83, farms would be required to apply the same approach to any of these uses of animals, and only if under the circumstances there is a reasonable probability that animals will contaminate covered produce (§ 112.83(a)). Farms in such circumstances must assess the relevant areas as needed during the growing season (§ 112.83(b)(1)), and if evidence of potential contamination is found, evaluate whether the covered produce can be harvested and take measures reasonably necessary to assist the farm later during harvest in identifying and not harvesting affected covered produce (§ 112.83(b)(2)). We also note that § 112.83, like the rest of this rule, applies only to covered produce. Farms may graze animals on growing areas used for crops other than covered produce, or use working animals in such areas, without triggering § 112.83. We will consider providing guidance on issues related to integrated or

diversified farming practices in the future, as needed.

(Comment 315) One comment suggests that farmers should be prohibited from cultivating covered produce and grazing animals on the same soil.

(Response) FDA believes this suggestion goes beyond what is reasonably necessary to minimize the risk of serious adverse health consequences or death, to prevent the introduction of known or reasonably foreseeable hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We acknowledge the longstanding co-location of animals and plant food production in agriculture, and we do not believe it is necessary to prohibit grazing in areas where covered produce is grown to achieve the statutory purposes set forth in section 419 of the FD&C Act. We are requiring farms to assess relevant areas used for a covered activity as needed during the growing season for evidence of potential contamination, to evaluate whether produce can be safely harvested, and to take measures reasonably necessary during growing to assist the farm later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard when, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce (§ 112.83). We believe this rule requires an appropriate level of public health protection while also appropriately providing sufficient flexibility considering the diversity of production and harvesting of produce (sections 419(a)(3)(A) and (c)(1)(B) of the FD&C Act).

(Comment 316) Some comments suggested that proposed § 112.82(a) would require covered farms to implement a waiting period every time they suspected that a domesticated or wild animal had intruded upon a growing area, and expressed concern that such a requirement would lead to a de facto requirement for farms to exclude wildlife from areas where covered produce is grown.

(Response) We are eliminating proposed § 112.82(a) for the reasons discussed in response to Comment 314. In addition, to remove any possible confusion, FDA has added § 112.84 to the rule explicitly stating that the rule does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy

animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

(Comment 317) Some comments ask that FDA clarify that working animals are permitted in growing areas and that terminating the use of working animals is not necessary to comply with the regulation.

(Response) Working animals are permitted in growing areas, and the regulation does not require termination of the use of working animals on covered farms. As discussed in response to Comment 314, we are revising requirements related to working animals, now established in § 112.83. Revised § 112.83 does not prohibit the use of working animals on covered farms. Therefore, covered farms can use working animals provided that the farm complies with § 112.83, as applicable.

(Comment 318) One comment suggests requiring domesticated animals to be vaccinated.

(Response) We do not agree that we should specifically require vaccination of domesticated animals on covered farms, including working animals. We are not aware of currently available vaccines that would prevent animal excreta from containing human pathogens, and the comment did not provide information from which we could conclude that such vaccines are available.

D. Animal Intrusion (§ 112.83)

(Comment 319) In response to the 2013 proposed rule, several comments express support for the monitoring requirement in proposed § 112.83, and assert that the proposed provisions provide sufficient flexibility to accommodate regional, operational, and commodity diversity in farming operations, and are consistent with current industry practices. On the other hand, several comments argue that proposed § 112.83 would be impracticable or burdensome. Some of these comments state that any requirement to monitor for animal intrusion is untenable, particularly in the case of monitoring for birds on open-air farms. Such comments argue that farms would not be able to prevent all wildlife interaction with covered produce or detect every animal intrusion that occurs and, therefore, no reasonable effort to monitor animal intrusion could provide assurance that covered produce is not contaminated or adulterated. Some comments suggest FDA should use an “outcome-based approach” to animal intrusion, and suggest that monitoring of crop during harvest as set out in § 112.112 is the most appropriate control point at which

to ensure contaminated produce is excluded. These comments appear to argue that monitoring as required by proposed § 112.83, during the growing season and immediately prior to harvest, is unnecessary in light of the requirements of § 112.112 that apply immediately prior to and during harvest.

(Response) We disagree with comments that state that monitoring for evidence of animal intrusion is burdensome or impracticable. As discussed in the preamble of the 2013 proposed rule, periodic monitoring for evidence of animal intrusion and deposition of their excreta is a reasonably necessary measure to prevent contamination of covered produce with biological food safety hazards when there is a reasonable probability that animals will contaminate covered produce. We consider that such assessment during the growing season is a practical and reasonably necessary standard to sufficiently ensure that potential hazards related to animal intrusion are identified for appropriate follow-up actions, including the requirements that apply immediately prior to and during harvesting in § 112.112. Section 112.83 provides flexibility for farmers to consider the nature of their covered produce, their practices and conditions, and their observations and experience to determine when and how often to assess the relevant areas during the growing season when there is a reasonable probability that animals will contaminate covered produce (see § 112.83(b)(1)). We do not expect the requirements of § 112.83 to, as one comment suggested, prevent all wildlife interaction with covered produce or detect every animal intrusion that occurs. We have added a new provision, § 112.84, to make explicit that this rule does not require exclusion of wild or feral animals from covered farms. By “wild” animals we refer to those animals living in a state of nature and not ordinarily tamed or domesticated, and by “feral” animals we refer to those that have escaped from domestication and become wild. In the title of subpart I, “Domesticated and Wild Animals,” we use the term “wild” to refer collectively to both wild and feral animals. These provisions are intended to provide you with information about animal movements on your farm, allow you to recognize significant animal intrusion, and facilitate your taking appropriate measures following significant animal intrusion without being unduly restrictive.

As discussed in response to Comment 314, §§ 112.83 and 112.112 are

complementary rather than duplicative, and we have revised them to remove overlap and clarify how they are different from each other, as well as revising § 112.83 to apply to grazing animals, working animals, and animal intrusion. We have deleted requirements from proposed § 112.83 that would have applied “immediately prior to harvest” and limited its application to “during the growing season.” By contrast, § 112.112 is a generally applicable requirement that applies immediately prior to and during harvest activities. We are revising both §§ 112.83 and 112.112 to make this distinction clear. We believe that § 112.83 adds an important level of public health protection beyond the general harvest-related requirement in § 112.112, and that the additional requirements of § 112.83 should apply whenever, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will result in contamination of covered produce. Under such circumstances, covered farms must do more than just identify and not harvest covered produce that is reasonably likely to be contaminated based on observations made during and immediately prior to harvest (§ 112.112). In these situations, covered farms must take proactive steps under § 112.83 to assess relevant areas during the growing season for evidence of potential contamination. Moreover, if such evidence is found (such as significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), § 112.83 requires covered farms to evaluate whether covered produce can be harvested and take measures reasonably necessary during growing to assist the farm later during harvest when the farm must identify and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. For example, if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time

of harvest, such as if a significant rain event washes away fecal deposits.

We understand that when covered produce is grown in an outdoor environment, wild or feral animals are likely to have access to production fields. We reiterate that the presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. However, wild or feral animals are known zoonotic disease reservoirs for human pathogens, and therefore their excreta may contaminate growing covered produce crops (Ref. 186) (Ref. 188). Therefore, we conclude that assessing for evidence of potential contamination and taking appropriate follow-up actions, as described in § 112.83, is a reasonably necessary when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We note that, as discussed in our response to Comment 314, not all circumstances present a reasonable probability that animals will contaminate covered produce, such that not all covered farms or growing areas will be subject to the requirements in § 112.83.

(Comment 320) Some comments request that any requirements for recordkeeping related to animal intrusion be eliminated from the regulation. In contrast, one comment suggests requiring records to be maintained in relation to the requirements in subpart I.

(Response) Part 112 does not include requirements for establishing or maintaining records related to subpart I. We do not believe such a requirement is warranted, although we encourage covered farms to prepare and keep documentation as appropriate to facilitate their implementation of the provisions of subpart I. Therefore, a covered farm is not required to develop or keep a record of its activities related to assessment for animal intrusion.

(Comment 321) One comment suggests that FDA add a requirement that covered farms take reasonable measures to keep animals out of growing areas and water sources based on the farm’s observations from assessment for animal intrusion.

(Response) We do not believe it is necessary to establish such a requirement in subpart I. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. We believe that assessing for animal intrusion and taking appropriate follow-up actions, as described in § 112.83, is an appropriate approach to ensure the safety of covered produce when, under the circumstances, there is a reasonable

probability that animal intrusion will contaminate covered produce. Moreover, § 112.42(c) requires covered farms to adequately maintain all agricultural water sources that are under the farm’s control (such as wells), including by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(Comment 322) One comment requests that FDA define more specifically the time period that would be appropriate for fulfilling the proposed requirement in proposed § 112.83(a)(2) to monitor for animal intrusion “immediately prior to harvest.”

(Response) We are eliminating the phrase “immediately prior to harvest” in § 112.83. As described in response to Comment 314, revised § 112.83 applies during the growing season. We are, however, retaining similar language in § 112.112. As discussed in section XVI.B of this document, we use “immediately prior to harvest” in § 112.112 to refer to the time period prior and as close to commencing harvesting as is practicable.

(Comment 323) One comment suggests that FDA consider including in the regulation the CA LGMA Animal Hazard/Fecal Matter Decision Tree.

(Response) We are aware that some decision-making tools, such as the CA LGMA Animal Hazard/Fecal Matter Decision Tree (the CA LGMA animal hazard decision tree) and the Cornell University National GAPs Program Wildlife and Animal Management Decision Tree (the Cornell animal management decision tree), are intended to help covered farms evaluate their fields for signs of animal intrusion and take follow-up action. Although these may be useful resources, we find the information and variables addressed in these tools to be more prescriptive than we consider necessary in this rule, and not necessarily applicable across all commodities and agro-ecological conditions. For example, the CA LGMA animal hazard decision tree is commodity-specific and tailored specifically for leafy greens operations in California. We decline to incorporate these decision-making tools into this regulation as requirements.

(Comment 324) Some comments argue that the requirements of proposed § 112.83 are vague and request that FDA provide guidance regarding methods for evaluating potential contamination of produce and determining if it is safe to harvest.

(Response) As discussed in section XVI of this document, we have revised § 112.112 to provide more specificity regarding the evaluation that is necessary during and immediately prior to harvest to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta. At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. We also explain in that section that this may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. For example, if you identify an article of covered produce that is visibly contaminated with excreta, you may not harvest that article of covered produce (e.g., watermelon with cow feces on it). As another example, if you identify an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area, the covered produce in that area may not be harvested (e.g., a “no harvest zone” in an area of a spinach field containing wild hog feces).

Section 112.83 applies during the growing season rather than during or immediately prior to harvest. It requires an additional step during the growing season applicable only when under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce. In such cases, covered farms must assess relevant areas used for a covered activity for evidence of potential contamination. This requires a visual assessment of all of the relevant areas used for a covered activity (including growing areas and any other areas in which there is a reasonable probability of contamination of covered produce from animals) and the covered produce. If evidence of potential contamination is found (such as significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), § 112.83(b)(2) requires covered farms to evaluate whether covered produce can be harvested. This evaluation described in § 112.83(b)(2) is the same type of evaluation described in § 112.112, but under § 112.83(b)(2) an evaluation is also performed earlier, during the growing season. This evaluation

requires a farm that becomes aware of potential contamination to evaluate affected areas and produce, and to take appropriate measures to facilitate its identification of produce that may not be harvested later in the season (such as marking affected areas or produce, as discussed in response to Comment 314).

(Comment 325) Some comments suggest that farms should be required to evaluate whether their covered produce can be harvested in accordance with § 112.112 upon finding *any* evidence of animal intrusion; suggesting that the phrase “significant quantities of” in proposed § 112.83(b) should be removed.

(Response) We disagree. As noted previously, we do not expect the requirements of § 112.83 to detect every animal intrusion that occurs or to require farms to take measures in response to every such intrusion. The requirements of § 112.83 are intended to provide you with information about animal movements on your farm, allow you to recognize *significant* animal intrusion, and facilitate your taking appropriate measures following *significant* animal intrusion without being unduly restrictive. We believe that the harvest-related requirement in § 112.112 provides sufficient protection to address less than significant animal intrusion (*i.e.*, intrusion that occurs without the farm observing, during required assessment, significant quantities of animals, significant animal excreta, or significant crop destruction).

(Comment 326) One comment suggests that, for tree crops, covered farms should be required to cover and remove animal excreta from the harvest area so that it does not contaminate workers or equipment. Other comments suggest that covered farms should be required to cordon off areas of ground crops where potential contamination may have occurred as a result of animal intrusion and ensure that covered produce is not harvested from those areas.

(Response) Specific determinations about whether certain covered produce can be harvested, and what specific measures to take to assist the farm later during harvest will likely vary dependent on the specific circumstances relevant to the commodity and/or the farm’s practices, procedures, and processes. The requirements of § 112.83 and related § 112.112 are purposefully flexible, to allow covered farms to take steps in compliance with those requirements that are most appropriate to their operations, in light of their covered produce and the nature of their covered activities. We note that section

419(c)(1)(D) of the FD&C Act directs us to minimize, as appropriate, the number of separate standards that apply to separate foods. We believe it is appropriate to establish one standard addressing the risk of contamination of covered produce from grazing animals, working animals, and animal intrusion, which is applicable whenever under the circumstances there is a reasonable probability that animals will contaminate covered produce. Therefore, we decline to establish more specific requirements such as those suggested by the comments. We will consider providing more specific recommendations with respect to how farms may implement these requirements for specific situations in the Produce Safety Regulation implementation guidance, which we expect to issue in the near term. We agree that the practices suggested by the commenters may be appropriate strategies for compliance with § 112.83, depending on the circumstances.

(Comment 327) One comment maintains that the provisions should differentiate between produce that is hand-harvested and that harvested by a machine. The comment urges FDA to create a less stringent standard with respect to animal intrusion for producers who employ hand harvesting, noting that a machine cannot detect animal intrusions or animal excreta and, therefore, the presence of animals on large-scale farms that employ machine harvesting poses a significantly different level of risk than on farms that use hand harvesting.

(Response) As discussed in section XVI of this document, we have revised § 112.112 to provide more specificity regarding the evaluation that is necessary during and immediately prior to harvest to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta. At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. We also explain in that section that this may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. Thus, we have revised § 112.112 to address the differences between hand harvesting and machine harvesting with respect to the ability to detect evidence of

potential contamination. We have also revised § 112.83 to specify that it applies only during the growing season and not during or immediately prior to harvest. Thus, we do not consider it to be necessary to take into account harvesting practices in § 112.83 because we consider that they are sufficiently addressed in § 112.112.

(Comment 328) Several comments express concern that proposed § 112.83 could be perceived as requiring measures to exclude wildlife from growing areas. Citing concerns that some on-farm food safety certification programs have resulted in farmers' abandoning conservation practices and actively excluding wildlife from farms, some comments ask FDA to explicitly clarify that the regulation does not require producers to exclude wild animals from the growing area. Some comments express concern that this proposed provision can be interpreted to conflict with other federal and State programs to establish buffer zones or other natural vegetation buffer strips intended to improve water quality, protect endangered species, and enhance wildlife habitat.

(Response) We believe that these concerns have been addressed through our addition of § 112.84, as discussed in the supplemental notice.

E. List of "Animals of Concern"

(Comment 329) Several commenters express support for FDA's tentative conclusion to not establish a list of "animals of concern," agreeing that current scientific evidence is inadequate to develop such a list. On the other hand, some comments request FDA to establish a list of "animals of concern" to assist farms in determining the risk of animal intrusion in growing area. One such comment states that some research indicates that certain types of animals are not routine carriers of specific pathogenic organisms.

(Response) We continue to find that currently available scientific data and information are insufficient to develop a list of specific animals that present the greatest risk for pathogens. The commenters that requested us to establish such a list did not provide specific scientific research or data in support of their request. Therefore, we decline the request to establish a list of "animals of concern."

XVI. Subpart K—Comments on Growing, Harvesting, Packing, and Holding Activities

In subpart K of proposed part 112, we proposed science-based minimum standards directed to growing, harvesting, packing, and holding activities that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed provisions, including proposed § 112.114 related to dropped produce; and proposed § 112.115 related to measures to prevent formation of botulinum toxin.

We are finalizing these provisions with revisions (see Table 22). We discuss these changes in this section. We are finalizing the other provisions of subpart K as proposed.

TABLE 22—DESCRIPTION OF REVISIONS TO SUBPART K

Final provision	Description of revisions
§ 112.111(a)	—Revision to add "(except when covered produce and excluded produce are placed together in the same container for distribution)" to make our intent clear that this provision does not preclude the placing together of covered and excluded produce in containers for distribution, such as in gift baskets.
§ 112.112	—Revision to clarify that § 112.112 applies during and immediately prior to harvest, in contrast to the related § 112.83, which applies during the growing season. —Revision to specify that "[a]t a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used."
§ 112.113	—Revision to add the phrase "to the degree practicable" considering covered commodities that are harvested near the soil line, where avoiding contact of cut surfaces of harvested produce with soil may not be practicable.
§ 112.114	—Revisions to clarify meaning of "dropped covered produce," including explicitly state that dropped covered produce does not include root crops (such as carrots) that grow underground, crops (such as cantaloupe) that grow on the ground, or produce that is intentionally dropped to the ground as part of the harvesting method (such as almonds). —Deletion of "unless it is exempt under § 112.2(b)" as confusing and unnecessary.
§ 112.115	—No change.
§ 112.116	—Revision to § 112.116(a) to clarify that food-packing materials used must be adequate for their intended use, which includes being: (1) Cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. —Revision to § 112.116(b) to remove the reference to "sanitizing" and to make clear the steps taken, including the frequency of cleaning or replacing liners, must be adequate.

A. Growing, Harvesting, Packing, or Holding Both Covered and Excluded Produce (§ 112.111)

(Comment 330) Some comments generally express support for this provision. Some comments request further clarification regarding the requirement to keep covered produce separate from produce not covered

under this rule. One commenter suggests defining "separate" as "preventing the ability of cross-contamination by separating in space so that covered and non-covered produce is not in direct contact with one another." Another commenter asks FDA to explain how this requirement would apply to covered and excluded produce items that are sold together, as in the

case of gift baskets. This commenter asks whether gift baskets with other ingredients such as chocolate, would be covered under this rule, and whether the place where the non-produce item is originally packed is a factor in this determination.

(Response) Section 112.111 requires covered farms to keep covered produce separate from excluded produce (that is

not grown, harvested, packed or held in accordance with part 112) during growing, harvesting, packing, and holding as applicable, to avoid physical contact between the two categories so as to minimize risk of transfer of pathogens from one to the other. We do not believe it is necessary to define the term “separate;” as used in this provision, we believe the common meaning of this term to be sufficiently descriptive for the purposes of conveying the intent of this requirement.

For the purposes of part 112, covered produce includes not only fruits and vegetables, but also mixes of intact fruits and vegetables (see § 112.1(b)(2)). However, it was not our intent to preclude the placing together of covered and excluded produce in containers for distribution, such as in gift baskets. We are revising § 112.111(a) to make this intent clear. This provision also does not prevent you from placing covered produce into the same container (such as a gift basket) with other food items not covered under part 112. Excluded produce and/or other food items not covered under part 112 must adhere to all other applicable requirements under the FD&C Act. In addition, to the extent the establishment that assembles the basket or package is a mixed-type facility (including a farm mixed-type facility) or other facility that is required to register with FDA, such an establishment may be subject to the requirements of part 117, the PCHF regulation.

B. Harvesting Covered Produce (§ 112.112)

(Comment 331) Some comments cite specific circumstances where contamination is likely and request clarification regarding applicable requirements under § 112.112. One comment argues that produce is likely to be contaminated with animal excreta when a flock of birds land on an iceberg lettuce field, and should not be harvested under § 112.112 although the excreta may not be visible. According to this commenter, some farms may routinely harvest produce that has been in contact with fecal material if the outer layers of the fruit or vegetable can be removed before depositing it into the harvest container, as in the case of lettuce. The commenter is concerned that, in such instances, all surfaces that come in contact with excreta may not have been identified or removed. Another comment points to an instance where covered produce comes into contact with water that is thought to be contaminated, and suggests that such produce should not be harvested under § 112.112.

(Response) Section 112.112 requires covered farms to take all reasonably necessary measures to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. See section IX of this document for a discussion of the definition of “known or reasonably foreseeable hazard.” We have revised § 112.112 to clarify when and how this provision applies, and to distinguish it from the related § 112.83. See our discussion of § 112.83 in section XV of this document. Section 112.112 applies immediately prior to and during harvest, while § 112.83 applies during the growing season. Section 112.112 applies generally to covered farms with respect to all covered produce, while § 112.83 only applies when under the circumstances there is a reasonable probability that animals will contaminate covered produce. Section 112.112 applies generally to all covered produce that is reasonably likely to be contaminated with any known or reasonably foreseeable hazards covered under this rule, while § 112.83 applies only when the reasonably likely source of contamination is animal activity.

Within § 112.112, we explicitly identify as an example one known or reasonably foreseeable hazard in relation to harvest activities, *i.e.*, pathogens are likely to be introduced into or onto covered produce by animal excreta when it is present. Thus, one important aspect of § 112.112 is that it requires farms to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta, or that is visibly contaminated with animal excreta. We are clarifying in the text of § 112.112 that identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of all covered produce to be harvested, regardless of the harvest method used. This may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. Underground produce that is not visible prior to harvest must be visually assessed during harvest to comply with this requirement.

Section 112.112 includes, but is not limited to, visibly contaminated articles of covered produce. For example, you would comply with this provision by

not harvesting a head of lettuce if you see excreta on the head of lettuce. As another example, if you see significant evidence of crop destruction from animal activity in an area of your field of carrots, you would comply with this provision by not harvesting the carrots from that area of the field, even if some of the carrots (not grazed on) may be intact, to the extent that these carrots, too, are reasonably likely to be contaminated as a result of the animal activity.

Section 112.112 requires that these actions be taken “immediately prior to and during harvest.” We use the term “immediately prior to . . . harvest” in § 112.112 to refer to the time period prior and as close to commencing harvesting as is practicable. We expect that in most cases covered farms will choose to take steps to identify covered produce that may not be harvested “immediately prior to harvest,” although this step may also be done during harvest. The required visual examination is most effective when done as close in time before beginning harvesting as is practicable, under the circumstances of the farm’s operation, or during harvesting itself. We are not specifying the exact time period when such visual assessment must be done, given the practicability of such assessment is dependent, in part, on the farm’s operation and commodity.

In addition to potential pathogen contamination from animal activity, there may be other known or reasonably foreseeable hazards that a covered farm would need to identify and address under § 112.112. We consider, for example, the circumstance a commenter raised where covered produce may come into contact with water that is likely to be contaminated with pathogens. In subpart E, we are establishing requirements related to agricultural water, including that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Subpart E provides the relevant requirements for what farms must do when agricultural water does not meet this standard (§ 112.45(a)), or other specific microbial quality criteria we are establishing for certain uses (§§ 112.45(a) and (b)), and therefore, we do not believe additional standards are needed under § 112.112 with respect to harvesting based on agricultural water quality. Circumstances may arise, however, in which water that is likely to be contaminated with known or reasonably foreseeable hazards, such as flood water, contacts covered produce. Flood water is outside the definition of agricultural water established in this rule and is

therefore not subject to the requirements in subpart E. However, both §§ 112.11 and 112.112 apply to flooding situations. In accordance with § 112.11, covered farms must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce as well as to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. Moreover, in accordance with § 112.112, a covered farm that has experienced flooding will be required to assess the extent of flooding and not harvest covered produce that is reasonably likely to be contaminated with known or reasonably foreseeable hazards through contact with flood water.

(Comment 332) One commenter suggests revising § 112.112 to provide that “harvesting covered produce that is visibly contaminated with excreta should be avoided to the extent practicable.”

(Response) We disagree with the suggestion to revise § 112.112 to provide that “harvesting covered produce that is visibly contaminated with excreta should be avoided to the extent practicable.” As discussed in the QAR, it is well established that animal excreta is a source of pathogens. Transmission of pathogens from animal excreta to covered produce and, subsequently, to humans through consumption is reasonably likely in cases where the presence of animal excreta can be visually confirmed. Therefore, we conclude that covered produce that is visibly contaminated with animal excreta must not be harvested.

Accordingly, § 112.112 requires that you take all measures reasonably necessary to identify and not harvest produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. Section 112.112 further specifies, to remove any possible confusion, that this includes taking steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. For these reasons, we are not making the requested change.

C. Handling Harvested Covered Produce (§ 112.113)

(Comment 333) One commenter recommends that we include the following types of explicit and specific requirements in § 112.113, and that such requirements should also be commodity-specific: ideal harvest time of day, postharvest chill requirement,

chill temperature, wash requirement(s), wash specifications, and ideal storage temperature(s). In addition, noting that many produce commodities cut during harvest grow near or in contact with the soil, the commenter questions the feasibility of the example provided in § 112.113, *i.e.*, “by avoiding contact of cut surfaces of harvested produce with soil,” and suggests revising it by adding the phrase “to the degree practicable.”

(Response) Due to the diversity of covered produce commodities and our desire to allow appropriate flexibility, FDA is not establishing commodity-specific handling requirements for harvested produce in this rule. We note, however, that FDA is working on certain commodity-specific guidance documents. We have issued draft guidances for tomatoes, melons, and leafy greens and will consider developing guidances covering other commodities.

With respect to the comment about the example listed within § 112.113, we agree that adding the phrase “to the degree practicable” is appropriate, considering covered produce commodities that are harvested near the soil line, such as herbs and celery, where avoiding contact of cut surfaces of harvested produce with soil may not be practicable. However, § 112.113 requires covered farms to handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards, including pathogens that may be present in soil. This includes taking all measures that are reasonably necessary and practicable.

Accordingly, we are revising § 112.113 to read as set forth in the regulatory text of this rule.

(Comment 334) Several comments support our tentative conclusion not to require washing of produce after harvesting. Some of these comments acknowledge that disinfectants added to wash water cannot be expected to kill all pathogens that may be present on produce, and may also accelerate decomposition of certain commodities.

(Response) In light of these comments, and in the absence of new data or factual information, we are not establishing any requirement to wash harvested produce in this rule. Wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 181) (Ref. 182) (Ref. 183). Bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is not readily washed off (Ref. 184) (Ref.

185). As appropriate, farms may choose to wash covered produce, and to add safe and suitable disinfectants to wash water, according to label instructions, to reduce the likelihood of produce contamination, including for example to help prevent the cross-contamination of surrounding produce with any pathogens that may be introduced into the wash water from a single fruit or vegetable.

(Comment 335) Specifically in the context of harvested produce, one comment requests FDA to require facilities handling “high-risk” produce to periodically test the finished product for pathogens, and cites cantaloupe as an example of a produce commodity that should be subject to such a requirement.

(Response) In the 2013 proposed rule (78 FR 3504 at 3533), we discussed the challenges associated with requiring microbiological product testing, either routinely or under specific conditions, as a strategy to minimize known or reasonably foreseeable hazards in covered produce. We have no new information suggesting that we should change our conclusion, nor did this commenter provide any new data or factual information. Therefore, we are not establishing a requirement for microbiological product testing of covered produce, except as established in subpart M under certain circumstances for sprouts (§ 112.144(b) and (c)). See section III.F of this document.

D. Dropped Covered Produce (§ 112.114)

In § 112.114, we proposed to prohibit you from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b) (*i.e.* if it receives commercial processing to adequately reduce the presence of microorganisms of public health significance). We also proposed to clarify in this provision that dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground. We also noted that produce that is intentionally dropped to the ground as part of the harvesting method would not be considered “dropped covered produce” as defined in proposed § 112.114 (*i.e.*, produce that drops to the ground before harvest). We are finalizing this section with certain changes as described in the paragraphs that follow.

(Comment 336) Several comments favor the requirements of this provision, as proposed. However, one comment expresses a view that this requirement

should be applied by a farm according to an operational assessment of risk specific to that farm.

(Response) We refer you to the discussion in section VII of this document, where we explain our conclusion not to require covered farms to conduct operational assessments or develop farm-specific food safety plans, although we encourage farms to do so voluntarily to identify any specific risks and operational efficiencies appropriate for their circumstances. We recognize the importance of tailoring your food safety practices to the commodities, practices, and conditions applicable to your individual operation. Covered farms may take steps to ensure the safety of their dropped covered produce as determined by a farm-specific operational assessment, as long as those steps are consistent with and do not violate the requirements of this rule, including § 112.114.

(Comment 337) Several comments express that certain produce commodities are intentionally dropped on the ground as part of their regular harvesting practice. For example, some comments refer to the harvesting practices of the tree nut industry in which some types of tree nuts (*e.g.* hazelnuts, chestnuts, and almonds) are typically shaken from the trees onto the ground as part of harvesting, and agree with our proposal that tree nuts and other commodities that are intentionally dropped as a part of harvesting should not be covered under this provision. Other comments request that FDA exclude from this provision any commodity that has an outer covering (such as a rind or husk) that is not typically consumed. Some comments generally question the scientific basis supporting this requirement. These commenters argue that there is no certainty that pathogens transfer into produce after contact with the ground, and assert that the likelihood of pathogens being at the exact spot where the produce drops is remote.

(Response) In the 2013 proposed rule, we acknowledged that some produce is intentionally dropped to the ground as a part of the harvesting practice (*e.g.*, some tree nuts), and that we expect that such harvesting practices were developed because the fall does not damage the edible crop, which is protected by a durable shell. Accordingly, we proposed to define “dropped covered produce” within § 112.114 in a manner that excludes produce that is intentionally dropped as part of harvesting (*i.e.*, produce that drops to the ground *before* harvest). Taking this into account and in light of other comments (see our response to

Comment 338) we are revising § 112.114 to explicitly state that dropped covered produce does not include produce that is intentionally dropped as part of the harvesting method (for example, when trees bearing tree nuts, such as almonds, are intentionally shaken to drop tree nuts to the ground to be harvested). We note that this rule, including § 112.114, is not applicable to produce commodities that are identified in 112.2(a)(1) as rarely consumed raw, such as hazelnuts.

However, we have concluded that we should not similarly exclude all produce that has an outer peel that is inedible or not typically consumed. Evidence from studies of tree fruit (*e.g.*, apples and pears) indicates that dropped and damaged fruit contain coliform bacteria in significantly higher numbers than intact tree fruit (Ref. 192). In addition, risk assessment models for apple contamination (Ref. 193) show that dropped apples are more likely to be contaminated with bacteria than tree-picked apples, and dropped fruit used in the production of apple products (*e.g.*, apple cider) are likely to increase rates of product contamination (Ref. 193). Moreover, fruits with outer layers that are inedible or typically not consumed have been implicated in illness outbreaks. In 2011–2012, outbreak events have been linked to whole, intact mangoes, papayas, and cantaloupes (Ref. 194) (Ref. 195) (Ref. 196). Although these outbreak investigations did not conclude that contamination was a result of dropped produce that was harvested and sold, each of these fruits has an outer covering that is either inedible or typically not consumed. Moreover, as discussed in our QAR, there are limited data on the effect of peeling (and cutting) on the levels of pathogens across the range of commodities. Some produce commodities have an inedible rind that is generally removed in such a way that minimizes the potential for any surface contamination to come in contact with the edible portion of the fruit. In such commodities, for example bananas and coconuts, peeling before consumption may significantly reduce the potential for contamination. However, other produce commodities (*e.g.*, mangos, oranges, carrots) are usually peeled in such a way (*e.g.*, using a knife) that contamination on the surface can be carried to the edible portion of the produce. Thus, FDA maintains that provision § 112.114 should apply generally to covered produce with only the exclusions specified in the provision, irrespective of whether such produce also has an

inedible or rarely consumed outer layer. This conclusion is based on the likelihood of damage to the outer layer allowing access to the interior of the commodity, increased rates of contamination observed on some types of dropped produce, and the uncertainty that having some kind of inedible or rarely consumed outer layer provides sufficient protection to counteract these concerns as a general matter.

(Comment 338) Several comments note that proposed § 112.114, as worded, suggests that covered produce that is unintentionally dropped to the ground during harvest would be acceptable for distribution. One comment recommends revising this provision to clarify that covered farms must not distribute covered produce that falls to the ground “before and during harvest.” Another comment states that dropped produce should not include produce that is still attached to the plant at the time of harvest.

(Response) Covered produce is subject to the requirements in § 112.114 unless it is specifically identified as not being included within the meaning of “dropped covered produce.” Under revised § 112.114, dropped covered produce does not include root crops (such as carrots) that grow underground, crops (such as cantaloupe) that grow on the ground, or produce that is intentionally dropped to the ground as part of the harvesting method (such as almonds). However, produce that grows off the ground, such as tomatoes and apples, and that drop to the ground before harvest is considered dropped covered produce, even if articles of produce are still attached to the plant when they contact the ground. Moreover, an article of covered produce that drops to the ground before that specific article can be harvested, regardless of whether the farm has started harvesting generally, is still dropped covered produce subject to § 112.114 unless it is otherwise excluded (*e.g.*, if dropping is an intentional part of the harvesting process). For example, when an apple drops to the ground before it is harvested, it is dropped covered produce, whether or not the covered farm has already begun harvesting apples from that orchard such that the farm might consider the apple to have unintentionally fallen “during” its harvesting of the orchard. The apple in this example dropped before the apple was harvested.

(Comment 339) One commenter requests that FDA clarify that dropped covered produce may be used for personal consumption, for commercial processing, or for food for animals.

(Response) We are removing the reference to produce that is exempt under § 112.2(b) from the codified text of this section. We are making this change because produce that is exempt from the requirements of part 112 under § 112.2(b) is exempt from all the requirements in part 112 except those specified in § 112.2(b). We are concerned that including a specific reference to exempt produce in § 112.114 might have misleadingly and incorrectly suggested that produce that is not covered by part 112 (under § 112.2(a), because it is rarely consumed raw, produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management, or not a RAC), or produce that is exempt from part 112 (under § 112.2(b), because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance), is subject to certain requirements other than as specified in § 112.2. In fact, neither produce that is not covered by part 112 (under § 112.2(a)), or produce that is exempt from part 112 (under § 112.2(b)) is subject to § 112.114.

E. Packaging Covered Produce (§ 112.115)

(Comment 340) Several comments generally support this provision. One such comment finds no reason to highlight mushrooms as an example, and requests removing it from the text of the codified provision. This commenter states that there have been significant updates to packaging practices since the research FDA cited, which was conducted in 1978. In addition, this commenter believes that packaging mushrooms is likely done in a packinghouse that would be subject to the PCHF regulation, rather than to the produce safety regulation. Furthermore, some commenters express a view that it is important to consider whether *Clostridium botulinum* (*C. botulinum*) is a potential hazard for any commodity, just as it is important to consider all pathogens, and not just anaerobic bacteria, to ensure appropriate packaging.

(Response) The provision in § 112.115 requires you to package covered produce in a manner that prevents the formation of *C. botulinum* toxin, if such toxin is a known or reasonably foreseeable hazard. This requirement applies to the packaging of any covered produce where the formation of *C. botulinum* toxin is a known or reasonably foreseeable hazard. Within this provision, we explicitly list mushrooms as an example because the

formation of *C. botulinum* toxin in mushrooms, when packaged under certain conditions, is a known or reasonably foreseeable hazard. As discussed in the 2013 proposed rule, the potential for toxin production by *C. botulinum* in mushrooms packaged under reduced oxygen conditions is well-established (Ref. 197). Mushrooms grow close to the ground, which is a source of *C. botulinum* spores, and mushrooms remain metabolically active after harvest, which may quickly reduce the amount of oxygen, particularly when mushrooms are packaged under conditions that limit the transfer of oxygen across the layer of packaging (Ref. 198). In such reduced oxygen or anoxic conditions, *C. botulinum* spores can germinate and multiply resulting in the formation of botulinum toxin, which can occur before any overt signs of mushroom spoilage (Ref. 197). Therefore, we continue to believe that mushrooms are an appropriate example.

Modified atmosphere or other reduced-oxygen packaging of produce other than mushrooms may present a similar risk for botulinum toxin formation (Ref. 199). Therefore, it would be incorrect to infer that packaging of mushrooms is the only circumstance where *C. botulinum* toxin formation is a known or reasonably foreseeable hazard. We continue to include mushrooms as an example, but they are only an example.

Moreover, covered farms must ensure their food packing (including food packaging) material is adequate for its intended use, as required in § 112.116 (discussed in the paragraphs that follow). Section 112.116 relates to all pathogens, and is not limited to *C. botulinum* toxin. Section 112.115 goes beyond the packing material requirements in § 112.116 and applies specifically to the hazard of formation of *C. botulinum* toxin. Whereas § 112.116 is aimed at ensuring that packing materials themselves do not introduce hazards into produce, § 112.115 is aimed at the specific hazard of *C. botulinum* toxin when produce is packaged in a manner that allows *C. botulinum* spores to germinate and multiply, resulting in the formation of botulinum toxin, which can occur before any overt signs of spoilage of the produce. A farm using reduced oxygen packaging might comply with this requirement by applying means to reduce the potential for toxin formation. For example, perforated packaging film allows free air access and is a means to reduce the potential for toxin formation in mushrooms (Ref. 200) (Ref. 201). Other means of preventing toxin formation in reduced oxygen packaging

may include use of time-temperature integrators on individual packages of produce to signal when a cumulative time-temperature combination has been reached that presents a risk for *C. botulinum* toxin formation, or use of antimicrobial compounds (Ref. 199). Scientific information should support the use of methods used to prevent toxin formation, such as use of perforated packaging film, time-temperature integrators and antimicrobial compounds.

We also note that, even if some packing or packaging of mushrooms may be done in facilities subject to the PCHF regulation, it is also likely that covered farms will conduct relevant activities within the coverage of the produce safety regulation. The definition of “farm” as provided in both this regulation (in § 112.3(c)) and the PCHF regulation includes packing of RACs, and packaging of RACs when such packaging does not include additional manufacturing/processing. An example of additional manufacturing/processing is irradiation. However, § 112.115 applies to packaging that does not include additional manufacturing/processing; such packaging includes modified atmosphere packaging and other methods of packaging of covered produce in a manner that creates anaerobic conditions where the formation of *C. botulinum* toxin is a known or reasonably foreseeable hazard. For example, packaging of mushrooms or other covered produce in semipermeable plastic films is a covered activity that fits within the farm definition and is, therefore, subject to this rule and to § 112.115.

Accordingly, we are finalizing § 112.115, as proposed, with no changes.

F. Food-Packing (Including Food Packaging) Material (§ 112.116)

(Comment 341) Several comments agree that food-packing and packaging material must be adequate for its intended use. One comment requests clarification of what is meant by “adequate for its intended use,” and suggests incorporating the following text from the preamble of the 2013 proposed rule into the codified provision: “To implement this provision, you would have to use food-packing materials that are: (1) Cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria.”

(Response) In the 2013 proposed rule, we provided some examples of what food-packing material would be adequate for its intended use in compliance with § 112.116(a). For

example, food packing material that is adequate for its intended use includes plastic bins for holding fresh-picked fruit, wax impregnated corrugated cardboard for broccoli to be hydro-cooled or top-iced after packing, plastic clamshells used for packaging strawberries for retail sale, and single-use cardboard containers for packing tomatoes. Wooden bins or boxes, and canvas bags that are used during harvest also must meet the requirement in § 112.116(a), and can be used if they are adequately clean and sanitary for their intended use. This section requires that you use food-packing materials that are adequate for their intended use, which includes being: (1) Cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. We are revising § 112.116(a) to include this additional information.

(Comment 342) Several comments discuss the use of containers (or bags or sacks) made from wooden, plastic, or cloth-like materials and pulp materials, as well as decorative containers used to enhance retail presentation. Many of these comments discuss the variety of on-farm and off-farm uses of such containers, and request that we allow the continued use of wooden containers and other porous materials during harvesting. Several other commenters point out requiring farms to switch to plastic containers would cause significant economic burden and may also result in loss of crop due to reduced air flow observed with plastic packing materials.

(Response) The only restriction we are establishing on the types of food packing materials you may use for covered produce is that such materials must be adequate for their intended use (§ 112.116(a)). As discussed in response to Comment 341, this includes being (1) cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. Thus, you may re-use food-packing material provided that it is cleanable and it is unlikely to support growth or transfer of bacteria. Moreover, if you re-use food packing material, you must take steps to ensure that food-contact surfaces are clean; for example, you must clean the food packing containers or use a clean liner on the food packing container to protect produce from contamination (§ 112.116(b)). The necessary frequency of such cleaning, and the necessary

frequency with which liners must be replaced, will likely vary depending on the circumstances. Therefore we are not specifying a single required cleaning frequency in this regulation. However, we are revising this section to make clear that the steps you take, including the frequency of cleaning or replacing liners, must be adequate.

We are not requiring farms that use wooden or other porous food packing materials to stop using them, but we are requiring that such materials be used only to the extent they are cleanable and unlikely to support the growth or transfer of bacteria. As noted in the 2013 proposed rule, although some food-packing materials are sufficiently sturdy to be used multiple times, such materials may serve as a source of contamination if they are not adequately clean and/or if the material is used beyond its shelf life and adequate cleaning cannot be achieved.

(Comment 343) One comment generally supports requiring that food-contact surfaces of reusable food packing material be cleaned and sanitized between uses. In contrast, a few comments object to provision § 112.116(b) to the extent it may require sanitizing food containers. One such comment states that it is not feasible for farmers to sanitize all harvest containers, and another comment notes some current practices involve using wooden bins, carpet-cushioned or cardboard-cushioned trailers and transporters, and other materials that cannot be sanitized. Yet another comment states that wooden bins used on farms during harvesting should be required to be kept clean, but not required to be sanitized.

(Response) We are not requiring you to sanitize all food packing containers or food-contact surfaces that you re-use during harvesting, packing, or holding of covered produce. Rather, per § 112.116(a), you must use food-packing material that is adequate for its intended use and, per § 112.116(b), if you re-use a food packing container, you must take measures to ensure that the food-contact surfaces of that container are clean. We recognize the use of “sanitizing” in the example we provided within proposed § 112.116(b) (*i.e.*, “such as by cleaning and sanitizing, when necessary, food-packing containers”) is confusing and implies a requirement that goes beyond that described in the established

measure (*i.e.*, “if you reuse food-packing material, you must take steps to ensure that food-contact surfaces are clean”). Therefore, we are revising § 112.116(b) by removing the reference to “sanitizing” such that the provision reads as follows: “if you reuse food-packing material, you must take adequate steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.”

However, under § 112.111(b), you are required to adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-contact surfaces for covered activities on covered produce. For example, if you use food packing containers that were previously used to pack or hold excluded produce, and the excluded produce is not grown, harvested, packed, or held in accordance with part 112, you must clean and sanitize, as necessary, the food-contact surfaces of the containers that came into contact with the excluded produce before subsequently using the same containers for packing covered produce. In summary, taking adequate steps to ensure that food-contact surfaces of food-packing materials are clean is required whenever you are re-using food packing material for covered produce, and sanitizing such surfaces is also required, as necessary, when re-using such materials after using them on excluded produce not handled in accordance with part 112.

XVII. Subpart L—Comments on Equipment, Tools, Buildings, and Sanitation

In subpart L of proposed part 112, we proposed to establish science-based minimum standards that are reasonably necessary to prevent equipment, tools, buildings, and inadequate sanitation from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. We asked for comment on the proposed provisions of this subpart.

We are finalizing these provisions with revisions (see Table 23). We discuss these changes in this section.

TABLE 23—DESCRIPTION OF REVISIONS TO SUBPART L

Final provision	Description of revisions
§ 112.121	—Revisions to delete the term “other contamination”, and replace “undesirable microorganisms” with “microorganisms of public health significance”.

TABLE 23—DESCRIPTION OF REVISIONS TO SUBPART L—Continued

Final provision	Description of revisions
§ 112.123(d)	—Revision to move “when necessary and appropriate” before “sanitize” to clarify applicability.
§ 112.124	—Revisions to delete the term “other contamination”, and replace “undesirable microorganisms” with “microorganisms of public health significance”.
§ 112.126	—Revision to eliminate proposed § 112.126(a)(3) and, instead, establish new provision § 112.126(b) requiring measures to prevent contamination of covered produce and food contact surfaces in buildings, as appropriate, considering the potential for contamination through floors, walls, ceilings, fixtures, ducts, or pipes, and drip or condensate.
§ 112.129	—Revision to clarify the required frequency of servicing and cleaning toilet facilities.
§ 112.130	—Revision to amend the list of examples of adequate drying devices (removing clean cloth towels and adding electric hand dryers).
	—Revision to use the term “antiseptic hand rubs” in lieu of “hand antiseptic/sanitizer or wipes”.
	—Revision to permit the use of “other effective surfactants” in lieu of soap.
§ 112.140	—No change.

We are finalizing the other provisions of subpart L as proposed. For §§ 112.127, 112.128, 112.131, 112.132, 112.133, and 112.140, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions.

A. Types of Buildings That Are Subject to the Requirements of Subpart L (§ 112.122)

(Comment 344) Some comments express concern with the applicability of the proposed provisions in subpart L to greenhouses (including high tunnels), germination chambers, or other protected environment production areas. A comment states that applying the proposed building requirements to greenhouses would negatively impact small farmers in areas without a warm climate for most of the year, such as in the North east, where farmers rely on greenhouses to grow produce throughout the year. Other comments contend that protected environment production areas enable farms to control various aspects of growing, such as humidity, temperature, or light, and believe it is highly improbable that a pathogen of public health significance would find its way into the controlled system.

(Response) The provisions in subpart L apply to any fully or partially-enclosed buildings used for covered activities, including greenhouses, germination chambers, or other such structures. These structures used for growing activities can create an enclosed system where potential hazards can be amplified (Ref. 202). Therefore, we do not agree that greenhouses, high tunnels, germination chambers, or “protected environment production areas” should be generally exempt from the standards in subpart L.

We do not discourage the practice of growing produce inside greenhouses,

germination chambers, or other such structures nor do we intend our requirements in subpart L to specifically impact small farms that use such structures for growing produce. Rather, our concern is to establish those procedures, processes, and practices that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. In response to these and other comments, we reviewed the provisions in subpart L to determine their appropriateness and practicability when applied to greenhouses (including high tunnels), germination chambers, and other such structures used for growing covered produce. We are deleting one provision in subpart L (*i.e.*, § 112.126(a)(3)) and replacing it with a new provision we believe is more appropriate to apply to all covered farm buildings, including greenhouses, germination chambers, and other such structures (see Comment 352).

(Comment 345) Some comments state many existing on-farm structures will likely not meet the proposed building requirements, and one comment additionally states there are no data available on the number or quality of on-farm buildings such as packing sheds and storage facilities.

(Response) We used available data sources to inform proposed provisions and our estimates of economic burden associated with the provisions in subpart L (Ref. 142). Under § 112.122(b), storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials) are subject to the requirements of subpart L. We believe it is important to apply the science-based minimum standards in subpart L to such buildings because contaminated food-contact surfaces can

contaminate covered produce (Ref. 203) and, thus, present a potential hazard.

B. Equipment and Tools (§ 112.123)

(Comment 346) Some comments recommend covered farms be allowed to clean equipment and tools as an alternative to the requirement related to storage and maintenance of equipment and tools in proposed § 112.123(b)(2).

(Response) We are establishing the requirement in § 112.123(b)(2) because appropriate practices for storing and maintaining equipment and tools can protect against contamination and reduce the potential for attracting or harboring pests, which can carry human pathogens. Pest harborage by equipment not only can contaminate the equipment; it can also increase the prevalence of pests near a building, and provide a place for them to live and breed. We have included sufficient flexibility in this requirement such that you may store equipment and tools in a manner that is practical but also protects against contamination and prevents attraction and harborage of pests. For example, you may satisfy this requirement by storing equipment indoors or outdoors, provided that the location appropriately protects against contamination and you appropriately minimize surrounding debris, check periodically for pests, and take any other measures reasonably necessary under the circumstances. Separate and distinct from this requirement regarding storage and maintenance is the provision in § 112.123(d)(1), which requires you to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities. This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools to covered produce. Appropriate storage, maintenance, and cleaning of equipment are all reasonably necessary to minimize the risk of produce

contamination, and we disagree that cleaning of equipment and tools alone should relieve a covered farm of the need for proper storage and maintenance of equipment and tools.

(Comment 347) Two comments question the applicability and practicality of the requirement to “sanitize” food-contact surfaces of equipment and tools under § 112.123(d)(1) with respect to the knife that cuts the asparagus below the ground if the part of the spear that the knife contacts is cut off before the spear is shipped to consumers. One comment acknowledges that asparagus was not covered under the 2013 proposed rule, and asks us to clarify what would be required with respect to sanitation of “asparagus boxes” containers, if asparagus were to be covered by the final rule.

(Response) We are establishing the requirement in § 112.123(d)(1) taking into account evidence that pathogens can be transferred to produce from contaminated coring devices and contaminated food-contact surfaces of tools (Ref. 204) (Ref. 205). We acknowledge that sanitizing all food-contact surfaces of equipment and tools used in covered activities is impractical, considering the wide range of equipment and tools used in covered activities and the diversity of produce growing, harvesting, packing, and holding practices. Therefore, in § 112.123(d)(1), we are requiring you to sanitize only when necessary and appropriate, but to always inspect, maintain, and clean all food-contact surfaces of equipment and tools used in covered activities, and to do so as frequently as reasonably necessary to protect against contamination of covered produce. As the commenter noted, asparagus is not covered under this rule because it is rarely consumed raw (see § 112.2(a)(1)).

(Comment 348) With respect to proposed § 112.123(d)(2) related to non-food-contact surfaces, some comments point out that non-food-contact surfaces (such as on trailers, tractors, and vehicles) are, by definition, not expected to come into contact with produce and, as such, are rarely designed to be cleaned to the same degree of cleanliness as food-contact surfaces. These comments request us either to provide clarification on how operations would be expected to implement this requirement or to delete this requirement.

(Response) As discussed in the 2013 proposed rule, the potential for equipment or a tool to come into contact with covered produce varies with the type and intended use of the equipment

or tool. Non-food-contact surfaces of tools and equipment used with covered produce can be sources of contamination. Therefore, it is important to maintain such surfaces of covered equipment and tools in a clean and sanitary condition. However, we acknowledge that such surfaces may not require cleaning as frequently as those that come into direct contact with produce, and also may not require sanitizing. Under this provision, you are required to maintain and clean all non-food-contact surfaces of equipment and tools used in covered activities during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce. We provide examples of equipment and tools subject to the requirements of subpart L in § 112.121.

In contrast to the requirements regarding food-contact surfaces in § 112.123(d)(1), the requirements related to non-food-contact surfaces in § 112.123(d)(2) do not require sanitizing such surfaces. As an example, the blades and conveyors in a harvesting machine that directly contact produce are considered a food-contact surface, but the portion of the truck that is used to hold boxes or crates containing harvested produce is not a food-contact surface. Likewise, the brush rollers on a sorting or grading machine where the rollers come in direct contact with the produce are food-contact surfaces, and must be inspected, maintained, and cleaned and, as necessary and appropriate, sanitized per § 112.123(d)(1). In contrast, a gear box attached to the rollers that does not come into contact with produce is a non-food-contact surface, and must be maintained and cleaned per § 112.123(d)(2).

C. Instruments and Controls Used To Measure, Regulate, or Record (§ 112.124)

(Comment 349) One comment generally supports proposed § 112.124. Another comment requests clarification regarding what is meant or intended by “other contamination”.

(Response) We are revising §§ 112.121 and 112.124 to delete the term “other contamination” and to replace “undesirable microorganisms” with “microorganisms of public health significance.” The requirements in this rule are intended to address microorganisms of public health concern and not all forms of contamination or undesirable microorganisms generally.

D. Equipment Used in the Transport of Covered Produce (§ 112.125)

(Comment 350) Some comments express concern that requiring cleaning of surfaces that come into contact with covered produce during their transport would be problematic for the watermelon industry. Comments state that harvest transportation from field to packing shed for watermelons is often done by using buses that are adapted for this purpose by, for example, covering the interior of the bus at the beginning of the season with either carpet or cardboard to cushion and protect the watermelons from damage and pathogen contamination from bruises or cuts that could occur during transport.

(Response) Section 112.125 is not prescriptive about the manner in which farms ensure that their equipment used to transport covered produce is adequately cleaned before use in transporting covered produce and is adequate for use in transporting covered produce. This provision requires covered farms to take measures to minimize the risk that equipment used during transportation becomes a potential source of contamination of covered produce. In the specific instance described in these comments, we expect the cushioning material(s) that comes into contact with the watermelons to be adequately cleaned prior to transportation and to be adequate for its intended use (meaning it must be cleanable or designed for single use, and unlikely to support growth or transfer of bacteria).

E. Buildings (§ 112.126)

(Comment 351) One comment states that, under proposed § 112.126, a cooler in a packing house would be required to have 18” of separation from the wall around the entire perimeter on the inside of the cooler, such that a 10,000 sq. ft. cooler might lose 5 percent of its floor space. This comment also notes that such a requirement would discriminate against smaller operations, and also create an unsafe working environment due to “free standing” stacks of bins.

(Response) Under § 112.126(a)(1)(i), buildings must provide sufficient space for placement of equipment and storage of materials. We are not establishing a precise amount of space needed for the placement or storage of materials, or a minimum distance required between an interior wall and any stacked bins or pallets. The intent of this provision is to ensure that buildings are spacious enough for the maintenance of sanitary operations and the conduct of covered activities. In the specific circumstance

described by the commenter, space between the bins or pallets and the interior wall is not necessary if the bins or pallets can be moved to allow for cleaning activities.

(Comment 352) Some comments express concern regarding proposed § 112.126(a)(3) requiring that buildings must be constructed in a manner such that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials. Comments note, by nature of the indoor growing process or cold-storage process, it would be impossible to prevent formation of condensate. Comments also note condensate sometimes is present in a produce growing room but that because growing rooms are cleaned and sanitized between each crop, the condensation does not come from an unsanitary surface and, therefore, poses no threat of contamination. Comments object to this proposed requirement particularly with respect to its applicability to certain types of buildings, such as greenhouses (including high tunnels) and cold storage buildings. Comments recommend excluding greenhouses (including high tunnels and low tunnels) and other season-extending, non-permanent structures used for growing, as well as cold storage buildings from coverage under proposed § 112.126(a)(3) and/or creating alternative standards, recognizing that condensation cannot be prevented in such buildings.

(Response) Proposed § 112.126(a)(3) would have applied equally to fully-enclosed structures used in growing activities as it would to storage sheds, packing sheds, barns, or other farm buildings used for packing or holding activities, and would have required that buildings be kept in good repair so as to prevent drip or condensate from pipes or ceilings to drop onto covered produce or food-contact surfaces. Upon review of these comments, we agree there is a need to incorporate flexibility in the implementation of this provision to account for differences inherent to certain covered activities conducted in fully- or partially-enclosed buildings. For example, condensation is a common occurrence in fully-enclosed buildings used for growing activities (such as greenhouses, including high tunnels, which are substituting for growing conditions in an open field), and may not represent a likely source of contamination of covered produce if produce is physically protected from condensate drip or the interior of the fully-enclosed building (such as walls and ceiling) where condensate is formed (and may drip onto covered produce) is

kept adequately clean. Similarly, condensation is a natural phenomenon during storage under high relative humidity conditions and if produce is physically protected from condensate drip or the interior of such cold-storage building is adequately clean, any condensate that forms on walls or ceiling is not likely to be a potential source of contamination. We are making revisions to the codified text so that a covered farm is required to take measures necessary to protect covered produce and food-contact surfaces from potential contamination from building surfaces such as floors, walls, ceilings, fixtures, ducts, or pipes, and generally through condensation or drip from these or other surfaces, rather than requiring farms to prevent condensation or drip contact with covered produce or food-contact surfaces.

We are deleting proposed § 112.126(a)(3) and replacing it with a new provision under § 112.126(b), which requires that covered farms implement measures to prevent contamination of covered produce and food-contact surfaces in the farm's buildings, as appropriate, considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) drip or condensate. For example, to comply with this provision, you must consider whether for your growing or storage practices in your buildings, the occurrence of drip or condensate presents a potential for contamination of your covered produce, and take measures to minimize or prevent that potential for contamination. Such measures include, for example, keeping buildings in good repair so as to prevent leakage of rainwater into the walls or ceilings of buildings, so that any drip or condensate from overhead pipes or ceilings that may drop onto covered produce or food-contact surfaces does not contaminate covered produce. Such measures also include adequately and regularly cleaning fixtures, ducts, or pipes inside the building where covered activities occur in order to minimize the presence or persistence of hazards, such as in biofilms, and the potential for contamination of covered produce.

(Comment 353) With respect to the requirement in proposed § 112.126(a)(3) that buildings must be constructed in a manner such that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair, one comment suggests that this requirement may preclude use of certain older barns, and further asserts that "modern" warehouses have been associated with foodborne illnesses.

(Response) It is not our intent to preclude the use of any specific types of buildings or barns; rather, we are establishing the provisions in subpart L to ensure that buildings used in covered activities are suitable and facilitate sanitary operations, and can be adequately cleaned and maintained to prevent contamination of the covered produce, food-contact surfaces, or packing materials. We are deleting § 112.126(a)(3) and replacing it with a new provision under § 112.126(b) that we believe is more appropriate to apply to all covered farm buildings (see our response to Comment 352). We have no data or information to suggest that large warehouse-like structures pose a greater risk of produce contamination compared to smaller barn-like structures, and the commenter provided no data to support this claim.

(Comment 354) One comment expresses concern that proposed § 112.126(a)(3) would require farms to prevent the pooling of water on the floor and lay out the crops in a manner that workers may move freely without their clothes touching the produce.

(Response) We are deleting proposed § 112.126(a)(3) and replacing it with a new provision under § 112.126(b); see Comment 352. Under § 112.126(a)(2), you must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. We acknowledge the potential for small pools of water to temporarily form on the floor of buildings used for growing activities, and that pooling of water of this nature, which is temporary and may occur in the normal course of watering practices, is not reasonably likely to contribute to the contamination of covered produce. We are not suggesting that it will always be possible to eliminate pooling. Avoiding pooling by careful control of greenhouse watering practices with consideration to your drainage system is ideal; however, to the extent pooling may be inevitable or may sometimes occur, despite adequate drainage, we expect covered farms to take steps to protect covered produce from any contamination that may build in the pooled water. Moreover, § 112.126(a), which addresses building design and construction requirements, does not impose any specifications regarding crop layout in buildings used for growing activities or establish measures for movement of workers within covered areas in a building. Rather, a covered farm is required to implement measures related to worker health and hygiene in accordance with subpart D of part 112.

F. Toilet Facilities (§ 112.129) and Hand-Washing Facilities (§ 112.130)

(Comment 355) A few comments note that it is not necessary for toilet facilities to be cleaned “on a schedule”, and request that § 112.129(b)(2) be revised to remove the reference to a schedule and require instead that they must be “serviced and cleaned at a frequency sufficient to ensure suitability of use.”

(Response) We intend for this requirement to provide flexibility for covered farms to determine the frequency of servicing necessary to keep the toilet facilities clean and suitable for use. We are revising this provision, as suggested by commenters, to make our intent more clear.

(Comment 356) One comment recommends that the requirements applicable to toilet facilities (in § 112.129) and hand-washing facilities (in § 112.130) should either simply reference OSHA field sanitation standards in 29 CFR 1928.110 or mirror those standards as closely as possible to avoid confusion and conflicting requirements.

(Response) The requirements for toilet and hand-washing facilities in §§ 112.129 and 112.130 are generally similar and consistent with the requirements in the United States Occupational Safety and Health Administration’s (OSHA) field sanitation standards in 29 CFR 1928.110, although the OSHA standards are more prescriptive in some provisions. For example, whereas we are establishing a general requirement that you must provide personnel with adequate, readily accessible toilet facilities, including facilities readily accessible to growing areas during harvesting activities (§ 112.129(a)), the OSHA standards include specific requirements on the number and proximity of such facilities. The field sanitation standards in 29 CFR 1928.110 specify that one toilet facility and one hand-washing facility must be provided for each twenty employees or fraction thereof (with additional exception) (paragraph (c)(2)(i)), and that the toilet and hand-washing facilities shall be located within a one-quarter-mile walk of each hand laborer’s place of work in the field (paragraph (c)(2)(iii)).

Nevertheless, we disagree that the toilet and hand-washing provisions in part 112 should simply refer to the field sanitation standards in 29 CFR 1928.110. Unlike the OSHA field sanitation standards, the requirements in §§ 112.129 and 112.130 relate specifically to the growing, harvesting, packing, and holding of covered

produce, with a focus on minimizing the risk of contamination of covered produce, food-contact surfaces, or areas used for a covered activity with human waste or by ill or infected workers. Moreover, the OSHA field sanitation standards apply only to an agricultural establishment where 11 or more employees are engaged on any given day in hand-labor operations in the field. (As defined in paragraph (b) of that regulation, hand-labor operations exclude those conducted in permanent structures such as in packing houses). It is not clear that this scope, established for the purposes of the OSHA field sanitation standards, sufficiently addresses the covered farms and covered activities defined in this rule for the purposes of produce safety standards. Therefore, we decline the request to simply refer to 29 CFR 1928.110 in lieu of establishing requirements for toilet and hand-washing facilities in part 112. Compliance with our provisions for toilet and hand-washing provisions in part 112 do not preclude compliance with OSHA field sanitation requirements, and we believe our requirements in part 112 can be met concurrently with those of OSHA field sanitation.

(Comment 357) According to one comment, hand-washing stations are typically located together with field toilets and, in the case of open fields, it would not be possible or realistic to have a hand-washing station located in a fully-enclosed building.

(Response) We are not requiring hand-washing stations to be located inside a fully-enclosed building. Rather, under § 112.129(c), during growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you are required to provide a hand-washing station that is in sufficiently close proximity to toilet facilities, such that it is practical for persons who use the toilet facility to wash their hands.

(Comment 358) One comment generally notes that employers must provide agricultural workers with necessary training, protective equipment, and hygienic supplies (such as enough clean bathrooms and hand-washing facilities) while working on the farm.

(Response) We agree that employers must provide agricultural workers with necessary training, and hygienic supplies while working on the farm. In this subpart L, we are finalizing provisions §§ 112.129 and 112.130 to establish requirements for toilet and hand-washing facilities, and in subpart

C of this rule, we are establishing requirements related to worker training.

(Comment 359) With respect to the provision related to hand-drying devices in proposed § 112.130(b)(3), one comment recommends that the use of “clean cloth towels” be limited to operations where only one person would be using the “clean cloth towel” to dry their hands. This comment notes that use of a “clean cloth towel” to dry multiple persons’ hands should not be allowed as this is likely to facilitate the transference of pathogens (if present) from one towel user to the next. An additional comment notes that the example of “clean cloth towels” listed as an adequate drying device conflicts with OSHA’s requirement of single-use towels. Finally, another comment requests that we provide for use of electric hand dryers because the quality of drying from these devices can be similar to paper towels.

(Response) Under OSHA’s field sanitation standards, a “hand-washing facility” means a facility providing a basin, container, or outlet with an adequate supply of potable water, soap and single-use towels (29 CFR 1928.110). In light of the OSHA definition and comments, we are revising § 112.130(b)(3), which requires that hand-washing facilities be furnished with adequate drying devices, to revise the examples of “adequate drying devices” to no longer include “clean cloth towels” because the repeated use of towels or use by multiple users can increase the potential for contamination (Ref. 103). We are also revising the list of examples to include electric hand dryers, which we agree can be adequate drying devices. We acknowledge that this provides additional flexibility compared to OSHA’s field sanitation standards; however, this provision does not prevent covered farms that are subject to this OSHA requirement from complying with the OSHA requirement. We also note that our list of examples is not intended to be exhaustive.

(Comment 360) With respect to the provision related to hand antiseptic/sanitizer in proposed § 112.130(d), some comments state that although hand antiseptic/sanitizer or wipes may not be a substitute for soap and water, this requirement prohibits the use of future innovation in hand sanitizers. Comments recommend revising this requirement to read “. . . as a substitute for soap and water unless validated by the manufacturer as effective for that purpose.”

(Response) As discussed in the 2013 proposed rule, “hand sanitizers” have not been found to be effective

substitutes for washing hands with soap and water, because the presence of dirt, grease, or soil reduces their effectiveness in eliminating bacteria. However, we are not prohibiting the use of antiseptic hand rubs because such products may be effective as an additional measure in reducing the number of bacteria on hands after proper washing with soap and water followed by drying. Should there be advancements in product development in this area, we will consider revisiting this issue in the future, as needed. We recognize, however, that effective surfactants other than soap may be used in lieu of soap during hand-washing, and we are revising § 112.130(d) to be consistent with § 112.130(b)(1), which we are retaining as proposed. We are also revising § 112.130(d) to use the term “antiseptic hand rubs” to collectively refer to leave-on antiseptic products, such as hand sanitizers or wipes.

G. Controlling Animal Excreta and Litter From Domesticated Animals (§ 112.134)

(Comment 361) One comment requests clarification on whether § 112.134 would allow cats and dogs to be present on produce farms if the

farmer can demonstrate reasonable precautions that can reasonably minimize the risk of their excreta contaminating covered produce.

(Response) You are permitted to have cats or dogs on your covered farm, provided that under § 112.134 you (1) adequately control their excreta and litter and (2) maintain a system for control of their excreta and litter. These measures are necessary to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with waste from your cats or dogs. In addition, you must comply with the requirements of § 112.127 regarding domesticated animals in and around a fully-enclosed building, and, when applicable, the requirements related to animals in subpart I.

XVIII. Subpart M—Comments on Sprouts

In subpart M of proposed part 112, we proposed to establish science-based minimum standards specific to the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that

are associated with serious adverse health consequences or death (in combination with the standards in other subparts of part 112 that also would apply to sprout operations). We tentatively concluded that it is necessary to incorporate this subpart establishing additional standards specific to sprouts because sprouts present a special concern with respect to human pathogens compared to other covered produce. We asked for comment on our proposed provisions in subpart M for sprouts, including on whether, or to what extent, the measures in this subpart should be applied to soil-grown sprouts; and on whether, in a final rule, a food safety plan and/or an operational assessment should be required for farms conducting covered activities related to sprouts, either in addition to, or in place of, the standards proposed in this subpart. We also requested comments on whether a supplier approval and verification program for seeds and beans intended for sprout production is practical and effective.

We are finalizing these provisions with several revisions (See Table 24). We discuss these changes in this section.

TABLE 24—DESCRIPTION OF REVISIONS TO SUBPART M

Proposed provision	Final provision	Description of revisions
§ 112.141	§ 112.141 § 112.142	—New section to describe the scope of subpart M. —Revision to combine all requirements for seeds and beans into § 112.142. —Revision to § 112.142(b) to include a requirement to discontinue use of a lot of seeds or beans that you know or have reason to believe may be contaminated with a pathogen due to association with foodborne illness or positive microbial test results and adding actions that must be taken with regard to a lot that may be contaminated. —Revision to establish in § 112.142(c) certain limited circumstances under which you are not required to take the steps set forth in § 112.142(b).
§ 112.142	§ 112.143	—Revision to summarize in this section all measures that need to be taken for growing, harvesting, packing, and holding, with relevant cross-references to other parts of subpart M. (We have added § 112.143(c) referring to testing requirements in § 112.144; § 112.143(d) referring to the written environmental monitoring plan required in § 112.145; § 112.143(e) referring to the actions you must take when <i>Listeria</i> spp. or <i>L. monocytogenes</i> is detected in the growing, harvesting, packing, or holding environment as required in § 112.146; § 112.143(f) referring to the written sampling plan required in § 112.147, and § 112.143(g) referring to the actions you must take when samples of spent irrigation water or sprouts test positive for a pathogen as required in § 112.148.) —Revision to move requirement for treating seeds and beans into § 112.42.
§ 112.143	§ 112.144	—Revision to clarify the soil-grown sprouts example in § 112.144(b)(2). —Addition of new § 112.144(c), and revision to § 112.144(b), to require additional pathogen testing when certain specified criteria are met.

TABLE 24—DESCRIPTION OF REVISIONS TO SUBPART M—Continued

Proposed provision	Final provision	Description of revisions
§ 112.144	§ 112.145	—Revision to clarify that you must aseptically collect environmental samples in § 112.145(d). —Addition of requirement in § 112.145(e) that your written environmental monitoring plan must include a corrective action plan that details the actions you will take if the environment tests positive for <i>Listeria spp.</i> or <i>L. monocytogenes</i> .
§ 112.145	§ 112.146	—New provision § 112.146(f) to indicate that you must take appropriate action to prevent any food that is adulterated from entering commerce.
§ 112.146	§ 112.147	—Addition of requirement in § 112.147(b) that you must not allow a production batch of sprouts to enter commerce until you receive negative pathogen testing results on spent sprout irrigation water or sprouts. —Addition of requirement in § 112.147(c) that your written sampling plan must include a corrective action plan if your spent irrigation water or sprouts test positive for a pathogen.
	§ 112.148	—New section to describe actions that must be taken if spent irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella spp.</i> , or a pathogen identified in accordance with § 112.144(c).
§ 112.150	§ 112.150	—Revision to § 112.150(b)(3) to clarify recordkeeping requirement related to written sampling plan for each production batch of sprouts in accordance with § 112.147(a) and (c). —Revision to § 112.150(b)(4) to require documentation of results of all analytical testing conducted to comply with subpart M. —Revision to § 112.150(b)(5) to clarify recordkeeping requirement related to any analytical methods used in lieu of methods incorporated by reference in §§ 112.152 and 112.153. —Elimination of proposed § 112.150(b)(6) as a corresponding change to final § 112.150(b)(5). —Addition of new provision (<i>i.e.</i> , final § 112.150(b)(6)) to clarify the recordkeeping requirement for actions taken in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

A. General Comments

(Comment 362) Several comments agree with FDA's proposal to establish additional standards specific to sprouts in subpart M. In contrast, one comment maintains that the proposed requirements for sprouts are unlikely to improve the safety of sprouts, and argues there is little known about the causes of sprout contamination and that many interventions, such as seed treatments, occur before sprouting whereas most pathogens of concern are introduced or proliferate during sprouting. Several comments also mention that additional research is needed to improve the safety of sprouts.

(Response) We are finalizing the rule with certain sprout-specific requirements in subpart M. We disagree with the comment arguing that little is known about the causes of sprout contamination. We have learned much in this area through extensive direct experience conducting inspections at sprout operations, as well as investigations to follow-up on foodborne illness outbreaks and/or positive sample findings. We also published guidances to industry (Ref. 97) (Ref. 206), and issued a letter to suppliers and distributors of seeds and beans to urge firms to review their

operations in light of our guidances and other available information (Ref. 207), and to modify their operations accordingly. FDA's 2014 sprouts assignment suggested that although many operations were taking some steps to implement at least some of the recommendations in our sprout guidances, this effort was not universal across sprout farms visited nor was it across all recommendations within a single operation (Ref. 208).

Sprouts have been frequently associated with foodborne illness outbreaks. Between 1996 and 2010, there were a total of 34 outbreaks, 2,150 illnesses, and 123 hospitalizations associated with sprouts (Ref. 26) (Ref. 27). Moreover, there have been an additional nine outbreaks associated with sprouts, accounting for 255 illnesses and 48 hospitalizations, between 2011 and 2014, including the first documented *L. monocytogenes* sprout outbreak in the United States that resulted in deaths (Ref. 28).

We have relied on available science and evidence to inform the development of the sprout-specific requirements in subpart M. For example, it is well-established that sprouts can become contaminated through the use of contaminated seeds for sprouting, and

we are aware of outbreaks associated with multiple sprout farms using the same lot of seed (Ref. 29). In addition, although treatment of seeds prior to sprouting does not guarantee pathogen-free sprouts, treatment can be expected to reduce the percentage of contaminated batches (Ref. 209) (Ref. 210). Therefore, we are including certain requirements applicable to seeds or beans used to grow sprouts to help prevent seeds and beans from serving as a vehicle for introducing contamination in sprouts. We are also requiring testing of spent sprout irrigation water (or production batches of sprouts) for certain pathogens, which is consistent with current recommendations in our guidances, and existing international guidelines and regulations (Ref. 23) (Ref. 211) (Ref. 212) (Ref. 213). Such testing is appropriate in addition to the seed treatment requirements because pathogens that are not eliminated by seed treatment could potentially grow out again when subjected to enrichment conditions, as experienced during sprouting (Ref. 21) (Ref. 23). We are also requiring testing the growing, harvesting, packing, and holding environment for *Listeria spp.* or *L. monocytogenes*. Contamination from *L. monocytogenes* from the environment is

common (Ref. 214) and, thus, targeted preventive controls to minimize *L. monocytogenes* in sprouts are warranted. While appropriate sanitation measures can minimize the presence of environmental pathogens in a sprouting operation, we conclude that environmental monitoring is still necessary for sprouting operations as an added safety measure. There have been positive sample findings and multiple recalls associated with *L.*

monocytogenes in sprouts (Ref. 215) (Ref. 216) (Ref. 217). Between 2002 and 2015, there have been 28 recalls involving multiple sprout types due to potential or confirmed contamination with *L. monocytogenes* (Ref. 218). In one of these recalls, the strain found in sprouts matched the strain isolated from 20 confirmed cases of Listeriosis in 6 States and positive sample findings from an environmental investigation at the sprouting operation (Ref. 215). Moreover, we are adding a requirement that sprout operations must not allow the production batch of sprouts to enter commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for certain specified pathogens (see § 112.147(b)). This requirement is consistent with current industry best practices (Ref. 219). Together with new § 112.148(a), this requirement will help ensure that sprout operations take appropriate steps to prevent contaminated sprouts from entering commerce.

We discuss these and other sprout-specific requirements in greater detail in this section. For additional information, see also sections II and V.M of the 2013 proposed rule.

The requirements in subpart M are consistent with recommendations in FDA's guidances (Ref. 97) (Ref. 206), industry guidance (Ref. 219), and international regulations and guidelines (Ref. 23) (Ref. 211) (Ref. 212) (Ref. 220).

We intend to promote and support additional research in this area, as needed. In addition, seeds have been the source of contamination in many, but not all, sprout outbreaks (Ref. 21) (Ref. 26) (Ref. 27) (Ref. 28)). Interventions applied before sprouting, such as those directed to seed, are meant to avoid, eliminate, or reduce pathogen load on seeds and, therefore, reduce the risk of pathogen proliferation during sprouting.

(Comment 363) Some comments ask whether microgreens would be subject to subpart M and/or to the general provisions of part 112. Some comments maintain that, because differences in the length of the growing period and practices followed for microgreen production result in a lower risk for cross-contamination than in sprout

production, microgreens should not be subject to requirements directed to sprouts. Other comments suggest microgreens are a ready-to-eat produce item that is growing in popularity and could carry risks similar to sprouts.

(Response) Subpart M applies to the production of all types of sprouts, including alfalfa, clover, and mung bean sprouts, except for soil-grown sprouts harvested without roots (see Comment 364). FDA agrees that microgreens and sprouts are different products. Our longstanding guidances to industry on sprouts do not list microgreens as sprouts. This interpretation is also consistent with other public and private standards, e.g., the IFSH Sprout Taskforce sprout-specific audit check list and the Food Safety Australia New Zealand (FSANZ) standards for sprouts. In addition, in the 2013 proposed rule discussion of potential differences in practices and risk factors related to soil-grown versus hydroponically-grown sprouts, we did not specifically mention microgreens because we do not consider microgreens to be sprouts. Historically, the primary criterion FDA has used to distinguish between the two product categories has been the growth stage of the leaves (Ref. 221). Sprouts are usually harvested when the cotyledons (or seed leaves) are still un- or under-developed and true leaves have not begun to emerge. In contrast, microgreens reach a later stage of growth, typically associated with the emergence of "true" leaves. Microgreens are also typically grown in soil or substrate and harvested above the soil or substrate line. Because microgreens are not sprouts, they are not subject to the requirements in subpart M. However, microgreens are considered "covered produce" for the purposes of this rule and, unless exempt or excluded under the provisions in subpart A, microgreens and microgreen farms are subject to all other subparts of part 112.

Additional research would be helpful to better define the risk profile of microgreens that are grown using conditions similar to those of sprouts (i.e., warm, moist, and nutrient-rich media) (Ref. 222). To the extent the specific microgreen production practices may present risks similar to those associated with sprouts, we encourage microgreen operations to consider voluntarily implementing the standards in subpart M, in addition to complying with the required provisions of part 112.

(Comment 364) Some comments seek clarification on whether soil-grown sprouts are covered under subpart M. One comment maintains that measures described under subpart M should be

applied to both soil-grown and hydroponically-grown sprouts. This comment states that, although they are not aware of any outbreaks associated with sprouts grown in soil or media, contaminated soil has been a concern in the context of other produce commodities. In contrast, one comment requests different standards for soil-grown sprouts, and states that FDA should require that sprouters take steps to minimize cross-contamination between hydroponic and soil-grown sprouts.

(Response) Soil- or substrate-grown sprout shoots that are harvested above the soil or substrate line, such that their roots are not harvested for human consumption, do not present the same risks as other types of sprouts and we are therefore excluding them from coverage under subpart M. We have added new § 112.141 to address this. New § 112.141 states that the requirements of subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots. However, soil- or substrate-grown sprouts harvested above the soil line are "covered produce" and, unless exempt or excluded under the provisions of subpart A, are subject to all other applicable requirements of part 112.

We believe the potential risks are sufficiently different between sprouts where the entire plant is consumed and sprout products that are harvested without the roots (Ref. 223) (Ref. 224). Microscopic examination of sprouts has been reported to show that pathogens target root hairs of sprouts for colonization, with presence of few viable cells elsewhere on the sprout, which indicates that root hairs provide a niche for pathogen proliferation (Ref. 224) (Ref. 225). Therefore, we do not see the need to apply the additional sprout-specific safety standards in subpart M to soil- or substrate-grown sprouts that are harvested above the soil or substrate line. However, we are applying the requirements of subpart M to soil- or substrate-grown sprouts that are harvested with the roots. We also agree that all hydroponically grown sprouts should be covered under subpart M. Under typical conditions for growing hydroponic sprouts, water runs through sprouts in the same growing unit, and any pathogens present in the seed or sprouting seed can spread throughout the production lot of sprouts (Ref. 21) (Ref. 226) (Ref. 227).

To avoid any confusion about the applicability of subpart M to soil- or substrate-grown sprouts, we are also revising the term "soil-grown sprouts"

used as an example in proposed § 112.143(b)(2) so that the example now refers specifically to “soil-grown sprouts harvested with roots” in final § 112.144(b)(2). To the extent production practices for soil- or substrate-grown sprouts that are harvested above the soil or substrate line may present risks similar to those associated with other sprouts, we encourage such operations to consider voluntarily implementing the standards in subpart M, in addition to complying with the required provisions of part 112. We are also including, in the examples in renumbered § 112.144(b)(2), “hydroponically grown sprouts that use very little water,” as another example for which testing spent sprout irrigation water may not be practicable such that you may, therefore, test each production batch of sprouts at the in-process stage (*i.e.*, while sprouts are still growing) for *E. coli* O157:H7 and *Salmonella* spp. in accordance with the requirements of § 112.147.

The potential for soil or substrate to be a source of contamination in a soil- or substrate-grown sprout operation is a valid concern, and we agree with comments stating that measures must be taken to minimize the risk of the soil or substrate serving as a source of contamination, for either sprouts grown in the soil or substrate, or for other produce that may be grown or handled at the sprout operation. We are establishing minimum science-based standards directed to biological soil amendments of animal origin and human waste under subpart F of part 112, which are applicable to all covered produce, including soil- or substrate-grown sprouts (however they are harvested).

(Comment 365) Some comments question whether wheatgrass would be covered under subpart M as a sprout, particularly since the seed is not consumed whether grown hydroponically or in a medium.

(Response) Sprouts, as a category, include many varieties, including wheatgrass. Wheatgrass has long been considered a sprout within the industry. For example, it was considered a sprout in the NACMCF recommendations (Ref. 21), the Sprout Testing Guide, and the FDA/CDPH sprout video (Ref. 228). We consider it a sprout for purposes of this rule and in particular for the application of subpart M of this rule. However, wheatgrass is typically grown in soil or substrate and harvested above the soil or substrate-line, and in those circumstances, it is not subject to subpart M.

(Comment 366) One comment requests that we subject small onions

that are thinned from a starter tray to the requirements of subpart M.

(Response) We understand that some operations use a starter tray, where seeds are sown thickly, and then weaker seedlings are thinned out, providing the stronger seedlings with more space to grow. When small onions are grown in starter trays, some operations discard the produce resulting from the first thinning and others sell that produce for use as food. In terms of potential hazards associated with production, such produce is akin to soil- or substrate-grown sprouts that are harvested above the soil line or to microgreens, both of which we are not subjecting to the requirements of subpart M. Therefore, we conclude that small onions grown in flats should not be subject to the requirements of subpart M, and we are not subjecting them to the requirements of that subpart. Such produce is subject to the other requirements of part 112, as applicable, however.

B. Seeds or Beans Used To Grow Sprouts (§ 112.142)

These requirements were proposed as § 112.141. We have now renumbered this section as § 112.142 as a consequential change from the addition of new § 112.141.

(Comment 367) Pointing out that seeds are often the source of contamination for sprouts, several comments argue that proposed subpart M lacks sufficient emphasis on the origin of seeds, their traceability, and the growing and production of seeds intended for sprouting. One comment suggests that seeds destined for sprouting should be labeled as such with the seed producer’s name and full address. Some comments maintain that seeds and beans should be covered under the produce safety regulation, and that FDA should require seeds to be grown and produced under good agricultural practices and specifically for sprouting for human consumption, rather than being potentially sourced from fields where the seeds were intended to be directed toward animal feed production. Several comments also support a requirement for a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes (including seed lot testing and use of a HACCP approach). In this regard, one comment suggests FDA should require documentation of the processes that the seeds are subjected to during their cleaning and preparation for sale while another argues that unless seeds from a particular crop or variety can be produced in a safe manner, industry

should be required to cease production of sprouts from that crop or variety.

(Response) Since 1999, FDA has taken a number of steps to provide guidance to the sprouts industry, including those involved in the growing and production of seeds (78 FR 3504 at 3509). In developing this rule, FDA has carefully considered the growing and distribution of seeds for sprouting. As noted in the 2013 proposed rule, various crops may be grown to produce seeds and beans for sprouting with different production practices, growing seasons, conditions, and crop needs. Harvesting, packing, and holding may also vary by seed type and by the conditions needed to maintain seed quality, such as germination. Because of the diversity of practices, processes, and procedures, the controls reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that are used for sprouting may vary. Therefore, we did not propose to prescribe specific provisions to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans during growing, harvesting, conditioning, or holding. Instead, we referred to our recommendations in relevant guidances, including the GAPs Guide (78 FR 3504 at 3595).

In the 2013 proposed rule, we considered proposing a supplier approval and verification program for seeds and beans received by sprout operations for sprouting purposes. Such a program would provide assurance that seeds or beans received from a third party for use to grow sprouts are grown, harvested, stored, and handled using measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting. However, we also noted that a supplier approval and verification program may not be practical or effective for seeds and beans received by sprout operations for sprouting purposes because, for most crops, only a small percentage of the harvested seeds or beans is used for sprout production. In addition, seeds and beans often pass through a number of business entities before their final sale. Therefore, the ultimate end use of seeds and beans will likely not be known by many growers, handlers, or distributors (at 78 FR 3504 at 3595–3596).

Information we have received subsequent to the 2013 proposed rule suggests that seed distributors may request that their seed growers and handlers provide assurance, through the use of agreements, that safe growing and handling practices are employed during

the growing, harvesting, conditioning, storage, handling, and transportation of the seeds that the distributor will sell to sprouting operations (Ref. 229). In addition, we believe that proposed § 112.141(a) would not have been effective at addressing hazards associated with the growing of seeds or beans used for sprouts because few, if any, sprout operations in the United States grow their own seeds or beans but instead, receive the seeds or beans from other entities, such as seed growers or distributors (Ref. 230). It is important that this rule includes measures to prevent the introduction of known or reasonably foreseeable hazards into seeds or beans that are used for sprouting. Therefore, and in light of information that sprouting operations typically receive (rather than grow their own) seeds or beans, we are revising proposed § 112.141(a), renumbered as § 112.142(a), to require the sprout operation to take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that they will then use for sprouting regardless of whether the sprouter also grew the seeds or beans.

Measures required under renumbered § 112.142(a) include, for example, keeping the seed storage area clean and dry, and dedicated to seed storage. Seed containers must be tightly covered or closed, stored off the floor and away from the walls, clean, identified with lot numbers, and, for reusable containers, emptied, cleaned, and sanitized between uses. Sprout operations must also complete a visual examination of seeds/beans and their packaging upon receipt and prior to use for potential contamination (e.g. visual exam and/or black light/UV exam of seed bags for evidence of insects, rodents, or other contamination).

As noted previously, we also asked for comment on a seed supplier program. While we believe that the agreements and assurances made between seed suppliers and other entities in the supply chain providing assurances that the seeds and beans have been grown and handled under good agricultural practices and that seeds that may be used for sprouting have been conditioned, stored, and transported in a manner that minimizes the likelihood that the seeds will be contaminated with pathogens, are valuable, we are not requiring that sprouters request, receive, or provide such agreements and assurances. We recommend these practices, consistent with recommendations in our 1999 guidance to industry, "Reducing Microbial Food Safety Hazards for

Sprouted Seeds," (the Sprout Guide) and recommendations or requirements by other competent authorities (Ref. 211) (Ref. 212) (Ref. 231), and are encouraged that some comments indicated that this is already happening. However, we do not believe that it is currently feasible for all seeds and beans used for sprouting to be produced under GAPs, particularly when the vast majority of seed is not produced for such use. If the situation changes, we may revisit this in the future. The other requirements in § 112.142 also address potential contamination in seeds and beans.

(Comment 368) Several comments state that sprout operations should not use sprouts if they have reason to believe that a lot of seeds or beans has been associated with foodborne illness. Comments also request that FDA further clarify that if a farm has reason to believe that a lot of seeds has been contaminated with a hazard likely to cause foodborne illness, the farm should not use that lot to produce sprouts, regardless of whether that contamination has caused illness. In this regard, one comment explains that farms will be unable to accurately and reliably assess whether a particular batch of seeds has been linked to consumer illness. Finally, one comment expresses concern with requiring sprout operations to discontinue use of a seed lot found to be contaminated through microbial testing. This commenter poses several questions regarding follow-up actions that a sprouter may have to take in response to a positive test finding.

(Response) Proposed § 112.141(b), now renumbered as § 112.142(b), focuses on reasonably necessary measures when it is known or there is reason to believe that a lot of seeds or beans that will be used for sprouting is contaminated. As proposed, § 112.141(b) would have required that if you know or have reason to believe that a lot of seeds or beans has been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts. As discussed in the 2013 proposed rule, we concluded that once you know or have reason to believe that a lot of seeds or beans is contaminated, through microbial testing or implication as the vehicle in an outbreak, there is reason to believe that other parts of that lot may also be contaminated, and you must not use that lot of seeds or beans to produce sprouts (78 FR 3504 at 3596). We are revising this section to make clear that relevant knowledge or reason to believe seeds or beans may be contaminated may be based either on an implication of the seeds or beans in a foodborne

illness outbreak or on a positive microbial test result, including a finding made after testing spent sprout irrigation water or sprouts. For example, section 112.144(b) requires testing of spent sprout irrigation water from each production batch of sprouts or, if such testing is not practicable, testing of each production batch of sprouts at the in-process stage. In either circumstance, *i.e.*, through implication in an outbreak or through microbial testing (including that required under § 112.144(b)), the information gathered is sufficient to indicate that the lot of seeds or beans *may* be contaminated and there is reason to believe that other parts of that lot *may* also be contaminated. Therefore, we continue to believe that it is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into sprouts that you discontinue use of all seeds or beans from that lot for sprout production (§ 112.142(b)(1)). We are also expanding the duties you have under § 112.142(b) beyond simply not using the seeds or beans to produce sprouts, to include ensuring that sprouts grown from that lot of seeds or beans do not enter commerce (§ 112.142(b)(1)), and reporting the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans (§ 112.142(b)(2)). Since the lot of seeds or beans may be contaminated, it is critical to discontinue use of the seeds and beans for sprout production for human consumption and ensure that sprouts grown from that lot do not enter commerce. Other national or international standards, too, require or recommend discontinuing use of a lot of seeds or beans that may be contaminated and is likely to present a health hazard (Ref. 23) (Ref. 211) (Ref. 212).

It is also important that the sprout operation report the findings to the entity (seed grower, distributor, or supplier) that supplied the seeds or beans so that the seed grower, distributor, or supplier, upon receiving such information, could then take appropriate follow-up actions, which may include reporting the finding to other buyers of the suspected lot of seeds or beans, destroying or diverting any remaining seed or beans to other uses, including non-food uses and/or investigating the potential source of contamination, as necessary. In such circumstance, where applicable, the seed grower, distributor, or supplier may be required to submit a report to the Reportable Food Registry (RFR), in

accordance with section 417 of the FD&C Act (21 U.S.C. 350d), which requires responsible parties for food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to report certain information to FDA when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

In addition, we are adding two provisions under new § 112.142(c) that apply only if your reason for believing the lot of seeds or beans may be contaminated is based only on microbial test results. First, we are providing that you do not have to take the steps in § 112.142(b)(1) if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans (may also be referred to as a “pasteurization” step) (§ 112.142(c)(1)). We are including this option to allow sprout farms flexibility in responding to a finding that would otherwise mean they would have to discontinue use of the seeds and to encourage future innovation in seed treatment processes. However, we note that processes that meet the description in (c)(1) are not currently commonly used in the sprouting industry. Such processes are far more robust than the seed treatment processes described in § 112.142(e) because the seed treatments described in § 112.142(e) typically only reduce microorganisms of public health significance (these treatments do not eliminate or destroy pathogens), and are therefore part of a multi-hurdle risk reduction framework that also includes spent irrigation water or sprout testing for pathogens on a lot by lot basis. Irradiation is an example of a process that may be able to meet the description in § 112.142(c)(1).

Second, we are adding new § 112.142(c)(2) to provide that you do not have to take the steps in § 112.142(b)(1) and (2) if you later reasonably determine through appropriate follow-up actions that the lot of seeds or beans is not the source of contamination (for example, the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

We expect that the situations in which you could take follow-up actions that would be adequate to make a reasonable determination that the lot of seeds or beans was not the source of the contamination are not extensive. However, the following are examples of

situations in which we believe such a determination might be appropriate:

1. Seed lot A is recalled by the seed supplier due to contamination with *Salmonella* while an operation has sprouting in process with that seed lot. The sprout operation immediately stops production of sprouts using seed lot A, disposes of the sprouts and returns unused seed to the distributor. The sprouts operation cleans the equipment and starts using the same equipment to grow another batch of sprouts using seed lot B. Spent irrigation water from the next lot of sprouts using seed lot B then tests positive for *Salmonella*, and follow-up sample analysis shows the same *Salmonella* serotype that was identified as contaminating seed lot A. The sprout operation discovers that cleaning and sanitizing protocols were not followed properly following sprout production using seed lot A, and swabs the equipment and finds a matching *Salmonella* serotype on the equipment that had been used to sprout both seed lots A and B. After adequately and thoroughly re-cleaning and sanitizing the equipment and re-testing food-contact surfaces for *Salmonella* with negative results, the sprout operation starts a new production batch of sprouts using seed lot B as a follow-up action to the positive test result to determine whether seed lot B may also be contaminated. The second time, all spent irrigation water tests from seed lot B sprouts come back negative. In this circumstance, the sprout operator could reasonably conclude that seed lot A had contaminated the equipment, which was not initially adequately cleaned and sanitized and therefore contaminated the first batch of sprouts produced from seed lot B. If the farm is following appropriate follow-up sanitation procedures, spent irrigation water from seed lot B is no longer testing positive for *Salmonella*, under these circumstances the farm may reasonably conclude that seed lot B was not the source of contamination that generated the positive test result when testing spent irrigation water from seed lot B sprouts. We note that in general a negative test for seeds or spent irrigation water would not, by itself, be enough evidence that seed lot B was not contaminated. However, in this example, the seed supplier's *Salmonella* serotype result from seed lot A that matches serotype found in the positive spent irrigation water sample and the swab from equipment used to sprout seed lot B, combined with the improper cleaning and sanitizing of equipment, negative subsequent test results, and the intervening improvements in cleaning

procedures, supports the conclusion that the positive spent irrigation water sample from sprouts made with seed lot B was most likely due to contamination of shared production equipment with seed lot A.

2. A sprout operation mixes two seed lots (lot A and B) together to result in a mixed sprout product for which the spent irrigation water tests positive for *Salmonella*. The sprout operation could sprout each seed lot individually. If upon follow-up serotype sample analysis, spent irrigation water from only one seed lot (lot A) tests positive for *Salmonella* matching the original positive, the sprout operation could reasonably determine that seed lot A was the source of the *Salmonella* positive in spent irrigation water from the mixed seed sprouts. The sprout operation would be required to discontinue use of all seeds from the affected seed lot for sprout production (unless it treats the seed lot in accordance with § 112.142(b)(1)), ensure that sprouts grown from that seed lot do not enter into commerce, and report the information to the grower, distributor, supplier, or other entity from whom the farm received the seeds, in compliance with § 112.142(b). Under § 112.142(c), the sprout farm could continue to use seed lot B, provided there were no subsequent positive test results and no information suggesting association of that seed lot with foodborne illness.

We recognize that there may be other microbial testing through which you may conclude that a lot of seeds or beans is contaminated. For example, testing of seeds (although not required under this rule) using statistically valid sampling and testing protocols may lead you to conclude that seeds or beans are contaminated. Information of this kind triggers the requirements in § 112.142(b) and requires farms to discontinue use of all seeds or beans from that lot, ensure that sprouts grown from that lot of seeds or beans do not enter commerce, and report the information to the grower, distributor, supplier, or other entity from whom the farm received the seeds.

Although we believe there may be follow-up actions that could allow a sprout operation to determine that a lot of seeds or beans that had been associated with a positive microbial test result from testing spent sprout irrigation water or sprouts at their operation (required under § 112.144(b)) were not the source of contamination, we do not believe the same is true of a lot of seeds or beans that have been associated with a foodborne illness. We are not aware of actions that a sprout farm could take to demonstrate that the lot of seeds or beans was not the source

of contamination following an outbreak of foodborne illness. A sprout farm, along with regulators, may make a determination that the farm's seeds or beans were not associated with a foodborne illness outbreak, but it is unlikely that the sprout farm would have adequate information (e.g., epidemiological data and traceback information) to make that determination independently. Therefore, we are not providing a similar option to § 112.142(c) applicable in instances where there is knowledge or reason to believe that a lot of seeds or beans has been associated with foodborne illness.

(Comment 369) One comment asked whether, in sprout production, sampling and testing can be properly defined as a process control, or whether it should be defined simply as a confirmation that a process control has worked as intended. The comment maintained that if sampling and testing is a process control then a positive test may not be grounds for discontinuation of a seed lot since the control worked as intended.

(Response) In the case of sprouts, sampling and testing of spent sprout irrigation water can be viewed as both a verification of a process control (e.g. of seed treatment) as well as a process control itself ("hold and release" testing that is used to prevent a contaminated lot from entering commerce (see § 112.147(b)). Even if a sprout operation's spent irrigation water testing is effective and identifies pathogen-positive lots of sprouts where seed treatment failed to eliminate a pathogen, the fact remains that seed is most often the source of contamination and that current seed treatments cannot guarantee the elimination of pathogens on seed. Currently available seed treatments typically reduce, but do not eliminate, pathogen presence on seeds, and these pathogens could potentially multiply when subjected to enrichment conditions, such as those experienced during sprouting. We view spent irrigation water sampling and testing as an additional reasonably necessary food safety measure to help ensure that contaminated product is not marketed. This measure is consistent with FDA's Sprout Testing Guide and also consistent with the Codex Guide. See also revised and renumbered § 112.142 and new § 112.148.

(Comment 370) Some comments request that FDA either specify "pathogens of concern" that are the most often associated with foodborne illness linked to sprouts (e.g., *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes*) in proposed § 112.141(a), or add language such as "contaminated with a hazard likely to

cause foodborne illness" to that provision.

(Response) For the purposes of the produce safety regulation, in § 112.3, we define "hazard" to mean "any biological agent that has the potential to cause illness or injury in the absence of its control" and "known or reasonably foreseeable hazard" to mean a hazard that is known to be, or has the potential to be, associated with the farm or the food. Given these definitions, we believe it is not necessary or appropriate to specify "hazard likely to cause foodborne illness" within § 112.142(a). We also do not believe it necessary or appropriate to list specific pathogens of concern or those most often associated with sprout-related illness outbreaks in lieu of the phrase "known or reasonably foreseeable hazards" in § 112.142(a). Although we agree that *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* have been most often implicated in sprout-related illness outbreaks, there may be other biological agents with the potential to cause illness or injury that may be associated with the sprouting farm or sprouts. We conclude that we should not restrict the scope of hazards that are expected to be controlled under this provision. See discussion under Comment 375 of other pathogens that have been associated with sprouts.

(Comment 371) One commenter believes that seed suppliers should be required to test seed for the presence of pathogens using statistically valid sampling and testing protocols and to provide sprout operations with a Certificate of Analysis for the seeds and beans, despite the recognized limitations of testing.

(Response) We considered and tentatively rejected this approach in the 2013 proposed rule, and the commenter did not provide any new information suggesting we should change our conclusion. We recognize that at least one other competent authority has established microbiological criteria and requirements for testing all batches of seeds intended for sprouting (i.e., European Commission Regulation No. 2073/2005). However, as explained in the 2013 proposed rule, although epidemiological investigations often identify seeds and beans as the most likely source of contamination, contamination may be at very low levels (4 CFU/kg seed) (Ref. 21) and laboratory analyses have frequently been unable to isolate pathogens from implicated seeds or beans (Ref. 223). Nevertheless, we recognize that a positive test result can detect contaminated seeds and beans even though a negative test result is not a guarantee of the absence of pathogens. Therefore, we encourage seed suppliers

and sprouters to test seed using statistically valid sampling and testing protocols. However, we continue to believe that testing seeds and beans is not sufficiently reliable to require it as a measure necessary to prevent the introduction of known or reasonably foreseeable hazards into sprouts.

C. Growing, Harvesting, Packing, and Holding Sprouts (§ 112.143)

These requirements were proposed as § 112.142. We have now renumbered this section as § 112.143 as a consequential change from the addition of new § 112.141. For purposes of clarification, we are revising final § 112.143 to summarize under this section the various measures related to the growing, harvesting, packing, and holding of sprouts required in this subpart M, with relevant cross-references to other sections of subpart M. Thus, we have added § 112.143(c) referring to testing requirements in § 112.144; § 112.143(d) referring to the written environmental monitoring plan required in § 112.145; § 112.143(e) referring to the actions you must take when *Listeria* spp. or *L. monocytogenes* is detected in the growing, harvesting, packing, or holding environment as required in § 112.146; § 112.143(f) referring to the written sampling plan required in § 112.147, and § 112.143(g) referring to the actions you must take when samples of spent irrigation water or sprouts test positive for a pathogen as required in § 112.148.

In addition, because the requirement for seed treatment proposed as § 112.142(c) establishes standards applicable to seeds and beans used for sprouting, it fits more directly under final § 112.142 rather than under final § 112.143 (which was proposed as § 112.142). Therefore, we are moving this provision, as revised, into renumbered final § 112.142 and finalizing it as § 112.142(e). We discuss other changes to this provision in response to Comment 368.

(Comment 372) Several comments agree with our proposed requirement for sprout operations to treat seeds or beans used for growing sprouts, and that prior treatment would not eliminate the sprout farm's responsibility for treatment immediately before sprouting. A number of these comments encourage FDA to support research to determine effective means of seed treatment prior to sprout production. Some comments express concern that this rule may require treatment of seeds using extremely high levels of chlorine (e.g., 20,000 ppm), and recommend allowing alternative effective treatments. One commenter believes seed treatment

resulting in at least a 3-log pathogen reduction should be required. Another comment suggests using the term “disinfect” rather than “treat” when referring to seed treatments. Some comments also ask that FDA not require seeds to be treated immediately before sprouting, and urge FDA to create an information-sharing portal where sprout farms can share valid treatment and testing methods and data to better inform the sprout community. Another comment requests that FDA reconsider allowing for the use of “proprietary research” to determine the scientific validity of seed treatment. Finally, one comment suggests that FDA require seeds used for sprouting to be irradiated by the seed supplier, noting that this sprout operation’s foreign seed supplier currently treats seeds in this manner.

(Response) We are retaining the term “treat” when referring to seed treatments because of its longstanding use in our guidances to industry and common use within the sprouts industry. Moreover, because most current seed treatments cannot guarantee the elimination of pathogens, we conclude that the term “disinfect” would not be an appropriate description. (See also Comment 368 comparing most current treatment processes to more robust treatments processes that are reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans).

FDA has been working independently and in collaboration with others to develop a framework to conduct research on effective seed treatments, and we will support a variety of mechanisms to make this information available to sprout farms. For example, we are working through the SSA to facilitate development of an educational curriculum and sharing of best practices among sprout farms. We acknowledge that a number of treatments have been shown to reduce levels of, but not eliminate, pathogenic bacteria present on seeds. Such treatments are likely to reduce the level of contamination if present and, in turn, decrease the risk for foodborne disease with sprouted seeds (Ref. 21). We cited 20,000 ppm calcium hypochlorite treatment in the Sprout Guide and in the 2013 proposed rule as an example of a treatment that has been shown to be effective for the reduction of pathogens. However, § 112.142(e) (proposed § 112.142(c)) allows you to use any scientifically valid method to treat seeds or beans that will be used to grow sprouts. We are also not precluding the use of

proprietary seed treatments. We would expect a farm using a proprietary seed treatment to take steps to ensure that it is in compliance with all relevant laws, including FIFRA, if applicable, and to ensure that its treatment is effective in reducing pathogens on seed. In the event of an inspection or investigation of a sprout operation, we may ask to review the science supporting the use of the proprietary treatment to ensure the scientific validity of the treatment.

We use the term “scientifically valid” in this rule to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Our use of proprietary research in this context is consistent with our considerations in other rulemakings (see Current Good Manufacturing Practice Requirements for Dietary Ingredients and Dietary Supplements; 68 FR 12157 at 12198).

Under proposed § 112.142(c), we proposed to require sprout operations to treat seeds or beans using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. We have since conducted a thorough review of currently available treatment methods as well as treatment methods under development and evaluation. Based on this review, we conclude that there are treatment methods that can be effectively applied by a grower, handler, or distributor of seeds or beans such that, when followed by good handling and packaging procedures, they can eliminate the need for follow-up treatment of the seeds or beans at the farm immediately before sprouting (Ref. 232). For example, as suggested by a commenter, irradiation is an option for seed treatment that could be applied by a seed supplier, handler, or distributor to reduce microorganisms of public health significance that may not be feasible for a sprout farm to apply on-site. In addition, hot water treatments have been demonstrated to reduce pathogens on seeds by more than 5 log CFU/g in one study (Ref. 233) and to undetectable levels in another (Ref. 234). However, these treatments can require use of equipment such as industrial-sized hot water pasteurization machines (Ref. 235) that might be cost-prohibitive for a small sprout farm. Therefore, in final § 112.142(e)(1), we are removing the requirement to treat seeds or beans used for sprouting “immediately before sprouting” as well as the provision that stated “prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to

treat seeds or beans immediately before sprouting at your covered farm.” We are also adding § 112.142(e)(2) to explicitly allow covered sprout farms to rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered sprout farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier of the seeds or beans that (i) the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and (ii) the treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

Finally, as discussed previously, because this provision establishes standards applicable to seeds and beans used for sprouting, it fits more directly under final § 112.142 rather than under final § 112.143 (which was proposed as § 112.142). Therefore, we are moving this provision, as revised, into renumbered final § 112.142 and finalizing it as § 112.142(e). In addition, we are revising the corresponding recordkeeping provision in § 112.150(b)(1) to require you to establish and keep documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e).

D. Testing During Growing, Harvesting, Packing, and Holding Sprouts (§ 112.144)

These requirements were proposed as § 112.143. We have now renumbered this section as § 112.144 as a consequential change from the addition of new § 112.141.

(Comment 373) Some comments suggest that FDA issue through guidance, rather than in regulation, recommendations to test for pathogens that have been linked to a sprout outbreak causing human illness. Other comments support our proposed requirements for environmental testing

and testing of spent sprout irrigation water or sprouts.

(Response) In developing the proposed provisions of subpart M, we tentatively concluded that testing the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* is a necessary measure to ensure the safety of sprouts. We also tentatively concluded that testing spent sprout irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* spp. is a necessary measure to ensure the safety of sprouts. Given the outbreaks associated with sprouts and these pathogens, we are finalizing our conclusion that requiring this testing is warranted. These comments did not provide information that would change our conclusion.

(Comment 374) Some comments state that requiring testing for *Listeria* at the genus level does not confirm the presence of a pathogen of interest and, therefore, recommend that FDA require testing for *Listeria* at the species level. In contrast, one comment states that frequent testing for *Listeria* would be expensive, arbitrary, and difficult to implement. The comment recommends that we instead require initial swab testing for *Listeria*, followed by a program of testing and cleaning until repeated tests are negative and, as an alternative, suggests that routine cleaning of equipment and facility inspections should be sufficient for controlling *Listeria*.

(Response) The purpose of environmental monitoring is to verify the adequacy, or lack thereof, of cleaning and sanitizing practices through monitoring for the presence of pathogens in the environment and, if pathogens are present, to eliminate or minimize their presence and prevent transfer of pathogens to food-contact surfaces or to sprouts where they might cause illness. Testing for either the pathogen directly or an indicator organism facilitates accomplishing these objectives and, therefore, we are providing for the option to either directly test for *L. monocytogenes* (pathogen) or for an indicator organism (*Listeria* spp.). As discussed in the scientific literature, the term "indicator organism" means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 236). *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes* because tests for *Listeria* spp. will detect multiple species of

Listeria, including *L. monocytogenes* (Ref. 237) (Ref. 238), and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for *Listeria* spp., have public health benefits (Ref. 239) (Ref. 240). With regard to the suggestion for initial swab testing with repeated cleaning until negative findings, we agree that negative findings from repeated tests indicate that current cleaning and sanitizing is likely effective. However, because *Listeria* can be reintroduced into the environment through different routes which can vary over time, it is important to continuously monitor the environment with routine sampling and testing, at a regular frequency, to verify effectiveness of cleaning and sanitizing practices.

(Comment 375) With respect to testing of spent sprout irrigation water or sprouts in proposed § 112.143(b), several comments express concern that additional pathogen strains may be associated with sprouts in the future, similar to the 2012 outbreak of *E. coli* O104:H4 linked to sprouts in Europe, and that requiring testing just for *Salmonella* and *E. coli* O157:H7 is too limited. Other comments were supportive of testing for *Salmonella* spp. and *E. coli* O157:H7. Another comment supports FDA's tentative decision not to require testing of spent irrigation water for *Listeria*, and believes that it would not be an appropriate use of resources to require such testing given the ubiquity of *Listeria* spp. in water and the limitations of current testing methods to detect *L. monocytogenes*.

(Response) With respect to requiring testing of spent sprout irrigation water or sprouts, we focus on the two pathogens most commonly associated with sprout outbreaks, while also taking into consideration currently available analytical methodology. There is a long history of sprout-related outbreaks associated with *E. coli* O157:H7 and *Salmonella* spp. (Ref. 26) (Ref. 27) (Ref. 28) (Ref. 241) and we are retaining the requirement from proposed § 112.143(b) in renumbered § 112.144(b) for testing spent sprout irrigation water or sprouts for these two pathogens.

We also recognize that two recent sprout-associated outbreaks in the United States, as well as the large 2012 sprout outbreak in Europe, were due to non-O157 STEC (Ref. 28). In the 2013 proposed rule, we requested comments on whether pathogens other than *Salmonella* spp. and *E. coli* O157:H7 should be included in testing of spent sprout irrigation water or in-process sprouts, either by specifically listing the

additional pathogens or by set criteria. We discussed the challenges of requiring testing for non-O157 STECs in the 2013 proposed rule (78 FR 3504 at 3598). For example, there are hundreds of serotypes of STECs, and many are non-pathogenic or of low pathogenicity such that detection of an STEC alone in spent sprout irrigation water or sprouts would not be necessarily indicative of a public health concern, as not all STECs cause illness. Moreover, although laboratory tests to detect non-O157 STECs are currently available, methods necessary for follow-up testing to determine pathogenicity are not readily available (Ref. 242). We also considered requiring STEC testing for the major six pathogenic STEC serogroups (O26, O103, O111, O121, O45 and O145) identified by FSIS for non-intact raw beef. In addition, we reviewed the European Commission Regulation No. 209/2013, which amended Regulation No. 2073/2005 and established microbiological criteria for the testing of sprouts in an approach similar to that of FSIS' serogroup testing. Four serogroups, *i.e.*, O26, O103, O111, and O145, are identified for testing in both the EC and FSIS approaches. However, available sampling data from the AMS' Microbiological Data Program (MDP) and from FDA's sampling assignments infrequently recovered these STECs from fresh produce, including sprouts (Ref. 242), and so it is not clear that these serogroups should be prioritized in terms of testing for sprouts. Because we recognize that in the future there may be additional pathogens associated with sprouts for which scientifically valid test methods become available such that testing for those additional pathogens would be warranted, we have revised § 112.144(b) and added new § 112.144(c) to address this situation.

Revised § 112.144(b) adds to the pathogens that covered sprout operations are required to test for in either spent sprout irrigation water or in-process sprouts "any pathogens meeting the conditions identified in § 112.144(c)." New § 112.144(c) requires sprout operations to conduct the tests required in § 112.144(b) for additional pathogens when the following conditions are met: (1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and (2) A scientifically valid test method is available to detect the pathogen in spent sprout irrigation water (or sprouts). These provisions require additional pathogen testing, in the future, if the criteria in § 112.144(c) are met. First, the

association of the pathogen and sprout-related outbreaks or illness must be established to the point that routine testing for such a pathogen is reasonably necessary to protect public health and minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts. As mentioned previously, both *E. coli* O157:H7 and *Salmonella* spp. have a long history of association with sprout-related illness. However, a new pathogen need not equal or surpass the history of association of *E. coli* O157:H7 and *Salmonella* spp. with sprout-related illness in order to warrant testing under § 112.144(b) and (c). To satisfy § 112.144(c)(1), a new pathogen would need to have an established association with sprout-related illness. Second, there must be a scientifically valid test method available to detect the pathogen in spent sprout irrigation water (or sprouts). As mentioned previously with regard to STECs, we are not currently aware of an appropriate test to identify pathogenic non-O157 STECs in spent sprout irrigation water (or sprouts) that is available to industry. However, test methods are continually under development and there will likely be improved methods in the future.

In the event that, in the future, both criteria are met for a particular pathogen such that testing would be required, FDA intends to issue guidance in accordance with good guidance practices to advise sprout farms of FDA's assessment that: (1) There is a pathogen, in addition to *E. coli* O157:H7 and *Salmonella* spp., for which testing is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts, and (2) a scientifically valid test method is available to detect the pathogen in spent sprout irrigation water (or sprouts). In this guidance, we would address the history of the association of the pathogen and sprout-related illness and also any relevant information about the testing protocol. We anticipate issuing such guidance initially as a draft for comment, unless, due to urgent circumstances, it is not feasible or appropriate to issue the document first in draft. Under those circumstances, we would invite comment on the final guidance, and revise it as appropriate. FDA intends to enforce the requirements for additional pathogen testing required in accordance with § 112.144(b) and (c) of this rule only after FDA issues a final guidance advising industry and the public of FDA's assessment that the criteria for

additional pathogen testing have been met.

With regard to testing spent sprout irrigation water for *L. monocytogenes*, for the reasons described in the 2013 proposed rule (78 FR 3505 at 3597–3599) and in light of comments received, we conclude that, at this time, monitoring the environment, rather than spent sprout irrigation water, for *Listeria* spp. or *L. monocytogenes* is the most effective approach for controlling *L. monocytogenes* in a sprout operation (see next section).

E. Environmental Testing for Listeria Species or L. monocytogenes (§ 112.145)

These requirements were proposed as § 112.144. We have now renumbered this section as § 112.145 as a consequential change from the addition of new § 112.141.

(Comment 376) Several comments agree with our proposed requirement for establishing and implementing a written environmental monitoring plan for *Listeria*. These comments maintain that it is critical that sprout farms recognize the importance of designing and maintaining a monitoring plan that is not simply compliant with regulations, but is also sufficiently tailored to their operations to be appropriately protective of public health. According to another comment, sprout farms currently routinely test spent irrigation water, but are not familiar with and do not currently utilize environmental monitoring.

(Response) Testing the environment of a sprouting operation for *L. monocytogenes* (or for *Listeria* spp. as an indicator of potential contamination with *L. monocytogenes*), and taking actions to eliminate *L. monocytogenes* or *Listeria* spp. when found in the environment of a sprouting operation, is an important component of controlling microorganisms of public health significance (Ref. 214) (Ref. 243). We conclude that testing the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* is a reasonably necessary measure to prevent the introduction of hazards into sprouts and to provide reasonable assurances that sprouts are not adulterated. Therefore, we are retaining the provisions of proposed § 112.144 in renumbered § 112.145, with three revisions. First, we are requiring that the sampling plan, a necessary aspect of the required environmental monitoring plan, must also specify the timing of collection of the environmental samples during production (see § 112.145(c)(2)). We believe this is an important addition to the sampling plan to ensure that

sampling is conducted in a manner to optimize detection of *Listeria*, if present, and ensure consistency in the sampling strategy and facilitate the tailoring of the corrective action plan to the finding of a positive at a certain point during production. Second, we are requiring that environmental samples must be aseptically collected. This revision is consistent with proposed § 112.146(b) regarding aseptic collection of samples of spent sprout irrigation water or sprouts, which we are retaining in final § 112.147(b) (see also Comment 233 where we explain the importance of aseptic sampling). Third, we are requiring that the written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* spp. or *L. monocytogenes* (see § 112.145(e)). Requiring that your written environmental monitoring plan include a corrective action plan aligns with the requirement for you to take appropriate actions under § 112.146. Establishing and implementing a written corrective action plan will help ensure that corrective actions are taken quickly in response to positive findings of testing the production environment. This requires you to review appropriate sprout safety resources and consider the likely scenarios in advance of needing to take corrective actions, rather than reacting to these scenarios on an ad hoc basis after the fact. The requirement to have a written plan is consistent with other FDA food safety regulations, such as our juice and seafood HACCP regulations.

(Comment 377) One comment suggests that daily verification of sanitation using rapid detection methods (such as bioluminescence, ATP, or protein tests) serves as a better indicator of sanitation than environmental sampling on food-contact surfaces.

(Response) While rapid detection methods such as those mentioned are very useful for monitoring overall sanitation, they cannot substitute for environmental monitoring for *Listeria* spp. or *L. monocytogenes* to help ensure that *L. monocytogenes* has not become established in a harborage site, or niche, in a sprout operation. Cleaning and sanitizing may not remove all microorganisms and rapid methods such as those mentioned may not detect the presence of *L. monocytogenes* in harborage sites. However, daily monitoring of sanitation with a rapid

method such as those mentioned that allows for corrections to be made in “real time” if the cleaning and sanitizing have not been effective can be useful and we encourage sprout farms to use them in combination with required periodic sampling for *Listeria* spp. or *L. monocytogenes* to provide a robust approach to verifying cleaning and sanitization practices are adequately addressing *L. monocytogenes* in the environment.

F. Follow-Up Actions for Positive Environmental Testing Results
(§ 112.146)

These requirements were proposed as § 112.145. We have now renumbered this section as § 112.146 as a consequential change from the addition of new § 112.141.

(Comment 378) Some comments state that the language in proposed § 112.145(d) is insufficient for public health protection. One comment notes that the requirement as written will cause sprout farms to target sampling in order to achieve negative results with a minimum number of tests, rather than to target sampling to identify any potential sources of *Listeria*. According to another comment, finished product testing as a follow-up to a positive environmental finding is both useful and advisable, but is itself insufficient without a commensurate action step upon a positive result. This comment states that mandating testing throughout production and of finished product is a critically important part of ensuring that food is not contaminated—but it is logically necessary that a discovery of contamination must carry an appropriate response. Some commenters also maintain that FDA should require the disposal of any food that has come into contact with contaminated water or production equipment.

(Response) We agree that environmental monitoring is only effective when designed to identify *L. monocytogenes* if present and if followed by appropriate and effective corrective actions, where necessary. For this reason, we specify in § 112.145(a) that sprout farms must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment. As previously discussed, we are revising the rule to require that you establish and implement a written corrective action plan (as required under § 112.145(e)) to help ensure that corrective actions are taken quickly in response to positive findings of testing the production environment. This requires you to

consider the likely scenarios in advance, developed through review of appropriate sprout safety resources, rather than react to these scenarios on an ad hoc basis.

Specifically with respect to renumbered § 112.146(d), finished product testing can provide useful information in certain situations when pathogens have been detected in the environment. For example, finished product testing is likely appropriate if a food-contact surface tests positive for *Listeria* spp. in tests conducted following cleaning and sanitizing the surface to address an initial positive for *Listeria* spp., especially if production has occurred between the positive findings. The finding of *Listeria* spp. after a production run on a food-contact surface following corrective actions indicates that product contamination is reasonably likely, because it may indicate that the *Listeria* has become established in a niche on the equipment and is being dislodged during production. Our draft guidance to industry, the *Listeria* Guide (Ref. 244), includes draft recommendations for responses to positive environmental testing. A positive finding from environmental testing, as appropriate, can be confirmed through finished product testing and, if confirmed, necessary steps must be taken to remove the contaminated sprouts from the market and/or prevent contaminated sprouts from entering the market. We expect to address this issue further as we finalize the *Listeria* Guide. Accordingly, we are retaining in renumbered § 112.146 the provisions proposed as § 112.145 to require sprout operations to take certain minimum actions when there is a positive finding of *L. monocytogenes* or *Listeria* spp. in the production environment. Among these actions, listed in renumbered § 112.146, we are also specifying that the sprout farm must take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (see § 112.146(f)).

G. Collection and Testing of Samples of Spent Sprout Irrigation Water or Sprouts
(§ 112.147)

These requirements were proposed as § 112.146. We have now renumbered this section as § 112.147 as a consequential change from the addition of new § 112.141.

(Comment 379) Several comments support our proposed requirement to develop a written sampling plan and to test spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella*. One comment states that testing of spent

irrigation water should apply to “green sprouts” (e.g., alfalfa, clover) only, and that mung bean sprouts should be exempt from this requirement.

According to this commenter, mung bean sprouts are periodically irrigated with large volumes of water (i.e., 200 gallons per growing container) and it would be difficult to collect and analyze a meaningfully representative sample of spent irrigation water during mung bean sprout production.

(Response) Sampling spent sprout irrigation water or sprouts is an important testing procedure to ensure contaminated product does not enter commerce, and, therefore, we are retaining the provisions in proposed § 112.146 as renumbered § 112.147 with certain revisions, as explained in the paragraphs that follow. We expect the written sampling plan to be developed taking into account the farm’s specific growing and irrigation practices so the samples collected and tested are representative of the farm’s spent sprout irrigation water or sprouts. For example, in some situations, a sprout farm may want to temporarily adjust the volume of water that flows through a growing unit for the purposes of collecting spent irrigation water samples. With regard to mung bean sprout production, research has shown that testing spent irrigation water of sprouting mung bean beds can provide a useful assessment of its microbiological status, and we disagree that mung bean sprouts should be exempt from the requirements of § 112.147 in light of certain irrigation practices (Ref. 227). One means to comply with § 112.147(b) is to follow the recommendations in the *Sprouts Testing Guide* (Ref. 97).

We are revising § 112.147(b) to reflect the new provisions in § 112.144(b) and (c) for testing for additional pathogens when the criteria in the rule are met. Thus, we are revising the introductory text in § 112.147 to refer to testing “for pathogens as required in § 112.114(b)” and revising § 112.147(b) to refer not to testing for *E. coli* O157:H7 and *Salmonella* spp., but instead generally to “pathogens,” by which we mean those pathogen tests required by § 112.144(b) and (c). We are also revising § 112.147(b) to require testing using a method as set forth in new § 112.153 (see discussion in section XIX.B of this document).

As we previously noted in Comment 369, testing of spent sprout irrigation water or sprouts is a process control as well as a verification step. Accordingly, we have added text in § 112.147(b) to require that you must not allow the production batch of sprouts to enter commerce unless the results of the

testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* spp., and, if applicable, a pathogen meeting the criteria in § 112.144(c). This is consistent with the requirement in § 112.148(a) that, if samples of spent sprout irrigation water or sprouts are positive for *E. coli* O157:H7, *Salmonella* spp., or a pathogen meeting the criteria in § 112.144(c), you must take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering commerce. The requirement to not allow sprouts to enter into commerce until pathogen testing results are negative is consistent with current industry best practices (Ref. 219).

In addition, as in § 112.145 for environmental testing (discussed in Comment 378), we are adding a requirement that your written sampling plan for spent sprout irrigation water testing (or sprout testing) include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* spp., or a pathogen meeting the criteria in § 112.144(c) (see § 112.147(c)). Establishing and implementing a written corrective action plan will help ensure that corrective actions are taken quickly in response to positive findings of pathogens in spent irrigation water or sprouts. This requires you to consider the likely scenarios in advance, developed through review of appropriate sprout safety resources, rather than react to these scenarios on an ad hoc basis. The requirement to have a written plan is consistent with other FDA food safety regulations, such as our juice and seafood HACCP regulations.

H. Actions if Spent Sprout Irrigation Water or Sprouts Test Positive for a Pathogen (§ 112.148)

(Comment 380) Several comments state that FDA should establish the steps that sprouters must take on a finished batch or lot of sprouts found to be contaminated through the testing requirements of this subpart. One comment states that FDA should require the immediate destruction or disposal of any finished product that may be adulterated, as indicated by a positive finding in the tests required under proposed § 112.146.

(Response) In light of these comments, we are establishing new § 112.148 to require sprout operations to take certain actions if the samples of

spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* spp., or a pathogen meeting the criteria in § 112.144(c). In part, § 112.148 requires you to take appropriate action to ensure that adulterated food does not enter commerce (see § 112.148(a)).

Testing of spent sprout irrigation water or sprouts for *Salmonella* spp., *E. coli* O157:H7, or a pathogen meeting the criteria in § 112.144(c) is required under § 112.144(b). A production batch of sprouts for which any of these pathogens is detected in the spent sprout irrigation water is considered adulterated under section 402(a)(4) of the FD&C Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. Similarly, a production batch of sprouts for which any of these pathogens is detected in the sprouts is considered adulterated under sections 402(a)(1) of the FD&C Act, in that the sprouts contain a poisonous or deleterious substance which may render them injurious to health. In such a circumstance, the covered farm must take appropriate steps to ensure that the adulterated food does not enter commerce, including, as appropriate, destroying or diverting the product to non-food use.

In addition, new § 112.148(b) requires you to take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c)). This provision is intended to make clear that the requirements in § 112.142(b) relating to seeds or beans apply to all situations in which your required testing of spent irrigation water or sprouts results in a positive pathogen finding, except as otherwise provided in section § 112.142(c). For a detailed discussion of these requirements, see section XVIII.B of this document.

In addition, § 112.148(c) requires you to clean and sanitize the affected surfaces and surrounding areas. This provision is consistent with our recommendations in the Sprouts Testing Guide. Anything in the sprouting operation that has come into contact with the contaminated production batch or its water (e.g., drums, trays, bins, buckets, tools and other sprouting equipment, testing equipment, and other possible surfaces, such as floors, drains, walls, and tables), must be thoroughly cleaned and sanitized to avoid contamination of subsequent batches of sprouts (Ref. 97).

Finally, § 112.148(d) requires you to perform any other actions necessary to

prevent reoccurrence of the contamination. For example, a sprout grower may consider re-evaluating their seed treatment protocol, consider switching their seed supplier, or consider switching to using seeds that have been grown under Good Agricultural Practices and conditioned, handled and stored under sanitary conditions.

I. Records Related to Sprouts (§ 112.150)

We are making conforming changes to this section to reflect renumbering and revisions to other provisions in this subpart. In addition, we note that while we have added requirements for covered sprout farms to establish corrective action plans, such plans are required as part of the written environmental monitoring plan already required under § 112.145 and the written sampling plan for each production batch of sprouts already required under § 112.147. Thus, we are not revising § 112.150 to add separate records requirements for these corrective action plans because they are already covered in § 112.150(b)(2) (written environmental monitoring plans) and § 112.150(b)(3) (written sampling plans for each production batch of sprouts). We are also adding new requirement in final § 112.150(b)(6), discussed further in Comment 381.

(Comment 381) Several comments state that the recordkeeping requirements should be expanded to include documentation of any corrective actions that farms employ to address problems identified and verification that those corrective actions were effective.

(Response) In proposed § 112.161(b), we proposed a general provision applicable to records are required under subparts C, E, F, L, and M of part 112 that you must establish and keep documentation of actions you take when a standard in any of these subparts is not met. For clarification, we are eliminating proposed § 112.161(b) and, instead, adding that requirement within the records provisions of two relevant subparts, including subpart M. As revised, under § 112.150(b)(6), you must establish and keep documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148. This requires covered sprout farms to keep documentation of actions taken related to seeds and beans that may be contaminated, in accordance with § 112.142(b) and (c), and corrective actions in accordance with §§ 112.146 or 112.148. For example, if your testing required under § 112.144(a) indicates a detection of *Listeria* spp. or *L. monocytogenes* in the growing, harvesting, packing, or holding

environment, this provision requires you to establish and keep a record of the corrective steps that you took in response to that positive finding in compliance with § 112.146.

In addition, in final § 112.150(b)(5), we are requiring records of any analytical methods you use in lieu of the methods that are incorporated by reference in new § 112.153 (see section XIX.B of this document). This requirement is consistent with proposed § 112.150(b)(5), in which we proposed to require records of any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152, which we have retained in final § 112.150(b)(5). That is, in final § 112.150(b)(5), we require records of any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153. In addition, we are eliminating proposed § 112.150(b)(6) as a corresponding change.

We are also revising proposed § 112.150(b)(4) to clarify that documentation of the results of all analytical tests conducted for purposes of compliance with subpart M is required. This revision is consistent with the records requirement for agricultural water in § 112.50(b)(2).

J. Compliance Periods for Covered Activities Involving Sprouts

(Comment 382) Some comments request clarification regarding coverage of sprout operations under part 112 and the applicability of the provisions of part 112 (other than subpart M) to sprout operations. Some comments request clarification on whether all sprout farms will be subject to part 112 in addition to proposed subpart M, and whether sprout farms may also be eligible for a qualified exemption or extended compliance periods based on the farm's size. Citing the high risk nature of sprout production, one commenter argues that sprout farms should not be eligible for the qualified exemption or extended compliance periods. Some comments specifically asked us to shorten the compliance periods for sprouts to protect public health.

(Response) As described throughout the 2013 proposed rule and in this rule, part 112 establishes the minimum science-based standards that we determine to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables, and to provide reasonable

assurances that the produce is not adulterated. Sprouts are produce (see definition of "produce" in § 112.3) and, therefore, sprout farms are subject to all of part 112, as applicable. In addition, as discussed in the 2013 proposed rule (78 FR 3504 at 3594), because sprouts present a special concern with respect to human pathogens compared to other covered produce due to the warm, moist, and nutrient-rich conditions required to produce sprouts, we have incorporated the additional standards in subpart M specifically targeted to sprout operations. Accordingly, covered sprout farms are subject to all applicable requirements of part 112, including the specific requirements of subpart M.

The threshold for coverage (under § 112.4(a)) and the qualified exemption and associated modified requirements (under §§ 112.4(b) and 112.5–112.7) all apply to sprout farms.

With regard to compliance dates for covered activities involving sprouts, we agree that our proposed compliance dates were not sufficiently protective of public health. There is a long history of food safety problems associated with sprouts (78 FR 3504 at 3594–3601) and, therefore, we agree that we should establish shorter compliance periods for sprouts as compared to other covered produce. Section 419(a)(4) of the FD&C Act provides that we shall prioritize the implementation of this rule for specific fruits and vegetables based on known risks which may include a history and severity of foodborne illness outbreaks. We believe it is appropriate to expedite the implementation of the provisions of part 112, including subpart M, for covered activities involving sprouts, based in part on the history and severity of sprout-related foodborne illness outbreaks, to reduce the likelihood of future sprout-related outbreaks.

We also believe it is not necessary to give sprout farms extra time to comply with the certain water provisions of subpart E as we are doing with respect to other commodities (see section XIII.K of this document). Based on information available to us, we believe that most, if not all, sprout farms already use public water supplies and/or ground water sources for all relevant purposes subject to the microbial quality criterion in § 112.44(a) (Ref. 245). The other provisions in subpart E for which we are allowing extended compliance dates for other commodities are either (1) directly linked to compliance with the microbial quality criterion in § 112.44(a); or (2) are not relevant to sprouts (*i.e.*, the criteria in § 112.44(b) are only for produce other than sprouts).

Therefore, for covered activities involving sprouts, we are establishing

that businesses other than small and very small businesses would have one year after the effective date of the final rule to comply with all of the provisions of this rule, whereas small businesses would have two years and very small businesses would have three years to comply with all of the provisions of this rule. This is consistent with the requirements in section 419(b)(3) of the FD&C Act that this rule shall apply to a small business after the date that is 1 year after the effective date of the final regulation, and to a very small business after the date that is 2 years after the effective date of the final regulation. See also XXIV of this document for additional information.

K. Other Comments

(Comment 383) One comment recommends that FDA require a food safety plan, and that this plan should also include a sprout-specific section.

(Response) As explained in section VII of this document, although we are not establishing a general requirement for covered farms to conduct an operational assessment or develop and implement a food safety plan, we encourage all farms to do so because food safety plans can help a farm to be more effective in ensuring the safety of produce grown, harvested, packed, or held at that farm.

(Comment 384) One comment asks us to consider establishing audit and inspection requirements specific to the sprout industry, and to provide appropriate training to auditors and inspectors. This commenter also suggests that FDA should require GFSI audits and unannounced inspections of sprout operations to verify best practices and food safety and quality standards.

(Response) We are not establishing requirements in this rule for audits of covered farms, generally, or of sprout farms, specifically. We do not see a reason to impose audit requirements specific to sprout farms in this rule. However, we recognize the role that third-party audits can play in promoting food safety. In the final human preventive controls rule (80 FR 55908) and the final FSVP rule (published elsewhere in this issue of the **Federal Register**), we are establishing certain supplier verification requirements that we expect to play a role in achieving compliance with this rule. In addition, we note that in the final third-party certification rule (published elsewhere in this issue of the **Federal Register**), FDA is establishing a voluntary program for the accreditation of third-party certification bodies that may conduct audits and issue certifications for purposes of establishing an entity's

eligibility to participate in the Voluntary Qualified Importer Program (VQIP) or to satisfy conditions set forth under section 801(q) of the FD&C Act.

We are also working with our partners to develop sprout-specific training, including training for use by inspectors. See section XXII of this document where we discuss our strategy for the implementation of the produce safety

regulation, including the role of our federal, State, local, territorial, and tribal partners as well as private entities.

XIX. Subpart N—Comments on Analytical Methods

In subpart N of proposed part 112, we proposed methods of analysis for testing the quality of agricultural water and the growing environment for sprouts, as required under proposed subparts E and

M, respectively. We asked for comment on our proposed provisions in subpart N, including specific methods and an allowance for alternative methods to be used provided they are at least equivalent to the proposed methods in accuracy, precision, and sensitivity.

We are finalizing these provisions with revisions (see Table 25). We discuss these changes in this section.

TABLE 25—DESCRIPTION OF REVISIONS TO SUBPART N

Final provision	Description of revisions
§ 112.151	<ul style="list-style-type: none"> —Revision to eliminate the Official Methods of Analysis of the AOAC International, the Standard Methods for the Examination of Water and Wastewater of the American Public Health Association, and the FDA’s Bacteriological Analytical Manual from the list of specified methods. —Revision to specify as the prescribed method of analysis, and to incorporate by reference, Method 1603 published by EPA. —Revision to clarify that methods used other than that specifically incorporated must be scientifically valid. —Revision to indicate that methods used for other indicators of fecal contamination must be scientifically valid. —Editorial revision, moving “a method of analysis” into subparagraphs. —Conforming revision to change cross-reference in title to § 112.46.
§ 112.152	<ul style="list-style-type: none"> —Revision to incorporate by reference a specific method that is based on methods and procedures described in FDA’s Bacteriological Analytical Manual (BAM), USDA’s Microbiology Laboratory Guidebook, and those used in FDA’s compliance activities (in lieu of specifying a chapter of FDA’s BAM) Revision to the locations where a copy of the specified method may be obtained or inspected. —Revision to clarify that methods used other than that specifically incorporated must be scientifically valid. —Editorial revision to shorten introductory text by removing duplicative phrase “by testing” and unnecessary reference to “in environmental samples”. —Conforming revision to change cross-reference in title to § 112.144(a), and to add “harvesting, packing, and holding” to title and introductory text.
§ 112.153	<ul style="list-style-type: none"> —New section to: (1) Prescribe a method of analysis for testing spent sprout irrigation water (or sprouts) from each production batch of sprouts for <i>E. coli</i> O157:H7 and <i>Salmonella</i> to satisfy the requirements of § 112.144(b), and to provide flexibility for use of other scientifically valid methods (see § 112.153(a)) and (2) specify that a scientifically valid method must be used for any other pathogens meeting the criteria in § 112.144(c) (see § 112.153(b)).

A. Responses to Comments

(Comment 385) One comment suggests revising proposed § 112.151(a)(1) to cite the 19th edition of the Official Methods of Analysis published by AOAC INTERNATIONAL in 2012, rather than the 18th edition that was issued in 2011.

(Response) We are revising final § 112.151 to eliminate the method of analysis, as published in the Official Methods of Analysis of AOAC International, as a prescribed method for testing the quality of water to satisfy the requirements of § 112.46. See section XIX.B of this document.

(Comment 386) Some comments seek clarification on the allowance for use of equivalent methods. One comment asks whether FDA would review a method to determine its equivalency to the relevant specified method(s), and requests clarification on how such equivalency should be determined. In addition, another comment suggests FDA should consider EPA-approved test methods for water acceptable for purposes of testing the quality of water required under this rule.

(Response) We have specified in subpart N certain analytical methods for use to satisfy the testing requirements related to agricultural water and sprouts. We reviewed EPA-approved test methods for water, and determined that Method 1603, an EPA-approved test method identified in 40 CFR 136.3, Table IH, is appropriate for testing water quality to satisfy the requirements of § 112.46 (see section XIX.B of this document).

However, we recognize that other scientifically valid methods, particularly test kits, may be available or may become available in the future. Therefore, we provide flexibility for covered farms to use any other scientifically valid method that is at least equivalent to a prescribed analytical method in accuracy, precision, and sensitivity. See also Comment 9. We are clarifying in §§ 112.151(b), 112.152(b), and 112.153(a)(2) and (b) that such methods must be scientifically valid. As noted in response to Comment 26, the term “scientifically valid” means an approach that is based on scientific information, data, or results published

in, for example, scientific journals, references, text books, or proprietary research. Any scientifically valid method can be used provided you ensure that the method is at least equivalent to the applicable prescribed analytical method in accuracy, sensitivity, and precision in detecting the relevant organism or indicator (e.g., generic *E. coli*, *Salmonella*, *L. monocytogenes*, or *Listeria* spp.) in the relevant sample matrix (e.g., ground water, surface water, environmental swabs, spent sprout irrigation water, or sprouts). We are not further requiring covered farms to notify or submit information about such methods of analysis for FDA’s review or approval prior to use, nor do we believe that such a requirement is warranted. We intend to disseminate useful scientific information, when available, including on any new scientifically valid methods of analysis at least equivalent in accuracy, precision, and sensitivity to our prescribed methods.

(Comment 387) Another comment states that if samples are not collected in a sanitary manner there is no

guarantee that the results will be scientifically valid.

(Response) We agree aseptic collection of samples is important, and have added this requirement under §§ 112.47(b) and 112.145(d). In addition, we have retained the requirement to collect samples aseptically, as previously proposed, in renumbered § 112.147(b). See also Comment 233 and Comment 376.

B. Other Revisions

With respect to the prescribed methods for testing agricultural water, we are eliminating proposed §§ 112.151(a)(1), 112.151(a)(2), and 112.151(a)(3). On further review, we find the testing methods specified in proposed § 112.151(a)(1) to (3) inadequate for the purpose of testing the quality of water to satisfy the requirements of § 112.46. The methods of analysis in the Official Methods of Analysis of AOAC INTERNATIONAL and the Standard Methods for the Examination of Water and Wastewater specified in proposed §§ 112.151(a)(1) and 112.151(a)(2), respectively, are not intended to capture discrete concentrations of microbial populations in sources of water that may be turbid or whose microbial quality may potentially vary irregularly. Likewise, the FDA's Bacteriological Analytical Manual (BAM) method specified in proposed § 112.151(a)(3) covers examination of bottled water only and does not explicitly address testing of agricultural water. Instead, for analysis of environmental water, the FDA's BAM method refers to EPA-approved test methods, which we have reviewed and we are specifying EPA's Method 1603 as a prescribed method in final § 112.151(a). We are also adding § 112.151(b)(2) to clarify that if you use an alternative indicator of fecal contamination in accordance with § 112.49(a) you must use a scientifically valid method to test for the indicator.

With respect to the prescribed methods for testing the sprout growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes*, we are retaining proposed § 112.152 with revisions. Under final § 112.152(a), we are prescribing the relevant method, *i.e.*, FDA's method of analysis described in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples," October, 2015, rather than prescribing a particular chapter of FDA's BAM (as in proposed § 112.152). On further review, we find the method that is described in the particular chapter of FDA's BAM (cited in proposed § 112.152) has been

validated for detection of *Listeria* spp. or *L. monocytogenes* primarily in food samples. For the purposes of testing environmental samples for detection of *Listeria* spp. or *L. monocytogenes* to satisfy the requirements of 112.144(a), we are incorporating by reference a method that is based on the methods and procedures in USDA's Microbiology Laboratory Guidebook, FDA's BAM, and those used in FDA's compliance activities. In addition, consistent with § 112.151(b)(1), under § 112.152(b), we are retaining the proposed flexibility for the use of other method(s) in lieu of the prescribed methods of analysis, provided the other method is scientifically valid and is at least equivalent in accuracy, sensitivity, and precision to the method in § 112.152(a). We believe these changes in final § 112.152 are necessary to prescribe the appropriate testing methods, while retaining flexibility for use of other scientifically valid methods, to meet our testing requirements in § 112.144(a).

We are revising both proposed §§ 112.151 and 112.152 to provide current information about the location where you may obtain or inspect a copy of the prescribed methods. We are also making certain conforming changes in these sections to update the cross-references to other provisions. We are also making certain non-substantive editorial changes in these sections (moving the phrase "a method of analysis" in § 112.151, and shortening the introductory text in § 112.152 by removing the duplicative phrase "by testing" and an unnecessary reference to "in environmental samples").

We are adding new § 112.153 to specify certain methods of analysis for testing spent sprout irrigation water (or sprouts) from each production batch of sprouts, which is required under § 112.144(b). We are specifying that you must test for *E. coli* O157:H7 and *Salmonella* spp. using FDA's method of analysis described in "Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts)," October, 2015 (§ 112.153(a)(1)); or using a scientifically valid alternative method (§ 112.153(a)(2)). The method described in § 112.153(a)(1) is based on the method described in the current edition of FDA's BAM with additional details for testing spent irrigation water or sprouts, and we are incorporating by reference this particular method into part 112 for the purposes of testing required under § 112.144(b). In § 112.153(a)(2), consistent with §§ 112.151(b)(1) and 112.152(b), we are providing flexibility for the use of an alternative method(s) for *E. coli*

O157:H7 or *Salmonella* spp., in lieu of the prescribed method of analysis, provided the alternative method is scientifically valid and is at least equivalent in accuracy, sensitivity, and precision to the method in § 112.153(a)(1). In addition, § 112.153(b) specifies that a scientifically valid method must be used to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for any other pathogen(s) that meet the criteria in § 112.144(c). By prescribing the method of analysis and incorporating sufficient flexibility for the use of scientifically valid alternative methods, we expect new § 112.153 to help covered farms meet our testing requirements in § 112.144(b).

C. Incorporation by Reference

In § 112.152(a), FDA is incorporating by reference "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples," Version 1, dated October 2015, U.S. Food and Drug Administration and, in § 112.153(a)(1), FDA is incorporating by reference "Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts)," Version 1, dated October 2015, U.S. Food and Drug Administration, which was approved by the Office of the Federal Register. You may obtain a free copy of the material from the Division of Produce Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; the Docket at www.regulations.gov; or from the Food and Drug Administration, at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. These methods are related to the detection of pathogens in the production of sprouts. We are specifying the prescribed method for testing of the sprout production environment for *Listeria* in accordance with § 112.144(a). This is an enrichment method for the detection of *Listeria* spp. in the environment of sprout farms and the confirmation of the presence of *L. monocytogenes* in samples that are positive for *Listeria* spp. We are also specifying the prescribed method for testing of spent sprout irrigation water or sprouts for two pathogens in accordance with § 112.144(b). This method includes: (1) Screening procedures by real-time PCR to establish the presumptive presence of *E. coli* O157:H7, followed by culture confirmation of *E. coli* O157:H7, and (2) screening procedures to detect a presumptive positive for the presence of

Salmonella spp., followed by confirmation of the presence of *Salmonella* spp. by a variety of confirmatory tests. We are specifying these prescribed methods, while also providing the flexibility for use of other scientifically valid methods, to help covered farms to meet our testing requirements in § 112.144.

In § 112.151(a), FDA is incorporating by reference “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC),” dated December 2009, U.S. Environmental Protection Agency (EPA), EPA-821-R-09-007, which was approved by the Office of the Federal Register. You may obtain a free copy of the material from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. 202-564-6620; http://water.epa.gov/scitech/methods/cwa/bioindicators/upload/method_1603.pdf; the Docket at www.regulations.gov; or from the Food

and Drug Administration, at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. This method is an EPA-approved analytical test method. It provides the procedures for testing agricultural water samples to determine the microbial quality of water to satisfy the requirements of § 112.46. We are specifying this prescribed method, while also providing the flexibility for use of other scientifically valid methods, to help covered farms to meet our testing requirements in § 112.46.

XX. Subpart O—Comments on Records

In subpart O of proposed part 112, we proposed requirements that would be applicable to all records required by part 112. We tentatively concluded that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and

requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112. We asked for comment on our proposed provisions.

We are finalizing these provisions with revisions (see Table 26). We discuss these changes in this section. Some comments support one or more of the proposed provisions without change. We discuss the comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. For § 112.166, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions.

TABLE 26—DESCRIPTION OF REVISIONS TO SUBPART O

Final provision	Description of revisions
§ 112.161	—Revision to eliminate proposed § 112.161(b) and, instead, add that requirement within the records provisions of the relevant subpart, <i>i.e.</i> , §§ 112.50(b)(6) and 112.150(b)(6). —Re-number proposed § 112.161(c) as § 112.161(b) and make conforming edits to update cross references. —Revision to add the phrase “except as otherwise specified” in § 112.161(a) to reflect that certain records requirements specified in the relevant subparts of part 112 include requirements that are different from the ones in subpart O. —Revision to cover new provision § 112.7 within renumbered § 112.161(b).
§ 112.162	—Revision to remove “after 6 months following the date the record was made” to allow immediate offsite storage of records provided they can be retrieved and provided onsite within 24 hours of request for official review.
§ 112.163	—Revision to clarify types of existing records that do not need to be duplicated to comply with this part. —Revision to clarify that such records must satisfy the requirements of this part. —Revision to add “Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part 112”. —Revision to clarify that the information required by this part need not be kept in one set of records, and any new information required by this part may be kept separately or combined with existing records.
§ 112.164	—Revision to add new § 112.164(a)(2) to specify that records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the farm’s status during the applicable calendar year. —Revision to § 112.164(a)(1) to replace “2 years” with “at least 2 years” so the length of record retention in this provision is harmonized with new § 112.164(a)(2). —Revision to § 112.164(b) to specify that “records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations” must be retained for at least two years after the use of such records is discontinued.
§ 112.165	—Revision to establish that electronic records maintained to satisfy this part 112 are exempt from the requirements of part 11 of this chapter, except to the extent that they are also required under other applicable statutory provisions or regulations and are therefore subject to part 11.
§ 112.167	—Revision to clarify that records “obtained by FDA in accordance with this part” are subject to the disclosure requirements under part 20.

A. General Comments

(Comment 388) Several comments express support for our proposed approach to limit recordkeeping requirements. These commenters state that records of required monitoring activities and corrective actions are sufficient for FDA to evaluate an operation’s level of compliance with the

requirements of the rule. Conversely, one commenter recommends that fruits and vegetables with little or no associated risk of foodborne illness should have a lower recordkeeping burden, whereas another commenter, while not providing specific suggestions, urges us to reduce the recordkeeping requirements to a minimum.

(Response) The recordkeeping requirements in this rule are limited to those specific instances where: (1) Maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards; (2) identification of a pattern of problems is important to minimizing the risk of such hazards; and (3) records are

important to facilitate verification and compliance with standards and such verification and compliance cannot be effectively done by means other than a review of relevant records. Therefore, we believe that the requirements for developing and maintaining records established in part 112 are the minimum necessary.

With respect to the comment about establishing different recordkeeping requirements for different commodities based on their associated risk of foodborne illness, we refer you to the discussion in section IV of this document, in which we explain our rationale for relying on an integrated regulatory approach that focuses on practices, processes, and procedures and the potential for contamination through common on-farm routes, rather than on a commodity-specific regulatory framework. The recordkeeping requirements in this rule stem from our integrated regulatory approach.

(Comment 389) Several comments state that recordkeeping may cause financial hardship, such as lost time and revenue, for small- to mid-size farms.

(Response) As we discussed in sections IV.E and V.O of the 2013 proposed rule, in determining the circumstances in which records are necessary as part of science-based minimum standards that minimize the risk of serious adverse health consequences or death and provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) “with special attention to minimizing” the recordkeeping burden on the business and collection of information as defined in that act.

We appreciate the concerns with respect to cost and burden to farms and, to the extent possible, we have established documentation requirements that are risk-based and capable of being tailored to an individual farm, taking into account the unique characteristics of the operation, the commodities handled, and the operation’s growing, harvesting, packing, and holding procedures. The recordkeeping requirements in subpart O of part 112 allow the use of existing records, provided such records satisfy all of the applicable requirements of part 112 (see § 112.163). We are further clarifying in this final rule that you are not required to keep all of the information required by part 112 in one set of records. In addition, per § 112.165, electronic records are acceptable, although not required.

Records in forms as diverse as hard copies of handwritten logs, invoices, and documents reporting laboratory results are also acceptable, provided they are indelible and legible. We estimated the costs associated with our recordkeeping requirements (Ref. 142).

(Comment 390) A few comments request that we more clearly define the records that must be kept and the content of such records. One of these comments asks whether FDA will provide training, including specific forms, templates or checklists, for farmers to comply with the records requirements.

(Response) The records required under this regulation are dependent, in part, on the nature of practices and procedures related to the covered activities in your operation, and are listed under the applicable sections of part 112, including in subparts A, C, E, F, L, and M (*i.e.*, §§ 112.2(b)(4), 112.7, 112.30, 112.50, 112.60, 112.140, and 112.150). We will consider providing guidance on the required records and their content, as needed. We also expect that the training curriculum and materials being developed by the PSA will address recordkeeping, and the SSA intends to provide “model” forms and training for sprout farmers on how to develop and maintain appropriate records.

(Comment 391) One comment suggests that records related to safety, including testing reports, should appear as part of labeling that accompanies produce as the commodity moves through the food chain. This commenter also asks us to make labels an active component of the food safety system instead of establishing the recordkeeping requirements we proposed.

(Response) Documentation of some practices is critical to ensure that this rule is adequately implemented on the farm. Records are useful for keeping track of detailed information over a period of time, and can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful during FDA inspections for investigators to determine compliance with relevant requirements of the rule. We are not establishing new labeling requirements in this rule other than as set forth in § 112.6(b) for farms eligible for the qualified exemption and § 112.2(b) for produce eligible for the commercial processing exemption. We do not agree that product labels or labeling should be used as a substitute for the recordkeeping requirements in subpart O of part 112. Produce commodities, in packaged form, are subject to certain

labeling requirements specified in 21 CFR part 100; however, such requirements are outside the scope of this rule.

B. General Requirements Applicable to Records Required Under Part 112 (§ 112.161)

(Comment 392) Stating that on-farm records are often recorded in pencil, one comment expresses concern that, under the proposed requirements of § 112.161, records would have to be recorded in ink. This commenter states that outdoor on-farm environmental conditions often dictate the use of pencils instead of pens because rain can cause smearing of ink-recorded paperwork.

(Response) This comment appears to be in response to the requirement in § 112.161(a)(3) that records must be, among other things, indelible. We believe it is important for records to be indelible, and are retaining this requirement, as proposed. If a covered farm were to prepare the required record in pencil, we could not be confident that the record had not been altered from its original content. In addition, we do not believe the requirement is impractical for farms because we understand that a number of products such as all-weather and ballpoint pens are available that can write on wet paper and also do not cause smearing. This requirement is consistent with the provisions of the PCHF regulation and we are finalizing it as proposed.

(Comment 393) Some comments express support for proposed § 112.161(c) requiring a supervisor or responsible party to review certain records. Another comment recommends that allowances be made for a situation where the person who is responsible for the initial record is the owner or supervisor, in which case he or she should also be allowed to document the review of the records.

(Response) We are making some changes by eliminating proposed § 112.161(b) and, instead, adding that requirement (as necessary) within the records provisions of the relevant subparts. Rather than a general requirement for documentation of actions you take when a requirement subparts C, E, F, L, or M is not met, we are limiting this requirement as compared to that in the 2013 proposed rule, and making our intent clear by specifying the corrective measures in relation to which your actions must be recorded and such records retained. As revised, under final §§ 112.50(b)(6) and 112.150(b)(6), you must establish and keep documentation of actions you take in accordance with certain specified corrective measures established in

subparts E and M, respectively. We do not see the need for a similar documentation requirement in subparts C or L because we are not establishing specific corrective measures in relation to requirements in those subparts. Subpart F, too, does not include specific corrective measures for which additional documentation requirements (beyond the provisions we are finalizing, as discussed in section XIV.H of this document) are necessary. Therefore, we are not adding additional documentation requirements in §§ 112.30, 112.60, or 112.140 solely as a result of eliminating proposed § 112.161(b). With the elimination of proposed § 112.161(b), we have renumbered proposed § 112.161(c) as § 112.161(b), and we have also made conforming edits to update the cross-references in the provision that is now § 112.161(b).

Regardless of who creates or prepares the initial documentation, if the record is one that is required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), 112.50(b)(4), 112.50(b)(6), 112.60(b)(2), 112.140(b)(1), 112.140(b)(2), 112.150(b)(1), 112.150(b)(4), or 112.150(b)(6), it must be reviewed, dated, and signed by a supervisor or responsible party. This includes the records being required under new § 112.7(b) (see Comment 139). In addition, in accordance with § 112.161(a)(4), applicable records must be dated, and signed or initialed by the person who performed the activity that is documented. Where the owner or supervisor is both the person who performed the activity as well as the responsible party, by signing and dating the record, the owner or supervisor will have satisfied the requirements in both §§ 112.161(a)(4) and 112.161(b).

We have also revised § 112.161(a) to add “except as otherwise specified” to reflect the fact that certain records requirements specified in relevant subparts of part 112 include requirements that are different from the ones in subpart O (e.g., § 112.7(a), providing that we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale) (see Comment 139).

C. Storage of Records (§ 112.162)

(Comment 394) Several comments express concern with our proposed provision § 112.162(a) that would prohibit off-site storage of records for the first six months after a record is created. These comments find this provision to be unnecessarily burdensome, and argue that operations that move seasonally or that operate multiple growing sites should be able to

retain records at an offsite location. These comments recommend revising this provision to read: “Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.” Another comment recommends also adding “or a reasonable period of time” as an alternative to help alleviate the burden.

(Response) We understand the seasonal nature of certain farming operations and the fact that many farms have multiple growing sites that may not be contiguous. Proposed § 112.162(a) would not require a farm with multiple growing sites to establish multiple records storage locations. Where multiple growing sites are operated under one management in one general (but not necessarily contiguous) physical location, they are part of one farm under our definition of farm (see § 112.3(c)). We consider records to be on-site at a farm as long as they are located at a site on that farm (or in the case of electronic records, accessible from a site on that farm, see § 112.162(b)). Thus, a farm’s records would be considered to be on-site even if records related to field A are stored at field B, provided both fields are operated by the same farm under our definition. This allows a covered farm to store all of its records, including those records created during covered activities on seasonally-rented field(s) or in multiple growing locations, in the main offices of the farm’s operation, for example, and does not require a single farm to set up a mechanism to store records related to each field separately at different locations. Nevertheless, we are revising § 112.162(a) to permit offsite storage of required records provided such records can be retrieved and provided onsite within 24 hours of request for official review. Because the records will be available within 24 hours of an official request, and because we expect that a farm will also be able to retrieve and review all necessary records from its recent operations within a 24 hour period (allowing them to use the records to review detailed information needed to keep track of measures minimizing the risk of hazards, and identifying patterns of problems for the same purpose), we consider that this provision will satisfy the purposes of record retention. In order to maintain inspectional efficiency and to ensure that farms can use their own records as described previously, we are requiring that the time period between an FDA request for the records and their arrival not exceed 24 hours. Allowing for offsite storage of

records under the conditions noted in § 112.162(a) is consistent with our regulation on Production, Storage, and Transportation of Shell Eggs, 21 CFR part 118, which allows for offsite storage of records, except for the written *Salmonella Enteritidis* prevention plan, which must be stored on-site (see § 118.10).

D. Use of Existing Records (§ 112.163)

(Comment 395) Several commenters express support for proposed § 112.163, and ask that we clarify that records already kept for other purposes and information presented across multiple records in different forms are sufficient to meet the recordkeeping requirements of the produce safety regulation.

(Response) We are revising proposed § 112.163 to provide additional clarity about the fact that the regulations in part 112 do not require duplication of existing records if those records contain all of the information required by part 112. We have minimized the burden of keeping records to that which is necessary to accomplish the intended purposes of part 112. As discussed in the 2013 proposed rule, for example, you are not required to duplicate existing records, such as records kept to satisfy the requirements of the NOP, if those records contain all of the information required by this part. Additionally, you are not required to keep all of the information required by this part in one set of records. Similarly, if you have records containing some but not all of the required information, the produce safety regulation provides you the flexibility to keep any additional information required by this part either separately or combined with your existing records, even where the formats for each record may not be the same. However, note that keeping records together in one place likely will expedite review of records in the event of a public health emergency or during an FDA inspection or investigation.

To make our intent clear, and consistent with a similar provision § 117.330 in the PCHF regulation, we are revising proposed § 112.163 to read as follows: (a) Existing records (e.g., records that are kept to comply with other federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part 112. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part 112; and (b) The information required by this part does not need to be kept in one set of records. If existing records contain some

of the required information, any new information required by this part may be kept either separately or combined with the existing records.

We acknowledge that the records required by this part may be multi-component—a web of related documents. This provision provides flexibility, but it is not without limitations. As an example, a farm that collects spent sprout irrigation water samples and sends them to a laboratory for testing may have sampling records that contain the information required by § 112.161(a)(1), such as the name and location of the farm, the date when the samples were collected, the signature or initials of the person collecting the samples and an adequate description of the sprouts applicable to the record (including a lot number or other identifier, when available). The laboratory report may not include some of the information, such as the location of the farm, but would contain some identifying information relating to the sample tested, such as the date of the sample or the lot number for the applicable sprouts. These records together contain all the required information to associate them with a farm and a specific lot of product. However, the following example for monitoring records illustrates there can be limitations on supplementing existing records with required information kept in other documents. Monitoring records must be created concurrently with the monitoring activity and contain the signature or initials of the person conducting the monitoring. If the existing records document the monitoring activity and the date and time but do not provide space for the name and location of the farm or the signature or initials of the person performing the activity, it would not be acceptable to supplement that record with the name and location of the farm and signatures on a separate page.

E. Length of Records Retention (§ 112.164)

We received some comments generally supporting proposed § 112.164. We are retaining § 112.164 with certain changes. First, we are adding new § 112.164(a)(2) to require that records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained at the farm as long as necessary to support the farm's status during the applicable calendar year. As discussed in section IX of this document, the criteria for a qualified

exemption established in this rule (in § 112.5) are based, in part, on average sales during the 3-year period preceding the applicable calendar year. Thus, a farm that does not retain records documenting its sales during the 3 to 4 years prior to the applicable calendar year will not have documentation adequate to demonstrate its eligibility for the qualified exemption. The actual retention time necessary to support its eligibility during the applicable calendar year could be as long as 4 years. For example, if a farm were to be inspected on May 1, 2024, the farm would have retained the records from 2021–2023 for 3 years and four months. On the other hand, if a farm were to be inspected on December 28, 2024, the farm would have retained the records from 2021–2023 for nearly 4 years.

Second, we are making a corresponding revision to § 112.164(a)(1) to replace “2 years” with “at least 2 years” so the length of record retention in this provision is harmonized with new § 112.164(a)(2).

Finally, we are revising § 112.164(b) to make clear that it covers such records as those related to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations. For example, the initial or annual surveys that a farm conducts to develop or update the microbial water quality profile under § 112.46(b) can be comprised of data derived from water tests conducted within the previous 4 years, and these results inform the farm's use of that agricultural water in accordance with § 112.45. Because these results are necessary to verify the use of the agricultural water in compliance with the microbial quality criteria in § 112.44 as well as any time interval in compliance with the microbial die-off provisions in § 112.45(b)(1)(i) and/or (b)(1)(ii), we conclude a retention period of 2 years after their use is discontinued (*i.e.*, 2 years after the test results are used to inform the microbial water quality profile) is warranted for these water test results. Likewise, the written environmental monitoring plan (required under § 112.145) and written sampling plan (required under § 112.147) that a sprouting operation establishes and implements must be retained at the farm for at least 2 years after their use is discontinued.

F. Acceptable Formats for Records (§ 112.165)

(Comment 396) Several comments express concern about the proposed requirement in proposed § 112.165(c) that any electronic records maintained to satisfy the requirements of part 112

be kept in compliance with part 11 of this chapter. These commenters state that while large operations may have invested in part 11-compliant software, other farm operations currently maintain electronic records using commonly available software, such as Excel. Comments also state that only a few farms currently have the computer training necessary to implement the requirements of part 11, and that adapting their existing systems to be in compliance with part 11 would require significant investments by many farms. These commenters request that the requirement for electronic records to comply with part 11 be deleted from the final produce safety regulation. In addition, one commenter recommends that FDA provide information in guidance as to how operations should protect electronic records from intentional or unintentional falsification. In contrast, another commenter agrees that electronic records should be required to be in compliance with part 11. This commenter notes that most electronic records include a date stamp indicating when they were last modified, suggesting that this should be considered sufficient evidence of compliance with part 11 and allow such records to be considered original records.

(Response) We agree that the need to redesign large numbers of already existing electronic records and recordkeeping systems would create a substantial burden, particularly in light of frequent software patches and security updates and the use of open source software by some farms. Therefore, we are revising § 112.165(c) to provide that records that are established or maintained to satisfy the requirements of part 112 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. We also are specifying that records that satisfy the requirements of part 112, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. This rule provides that a farm may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the PCHF regulation, we are establishing a conforming change in part 11 to specify in new provision § 11.1(k) that part 11 does not apply to records required to be established or maintained under part 112, and that records that satisfy the requirements of part 112, but

that also are required under other applicable statutory provisions or regulations, remain subject to part 11. Although we are not specifying that part 11 applies, covered farms should take appropriate measures to ensure that electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Note, however, that we are not requiring electronic records. Indeed, to minimize the burden this regulation may have on covered farms, FDA is not specifying the form or format of the records that must be established and maintained except as set forth in part O. To satisfy the requirements of the produce safety regulation, paper or electronic records or a combination of the two may be used. We also expect that the training curriculum and materials being developed by the PSA and SSA will include training on how to develop and maintain appropriate records.

G. Disclosure of Records Submitted to FDA (§ 112.167)

(Comment 397) One comment asks FDA to affirm that the regulations under 21 CFR part 20 will be followed. This comment also generally expresses concern about disclosure of confidential information submitted by a covered farm to FDA, and that small businesses may not be fully aware of FDA’s ability to disclose certain types of materials. The commenter asks FDA to provide

guidance to assure that covered farms understand FDA’s procedures for publicly disclosing certain submitted materials.

(Response) We understand the concerns regarding confidentiality. Section 112.167 explicitly states that records obtained by FDA in accordance with part 112 are subject to the disclosure requirements under 21 CFR part 20. Our disclosure of information is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under 21 CFR part 20, which include protection for confidential commercial information and trade secrets. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule. We will consider addressing this topic in our SECG to be issued in the near term following this rule. We are revising this provision to specify that records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20. FDA is making this change to clarify that the requirements in part 20 attach to those documents obtained by FDA under this rule.

XXI. Subpart P—Comments on Variances

In subpart P of proposed part 112, we proposed a process by which a State or

a foreign country may request a variance(s) from one or more requirements of part 112, consistent with the statutory provisions in section 419(c) of the FD&C Act. We proposed that the competent authority for a State or foreign country submit the petition requesting the variance, what information must accompany such requests, and the procedures and circumstances under which FDA may grant or deny such requests, and modify or revoke such variances.

We asked for comment on our proposed provisions in subpart P for variances, including related process and scientific data and information to support a request for variance, and circumstances for approval or denial of a request for variance and for modification or revocation of an approved variance. We also asked whether there are any specific concerns that we should consider in finalizing the procedures and processes for requests for variances, as applicable to foreign governments.

We are finalizing these provisions with revisions (see Table 27). We discuss these changes in this section. We are finalizing the other provisions of subpart P without change. For §§ 112.174, 112.175, 112.177, 112.178, 112.179, 112.180, and 112.181, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions further.

TABLE 27—DESCRIPTION OF REVISIONS TO SUBPART P

Final provision	Description of revisions
§ 112.171	—Revision to establish that Federally-recognized tribes may submit a variance petition; and corresponding changes throughout subpart P.
§ 112.172	—Revision to make clear that a competent authority, for purposes of submitting a request for a variance in accordance with this rule, is the regulatory authority for food safety (replacing “e.g.,” with “i.e.”).
§ 112.176	—Revision of § 112.176(b) to replace “either” with “e.g.” to make clear that the situations described are merely examples and not limitations on who may comment. —Editorial revision to treat “website” as one word.
§ 112.177	—Editorial revision to treat “website” as one word.
§ 112.179	—Editorial revision to add the word “on” before “the date of our written decision”.
§ 112.181	—Editorial revision to treat “website” as one word.
§ 112.182.	—Revision to clarify that the permissible types of variances are not limited to the examples provided (adding “A variance(s) may be requested for one or more requirements in subparts A through O in part 112”). —Revision to include additional examples and delete examples that are no longer applicable due to revisions in other sections of part 112. —Revisions to update cross references in examples and descriptions of cross referenced requirements.

A. Requesting a Variance (§§ 112.171 and 112.172)

(Comment 398) Several comments express concerns about the lack of allowance for tribes to request variances from the requirements of part 112.

(Response) Tribal governments may request a variance(s) from part 112 under the same provision that permits States to request a variance(s) from part 112. FDA interprets 21 U.S.C. 350h(c)(2) to allow Federally-recognized tribes (which we refer to in the rule as “tribes”) to be treated in the same

manner as States for the purpose of the variance provision. Therefore, any one or more of Federally-recognized tribes may submit a variance petition, in accordance with § 112.171, and all other provisions in subpart P that apply to a petition submitted by a State apply equally to a petition submitted by a

Federally-recognized tribe (Ref. 246). In light of comments, we are adding “tribe” in part 112 to clarify for purposes of this rule that “tribes” are included. To make this explicit, we are revising § 112.171 to establish that a State, tribe, or foreign country may submit a petition requesting a variance(s) from the requirements of part 112, and making corresponding revisions throughout subpart P.

(Comment 399) One comment seeks clarification on who would be considered a competent authority for a State or foreign government, as proposed in § 112.172.

(Response) A competent authority is commonly understood to be a person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. For the purposes of the produce safety regulation, a competent authority is the regulatory authority for food safety for a State (*e.g.*, State Department of Agriculture, etc.), tribe, or a foreign country importing food into the United States. Our reference to this term in the produce safety regulation is consistent with the use of term in other regulatory contexts. For example, competent authority is used in various Codex guidelines, referring to the official government agency having jurisdiction (Ref. 247) (Ref. 248). This term is also used to refer to relevant regulatory authorities in the European Union (Ref. 249). We are editing § 112.172 to replace “*e.g.*” with “*i.e.*” to make this clear.

(Comment 400) Some comments state that entities allowed to submit variance requests should not be limited to State and foreign governments. A number of comments contend that additional groups, including State and federal commodity organizations, commodity boards, commodity commissions, trade associations, or other coalitions of farms should also be permitted to request variances using the same procedures available to States and foreign governments. These comments maintain that such groups are more likely to encompass the affected industry and are in a better position to consider and represent the risks and practices of the covered commodity. One comment states that a commodity commission is a State entity and should be able to submit a variance on behalf of a State. Some comments note that commodity boards have long partnered with research institutions and farms to investigate ways to improve produce safety, and are well positioned to present the information necessary to support a variance request. Some comments also state that allowing

petitions for variances from parties other than State governments would reduce the burden currently placed solely on State agencies.

(Response) The provision in § 112.171 establishes that a State, tribe, or foreign country from which food is imported into the United States may request a variance from one or more of the requirements proposed in part 112. This provision implements the statutory provisions in sections 419(c)(1)(F) and 419(c)(2)(A) of the FD&C Act, which specify the criteria for the final regulation and explicitly provide for “States and foreign countries from which food is imported into the United States” to request variances from the requirements of the produce safety regulation. These statutory provisions do not identify private industry groups or trade associations. With respect to an entity that may be a State entity, such as a State commodity commission, but that is not the competent authority for that State, such entities are not eligible to request a variance. We are limiting this provision to competent authorities for a State, tribe, or foreign country because these entities with legally delegated or invested authority for food safety issues are the most appropriate to represent a State, tribe, or foreign country in food safety regulatory matters.

FDA recognizes the knowledge of industry groups and appreciates their contributions to public and private partnerships to improve produce safety. FDA also appreciates that many groups have already instituted or are developing their own commodity-specific programs and guidelines (for example, in the case of strawberries, tomatoes, leafy greens, potatoes, and mushrooms) as well as with programs and guidance that cut across different commodity groups (for example, the AFDO Model Code; the Global GAPs (Ref. 250); and the Produce GAPs Harmonization Initiative (Ref. 251) (Ref. 252)). As noted previously, the processes in part 112, subpart P, do not preclude any entity from working with the competent authority (*i.e.*, the regulatory authority for food safety) for their State, tribe, or foreign country to develop a petition to request a variance. FDA anticipates that industry groups and other relevant stakeholders would be willing to provide assistance to reduce the burden on States, tribes, and foreign governments, including, as appropriate, by developing the necessary scientific data to support a request for a variance and/or drafting the variance petitions for signature and submission by the State, tribe, or foreign country. As discussed in the paragraphs

that follow, FDA also intends to take a number of steps, including providing for pre-submission consultations and making public scientific data and other information in petitions submitted, which may further ease the burden on States, tribes, and foreign governments with similarly situated covered farms.

(Comment 401) A comment states that the process of submitting a variance would require significant resources.

(Response) As noted previously, if a State, tribe, or foreign government chooses to submit a variance, we encourage them to work with other entities to develop variance petitions. FDA also intends to take a number of steps to provide assistance to States, tribes, and foreign governments interested in submitting petitions requesting a variance, including providing for pre-submission consultations and making public scientific data and other information in petitions submitted (see § 112.174), which may ease the burden on States, tribes, and foreign governments. In addition, in accordance with § 112.177, we may extend a variance granted to a State, tribe, or foreign government petition to another State, tribe, or foreign country that requests a similar variance for covered farms who are similarly situated within its jurisdiction.

(Comment 402) One comment requests us to follow the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) guidelines for the process for requests for variances from foreign competent authorities. This comment notes unfamiliarity with the petition process in § 10.30, but expects FDA to compare and contrast, and modify the currently proposed process to fit with WTO guidelines.

(Response) The process established under part 112 is appropriate not only for the petitioners for a variance, but also for the specific nature of the determinations that FDA is required to make when considering a variance request. In developing this process, FDA took into account WTO guidelines for considering petitions for variance, including documents by the relevant international organizations such as the Codex. Where appropriate, the petition process established by this rule should satisfy the recommendations of such guidelines.

B. The Statement of Grounds in a Variance Petition (§ 112.173)

(Comment 403) Comments generally support the proposed requirements related to processes, scientific data, and information to support a variance

request. Contrastingly, some comments request additional clarification on the scientific data and information necessary to support variance requests. Comments express concern with the availability, accessibility, and adequacy of the scientific data or information needed to demonstrate that the variance provides the same level of public health protection as the requirements of the produce safety regulation. Comments note that the lack of peer-reviewed scientific information will hamper the practicality and usefulness of the flexibility of variances, and information does not need to be published in peer reviewed journals in order to be used in support of a request for variance. Comments also support the use of industry-generated scientific data conducted through accredited or university laboratories, and suggest that data sets, methodology and analysis should be publicly shared so that other stakeholders can access and leverage such scientific information.

(Response) With regard to the scientific data and information necessary to support variance requests, States, tribes, and foreign countries may, among other things, consult scientific papers. FDA agrees that information does not need to be published in peer reviewed journals in order to be used in support of a request for variance, although we encourage use of peer-reviewed data and information, to the extent available. A State, tribe, or foreign country is required to submit relevant and scientifically-valid information or materials specific to the covered produce and/or covered activity to support the petitioner's request for a variance(s) from corresponding requirements established in part 112. Depending on the variance(s) requested, this could include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region. For example, a State, tribe, or foreign country may conclude that meeting certain requirements of the rule would be problematic in light of local growing conditions and that a variance from some or all provisions of this proposed rule is necessary. The State, tribe, or foreign country might consider the historical performance of an industry within their jurisdiction (*e.g.*, as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance. In requesting a variance, among other things, the State, tribe, or foreign country would submit information that, while the procedures,

processes and practices to be followed under the variance would be different from those prescribed in this rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the corresponding requirement(s) of the produce safety regulation for which a variance is requested. FDA encourages consideration of these types of information to support a request for a variance.

For example, the microbial die-off rate of 0.5 log per day to determine an adequate time interval, no greater than four consecutive days, between last irrigation and harvest is established in § 112.45(b)(1)(i). We derived this die-off rate based on a review of currently available scientific literature that shows a range of microbial die-off rates of 0.5 to 2.0 log per day, dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. Our analysis led us to conclude that a rate of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables to include microbe characteristics, environmental conditions, crop type, and watering frequency (see discussion on 79 FR 58434 at 58445–446; see also (Ref. 45)). Nevertheless, we acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity could result in higher die-off rates between last irrigation and harvest, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation. A State, tribe, or foreign country may submit a petition for a variance to the microbial die-off rate, as well as to the accompanying maximum time interval between last irrigation and harvest, established in § 112.45(b)(1)(i), along with scientific information and data demonstrating that the requested microbial die-off rate is appropriate for the specific crop, based on climate, soil, and/or geographical or environmental conditions of a particular region, and/or the processes, procedures, or practices followed in that region for the specific crop, as described in its petition to FDA. (Note that a covered farm can also establish an alternative microbial die-off

rate and an accompanying maximum time interval, in accordance with §§ 112.12(a) and 112.49(b), without the need for a variance for this specific requirement, although a variance approved by FDA could provide assurance to covered farms of the scientific basis for the deviation from FDA-established microbial die-off rate and also minimize the resource burden on individual farms developing the scientific support for an alternative as opposed to a State requesting a variance for all covered farms for which a variance would apply in a specified region.) Such scientific information and data may include scientific literature, such as research data on microbial populations and survival and/or die-off rates under conditions representative of that specific region (*e.g.*, temperature, humidity, precipitation); weather station data comparing their environment to that in the scientific literature; any historical, reliable water sampling or survey data relevant to the specific region; and/or data on current industry practices for the commodity in the specific region. The weather conditions are likely to vary based on factors such as topographic and environmental conditions. Therefore, we envision that the information and data supporting such a request for a variance would demonstrate the microbial die-off between last irrigation and harvest for a specific commodity, and under the environmental conditions of a particular region, that is requested in the petition to FDA.

Interested parties may work independently or in collaboration with their competent authority to compile supporting information for use by the State, tribe, or foreign country in its submission of a variance petition. In addition, § 112.177 ensures consideration of the application of variances to similarly situated persons and provides for transparency and accountability in FDA's review of requests and decision-making. FDA also welcomes pre-petition consultations with interested States, tribes, or foreign countries to facilitate the development of variance petitions, including a discussion of the types of data and information that would be needed to support the specific variance the State, tribe, or foreign country expects to request in its petition.

C. Process for Requesting a Variance (§ 112.176)

(Comment 404) One comment recommends that we clearly delineate the processes associated with the approval or denial of the variance, while another comment asks us to establish

criteria for how information supplied in support of variances will be evaluated.

(Response) We are establishing the general procedures applying to variance petitions in § 112.176. Under these procedures, a State, tribe, or foreign country from which food is imported into the United States may in writing submit a request for a variance(s) to the FDA using the process described in § 10.30. Such a request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the produce safety regulation. Under the procedures described in § 112.176, FDA will review such requests and may approve the variance requested either in whole or in part, as appropriate, and may specify the scope of applicability of the variance to other similarly situated persons. FDA will publish a notice in the **Federal Register**, requesting information and views on the filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted. FDA will respond to the petitioner in writing and will publish a notice on our Web site announcing our decision to either grant or deny the petition. If the petition is granted, either in whole or in part, FDA will specify the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply. If the petition is denied (including partial denials), FDA will explain the reason(s) for the denial in its written response to the petitioner and will post this information on our Web site. We intend to make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition.

In evaluating petitions, FDA will look to see if the petition addressed the relevant requirements, for example, whether the petition included information on the need for the variance and that procedures, processes, and practices to be followed under the variance provide the same level of public health protection as the relevant requirement(s) of part 112 (see § 112.171). We will also look for a Statement of Grounds describing with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply (§ 112.173(b)). We will assess whether the scientific

information, data, and materials included in the petition sufficiently support the variance requested and accompanying rationale for the request. If FDA finds that we need additional information to make a decision, we intend to communicate with the petitioner. As noted previously, we welcome pre-submission consultations so that data and information necessary to adequately support a specific variance can be identified. FDA anticipates providing guidance and other information, as appropriate, to assist States, tribes, and foreign countries in preparing petitions for requests for variances and developing the necessary scientific basis to support such requests.

(Comment 405) One comment asks whether we would be able to assess and provide a decision on variance requests before the implementation date if FDA were faced with large number of variance applications. This comment also suggests that, if we are not able to decide on a variance request before the implementation date, variance requestors should be able to continue operating under their existing practices until the FDA decision has been made. Another comment states that rapid approval of variances is a critical component to ensuring continuity in farming operations in areas where water quality is an issue yet food safety of certain commodities has not been impacted.

(Response) We expect the compliance periods we have established for this rule allow sufficient time for variance petitions to be developed, submitted, and reviewed by FDA. Per section 419(c)(2)(A) of the FD&C Act, FDA will review variance petitions and respond to petitioners in a reasonable timeframe. FDA welcomes pre-petition consultations, which could facilitate FDA's timely review and decisions on variance petitions.

(Comment 406) Comments asked us to establish a stakeholder group to review variances.

(Response) We deny the request to establish a stakeholder group to review variances submitted to FDA. Rather, FDA will review all variance petitions submitted to the agency. However, the citizen petition process, which we are employing in relation to requests for variances, allows opportunity for stakeholders to provide comment on variance petitions filed with FDA, including on the requested variance and the scientific merits of the request.

D. Permissible Types of Variances (§ 112.182)

(Comment 407) One comment notes that while a variance can be requested for one or more requirements of the produce safety regulation, the examples of permissible types of variances provided in § 112.182 of the rule creates the impression that only variances in those areas will be approved. This comment requests us to revise this provision to make it clear that a variance is not limited to certain elements of the rule.

(Response) The list in § 112.182 is intended to provide examples of the types of variances that may be requested and, if FDA deems appropriate, granted. Therefore, variance petitions are not intended or required to be limited to these examples. A State, tribe, or foreign country may request a variance from any one or more requirements in subpart A through subpart O in part 112, under the conditions described in § 112.171. We are revising § 112.182 to make our intent clear and to revise and update the list of examples. As revised, § 112.182 states that a variance(s) may be requested for one or more requirements in subpart A through O in part 112. Examples of permissible types of variances include: (1) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b); (2) variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and (3) variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

E. Other Comments

(Comment 408) One comment seeks clarification on how a variance request would work for countries seeking equivalence or systems recognition arrangements. This commenter states that FDA recognition of food safety systems in the foreign country should be an accepted variance to this rule. The organization also requests FDA to provide direction to foreign governments to help them determine which of the two options—a request for variance or for systems recognition—is more appropriate given their particular circumstances.

(Response) Variances, systems recognition, and equivalence are distinct regulatory tools, each requiring

different analyses, although they do overlap somewhat. As described in this rule, a foreign country may submit a request for a variance(s) by, among other things, demonstrating that local conditions and practices, while different, achieve the same level of public health protection as the relevant standard under the produce safety regulation. Variances may be requested for one or more requirements established under part 112. Systems recognition, as developed by FDA, applies to and evaluates the robustness of a foreign country's oversight of their food safety system and its comparability with United States controls and standards based on a comparison of key elements of the overall food control system and a rigorous in-country audit of food safety controls. Equivalence, as described in the WTO SPS Agreement, provides for exporting countries to demonstrate that they achieve the importing member's appropriate level of protection. Equivalence can be determined for a specific measure, a set of measures, or the entire food control system.

A country does not need equivalence or a systems recognition arrangement to obtain a variance. Systems recognition involves an intensive and extensive review of key aspects of the overall food safety control system. Indeed, an overall food safety system may not be comparable to that of the United States for FDA-regulated products, but the country may be able to successfully demonstrate that a specific produce production practice or set of practices provides the same level of public health protection for a specific measure or a set of measures as described in the requirements contained in part 112 of this rule.

Ideally, FDA's systems recognition of a food control system should include a successful assessment of its produce production practices. However, it is premature to determine that variances will not be needed or considered for countries with existing or future arrangements. We note that FDA's pilot systems recognition activities pre-date FSMA and FDA is currently refining the program and transitioning it from a pilot to the full program operations stage. Part of this process entails ensuring alignment, where appropriate, with FSMA. While all systems recognition

assessments have followed a similar process, each assessment varies in scope of the review for oversight of specific products. In the future, FDA will likely consider including additional consideration for produce standards, oversight and production practices particularly with respect to the country's practices and oversight regarding the specific provision(s) in part 112 in its systems recognition assessments. Any proposed changes to our process for existing arrangements and future assessments will be transparent and publically notified. For existing arrangements, FDA will work with the regulatory partner to determine if additional evaluation may need to be considered for any proposed variances.

Given varying scenarios and possibilities regarding the scope of each respective systems recognition arrangement currently being considered, FDA concludes that whether or how requests for a variance relate to current and future systems recognition assessments will need to be evaluated on a case-by-case basis and will be undertaken in consultation with the foreign country involved.

More information on systems recognition can be found at FDA's Web site: <http://www.fda.gov/food/internationalinteragencycoordination/ucm367400.htm>.

(Comment 409) One comment asks whether FDA considered extending the applicability of a variance to produce that is subject to another United States government regulatory framework that provides the same level of public health protection as the produce rule. This comment maintains that not recognizing the requirements mandated by another United States government regulatory framework could result in duplicative or contradictory standards and costs, with no additional public health benefit.

(Response) We are not aware of any federal regulatory programs that are duplicative of the produce safety regulation. We welcome pre-petition meetings to discuss any such regulatory programs and how the provisions of subpart P might apply.

(Comment 410) One comment expresses concern that although State-by-State variances can provide appropriate relief and recognition for localized alternate approaches, they can create a patchwork effect instead of

uniform protection, especially if one State has the resources to pursue a variance and another does not. This comment suggests that a different approach to variances may be to take a regional approach for certain aspects of the rule, or to implement first only those portions of the rule that can be applied uniformly or consistently while options for addressing more variable aspects are explored. The comment provides, as an example, that risk-based modeling or system-wide approaches may be appropriate methods for assessing risk and conditions such as water quality, and that tested, safe, and common alternatives could be accommodated within the body of the rule as regional or condition-based standards, thus reducing the need for some variances.

(Response) FDA agrees that some variances may be appropriate on a regional basis, not just at a State level. As discussed previously, this subpart provides a variety of mechanisms for applying some or all parts of a variance to other similarly situated persons, including to a region, rather than to a single State.

XXII. Subpart Q—Comments on Compliance and Enforcement

In the 2013 proposed rule, we outlined our overall strategy for implementation and compliance (78 FR 3504 at 3608–3609). In subpart Q of proposed part 112, we included certain proposed provisions regarding how the criteria and definitions in part 112 relate to the FD&C Act and the PHS Act, the consequences of failing to comply with this part, and coordination of education and enforcement. We asked for comment on the overall implementation and compliance strategy and proposed provisions in subpart Q, including specific strategies we should employ in order to best prioritize our implementation of the rule, and coordination of education and enforcement activities by relevant State, territorial, tribal, and local authorities.

We are finalizing these provisions with revisions (see Table 28). We discuss these changes in this section. We did not receive any comments or received only general comments in support of proposed § 112.191 and 112.192 and, therefore, we do not discuss final § 112.192 further.

TABLE 28—DESCRIPTION OF RE-ARRANGEMENT AND REVISIONS TO SUBPART Q

Proposed provision	Final provision	Description of revisions
§ 112.191	§ 112.192	—Revision to combine proposed §§ 112.191 and 112.192, all of which relate to the applicability and status of part 112, including the results of failures to comply with part 112, into one section. —Revision to include proposed § 112.191 as new provision § 112.192(b), along with revisions for clarity to separate the authorities cited from FD&C Act from that cited from the PHS Act.
§ 112.192. § 112.193	§ 112.193	—Revision to clarify that FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials “by helping develop education, training, and enforcement approaches”.

A. General Comments on Compliance and Enforcement Strategy

(Comment 411) Several comments ask for information on FDA’s compliance strategy. One comment urges that inspections, which the commenter feels will assure compliance and promote consumer confidence, should be the center of FDA’s core strategy. Noting FDA’s limited resources, one comment encourages FDA to adopt a voluntary program, rather than require compliance with a regulation, and asserts that FDA should pursue meaningful relationships with producers in order to make the goal of the produce safety rule a reality. One comment asks FDA and other relevant agencies to ensure their implementation strategies include and are informed by community input. Another comment suggests that FDA’s priority during the first several years after the regulation is finalized should be on education rather than enforcement.

(Response) During this rulemaking process, our FSMA implementation teams have been working concurrently on developing strategies and frameworks to operationalize the new FSMA prevention-focused food safety standards, including the produce safety rule. In May 2014, FDA published “Operational Strategy for Implementing the Food Safety Modernization Act (FSMA)” which describes guiding principles for FSMA implementation, including for the produce safety rule (Ref. 253). Stakeholder engagement is also central to operationalizing FSMA. FDA has engaged and sought input from the farming community and other stakeholders consistently throughout this rulemaking process. In addition, FDA held a public meeting on April 23–24, 2015 and opened a public docket to present our current thinking and gather stakeholder input on our operational work plans (Ref. 254) (Ref. 255). FDA intends to make the FSMA operational work plans public, once they are finalized.

FDA’s implementation of the produce safety rule will entail a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance, coupled with accountability for compliance from multiple public and private sources, including FDA and partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers. In keeping with this broad vision, FDA intends to focus its efforts on:

- Deploying a cadre of produce safety experts in headquarters and the field with the depth and breadth of capacity to develop the guidance needed to support implementation and provide technical support to government and industry parties working to foster compliance;
- Actively supporting education and technical assistance for farms, primarily through collaboration with other public and private parties;
- Supporting public and private parties involved in audits and other accountability functions with technical assistance and other collaborative support;
- Conducting targeted on-farm surveys and inspections to understand current practices and identify gaps in compliance;
- Taking administrative compliance and enforcement action when needed to correct problems that put consumers at risk;
- Responding to produce outbreaks effectively to lessen impact on public health; and
- Conducting in-depth environmental assessments where appropriate to identify root causes of outbreaks associated with produce and inform future prevention efforts.

FDA’s inspection resources will be targeted based on risk. In addition to conducting its own inspections, FDA also plans to rely heavily on States to conduct a large proportion of the routine inspections on farms. Thus,

inspection will play an important role in the overall compliance effort.

B. FDA Enforcement Decisions

(Comment 412) Several comments suggest specific criteria that FDA should use in determining how to respond to violations of this rule, such as whether the violation represents an “immediate public health risk,” and whether the farm demonstrates a willingness and effort to correct violations. Another comment requests that FDA be clear in explaining to farmers what is wrong to allow them to come into compliance. Some comments express concern about the potential impact of FDA’s compliance and enforcement determinations on their business.

(Response) We intend to assess a farm’s compliance with this rule on a case-by-case basis. In considering what action is appropriate, we are likely to consider factors including the severity of the violation, the willingness of the farmer to cooperate and take corrective actions, and the risk to public health. While many farms already follow some or all of the requirements in this regulation, we recognize that this is the first national standard for on-farm practices related to produce safety and that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when appropriate. However, we realize that no food safety regime can provide complete assurance against the emergence of foodborne illness, and there might be circumstances in which the failure to prevent foodborne illness might not mean that the farm has violated the Produce Safety rule. See also our response to Comment 411 describing our implementation and enforcement strategy.

(Comment 413) One comment suggests that compliance with FSMA should be presumed for certain farms. The comment cites North Carolina

Session Law 2013–265 (Senate Bill 63) (NC Farm Act of 2013) as providing protection to farmers by entitling them to “a rebuttable presumption that the commodity producer was not negligent when death or injury is proximately caused by consumption of the producer’s raw agricultural commodity” under certain conditions.

(Response) We are aware that North Carolina has passed this law in their State, and that other States may choose to establish similar laws. However, State law tort duties are not relevant for purposes of this rule.

C. Coordination of Education and Enforcement (§ 112.193)

(Comment 414) Several comments address the degree to which FDA will enforce the rule, and the extent to which States will be involved. Several comments request clarification, including on the framework for coordination, timeline for inspection-related activities, expectations from State agencies, and securing necessary funds and resources. Several comments favor FDA working with State governments using existing established efforts, including State-industry educational and regulatory interfaces and assistance programs, as well as education and standards of current protocols developed by extension services, State departments, other farming good management practices, and local regulations. Several comments express a belief that such an approach would be most successful because State governments best know the realities of agricultural practices within their borders and often have an established history of successful inspection processes. Some comments express a preference for State agricultural agencies to be involved in compliance activities related to this rule, rather than other State agencies (such as health- or environmentally-oriented agencies), arguing that State agricultural agencies have a deep understanding of local agricultural practices and have developed strong working relationships with farmers. One comment notes some potential challenges with implementation by States, including that in some circumstances, State agencies lack the authority to enter farms. Some comments also express concerns related to resources necessary for States to conduct inspections.

(Response) As discussed previously, we are revising § 112.193 to clarify that FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches. FDA plans

to work closely with States to implement the produce safety rule. We agree that our State counterparts have substantial knowledge about the farms in their jurisdiction. FDA intends to work collaboratively with our federal and State regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with this rule. Section 702(a)(1)(A) of the FD&C Act (21 U.S.C. 372(a)(1)(A)) expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. Qualified State, territorial, tribal, or local regulatory officials may be commissioned or serve under contract with FDA to conduct examinations, inspections, and investigations for purposes of the FD&C Act. In addition, section 702(a)(2) [21 U.S.C. 372(a)(2)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through officers and employees of another federal department or agency, subject to certain conditions set forth in that section. We expect to continue to cooperatively leverage the resources of federal, State, tribal, and local government agencies in this and other ways as we strive to obtain industry-wide compliance with this rule. We agree that FDA should leverage existing State programs when feasible. The roles of FDA and State partners are likely to vary based on the nature of the task and the State involved.

We have entered into a cooperative agreement with NASDA to obtain critical information related to implementation of this rule, in partnership with State regulatory agencies (Ref. 256). As part of the cooperative agreement, NASDA will conduct an assessment of the current foundation of State law, the resources needed by States to implement this rule, as well as develop a timeline for successful implementation.

In addition, FDA anticipates that some States may choose to adopt requirements modeled after the provisions of this rule and may choose to perform inspections under their own authorities to enforce the provisions of their State laws. Such actions would further drive compliance with the produce safety standards in this rule.

(Comment 415) One comment notes that a State agency would not be the appropriate enforcement agency on tribal lands regarding food and water systems. This comment also states the

final produce safety rule should include issuance of a tribal regulatory authority for training and implementation and limit the authority of State law enforcement officers on tribal lands, or exclude tribal lands altogether from State enforcement unless at the request of the tribe.

(Response) FDA recognizes the importance of engaging tribal regulatory authorities for successful FSMA implementation on tribal lands. FDA intends to work collaboratively with tribal regulatory partners to develop the appropriate education, enforcement, and training needed to facilitate compliance with the produce safety regulation on tribal lands (see FDA’s recently released FSMA training strategy at www.fda.gov/fsma). We do not expect to use State officials to conduct inspections on FDA’s behalf on tribal lands, but rather we intend to work with tribal authorities to commission tribal officials, as appropriate, to conduct these inspections.

(Comment 416) One comment requests adding to § 112.193 a list of entities, including State and federal partners, that will be working with FDA to implement the rule, as well as a timeframe for when operations will begin.

(Response) FDA declines to establish a list of partnerships in the regulatory text. Such partnerships may change over time. Similarly, our operations timeframes will depend on the specific operational strategies we adopt in various circumstances. We plan to make information on our FSMA operational work plans public as previously described in Comment 411.

D. On-Farm Inspections

(Comment 417) Several comments seek information about on-farm inspections. Some comments argue that, because farmers make the majority of their money in a relatively small period of time, inspectors should be sufficiently familiar with agricultural production, harvesting, and handling methods to minimize potential disruptions to the farm business, particularly when inspections occur at the peak of harvest season. In addition, some comments ask FDA to develop specific training modules to ensure consistency in inspections and inspectors’ awareness of farming practices. Some comments also recommend that inspectors should have familiarity with acceptable on-farm practices taking into consideration the diversity of agricultural practices, conditions and commodities.

(Response) See our response to Comment 411, in which we discuss our expectation that inspections will play an important role in the overall compliance effort, along with a range of other public and private efforts ranging from education, training, and technical assistance to private third-party audits. We anticipate developing educational materials related to compliance and enforcement activities for produce safety. As discussed previously (in Comment 411 and Comment 414), FDA plans to collaborate with State and other partners in implementing the produce safety rule. Personnel performing farm inspections may include federal investigators, State inspectors, or other authorities, and will likely vary by State. In addition, FDA plans to deploy a cadre of produce safety experts in headquarters and the field with the depth and breadth of capacity to support implementation and provide technical support to government and industry parties working to foster compliance.

We anticipate that FDA and State investigators, as well as other partners conducting inspections, will receive joint training and education, which will include refresher training as needed. FDA intends to work closely with State, local, territorial, and tribal partners to develop the tools and training programs needed to help implementation activities, including inspections, to be conducted consistently. We expect to build on our collaboration with State, local, territorial, and tribal officials in the development of tools and training for use by inspectors in farm investigations on issues specific to food safety during growing, harvest, packing and holding produce. Funding may be made available through various mechanisms, such as grant programs, to support inspector training.

(Comment 418) Some comments ask questions regarding when farms would be inspected and for what reasons. Some comments ask FDA to clarify whether or not FDA may inspect a farm without prior notice. One commenter believes all farm inspections should be “for-cause” only, and that Congress did not intend for FDA to routinely inspect farms.

(Response) FDA’s authority to conduct on-farm examinations and investigations for the purposes of the FD&C Act is not limited to for-cause situations and FDA is not required to give a farm prior notice of an inspection. As discussed in Comment 411, FDA intends to prioritize inspections based on risk. FDA intends to develop a work plan regarding routine farm inspections. FDA is exploring the possibility of pre-

announcing at least some farm inspections; however, there will likely be instances where a farm will not receive prior notice regarding an inspection.

E. Third-Party Audits, Inspections, and Other Arrangements

(Comment 419) One comment urges FDA to encourage retailers and other customers who require audits to minimize the number of individual audits and align the standards against which farms are audited with the standards in the produce safety regulation. The comment notes that such an approach will minimize the economic and operational burden created by multiple audits, especially on smaller operations.

(Response) FDA supports streamlining audit standards for efficiency and supports harmonizing existing industry standards with the requirements of this rule. We also recognize the value in industry’s continued development of innovative and effective methods to ensure the production of safe foods.

(Comment 420) Several comments note the existence of third-party audits, stating that existing groups already conduct various farm audits. Some comments suggest that FDA should utilize these third-party audits as part of FDA’s compliance strategy for this rule. Some comments ask FDA to “recognize” certain types of audits as sufficient for certain purposes.

(Response) FDA anticipates that significant incentives and accountability for compliance with this rule will come through third-party audits and supply chain management initiated by produce farms, their customers, or other private entities. As outlined in Comment 411, third-party audits are an important part of our overall compliance strategy. We believe it is important to have significant oversight of farms to ensure compliance with the rule. Thus, as a complement to State and FDA inspections of farms, we intend to leverage the conduct of reliable third-party farm audits by USDA and others, as well as compliance with marketing agreements, with a goal of annual verification of farms that must comply with the rule.

In addition to audits conducted to meet buyer-specific criteria, a number of retail produce buyers currently require, as a condition of sale, that their produce suppliers comply with and be audited by third parties for conformance with the GAPs guide, USDA GAP and GHPs, CA LGMA and AZ LGMA standards, and other voluntary programs. Whether conducted under such programs or in

response to specific buyer demands, adequately rigorous and reliable private audits can be an important additional tool for fostering food safety and ultimately compliance with this rule. We note further that private audits may be relevant to some aspects of compliance with the supplier verification requirements in the FSVP and preventive controls regulations, where a farm supplies produce to an importer or receiving facility that seeks to verify that the farm has adequately controlled applicable hazards.

We intend to pursue the goal of making third-party audits an important part of our compliance strategy by building on current private audit activity and by working with the produce industry and other government and private partners to improve the rigor and reliability of private audits. We believe that strengthening both the quality and credibility of private audits will help improve food safety, especially if conducted on the basis of the standards in this rule, but it can also be the basis for streamlining current audit practices and making them more efficient. Potentially, a single annual audit that is recognized to be a rigorous and reliable means of verifying compliance with this rule could substitute for multiple audits conducted under disparate standards with less well-established credibility. We seek public-private collaboration to achieve this goal.

We also note that in the final third-party certification rule (published elsewhere in this issue of the **Federal Register**), FDA is establishing a voluntary program for the accreditation of third-party certification bodies that may conduct audits and issue certifications for purposes of establishing an entity’s eligibility to participate in VQIP or to satisfy conditions set forth under section 801(q) of the FD&C Act.

FDA is not recognizing any auditing body in this produce safety rulemaking.

(Comment 421) Some comments recommend that FDA should both permit the use of any government-approved inspector or inspection service and also require farms’ customers to accept certification or approval by any such approved inspector or service. The commenters believe that this step is necessary to protect farms from having to pay large fees to private companies.

(Response) It is beyond the scope of this rule to require that entities in a supply chain accept certifications or approvals provided by third-party inspection services for other entities in the supply chain. To the extent that the

comments request that FDA allow farms to undergo inspections or audits, nothing in this rule prohibits such use of inspection or auditing services.

(Comment 422) One comment suggests that, where FDA has systems recognition arrangements with foreign governments, importers who import produce from such countries should be subject to lesser requirements than they otherwise would be, and FDA should not inspect covered farms from that country.

(Response) As discussed previously (see our response to Comment 408), systems recognition involves an intensive and extensive review of key aspects of a country’s overall food safety control system. The comment addresses the requirements applicable to an importer when there is a systems recognition arrangement. Requirements for importers are outside the scope of this produce safety rule. FDA addresses requirements applicable to importers who import food from countries whose food safety systems FDA has officially recognized as comparable or equivalent in the final FSVP rule (published elsewhere in this issue of the **Federal Register**).

This comment also addresses FDA inspections of covered farms in countries with which FDA has systems recognition arrangements. Ideally, FDA’s systems recognition of a food control system should include a successful assessment of its produce production practices. We note that FDA’s pilot systems recognition activities pre-date FSMA, and FDA is currently refining the program to ensure alignment, where appropriate, with FSMA. While all systems recognition assessments have followed a similar process, each assessment varies in scope

of the review for oversight of specific products. In the future, FDA will likely consider including additional consideration for produce standards, oversight, and production practices particularly with respect to the country’s practices and oversight regarding the specific provision(s) in part 112 in its systems recognition assessments. Further, systems recognition does not mean that no oversight of produce from such a country is warranted; therefore, it would not be appropriate to state that farms in countries with systems recognition are not subject to FDA inspection. It is also premature at this point to determine whether or how existing or future systems recognition arrangements may affect our inspections of foreign farms.

XXIII. Subpart R—Comments on Withdrawal of Qualified Exemption

In the 2013 proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Specifically, proposed § 112.201 listed the circumstances under which FDA may withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specified the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provided for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211

provided a procedure for appeals, hearings, and decisions on appeals and hearings. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3611 through 3616). We requested public comment on our proposed provisions, including on related process and timeframes for actions to be taken by FDA and covered farms.

In the supplemental notice, in part, taking into account public comment on the 2013 proposed rule, we proposed certain amendments to §§ 112.201 and 112.202 related to the circumstances under which FDA may withdraw a qualified exemption and the procedure for issuing an order to withdraw a qualified exemption; and added a new proposed provision § 112.213 to list the circumstances under which FDA would reinstate a farm’s qualified exemption that is withdrawn. We asked for public comment on our new and amended proposed provisions (79 FR 58434 at 58464–58467).

In this section of this document we discuss comments that we received on the withdrawal provisions in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the new and amended proposed withdrawal provisions in the supplemental notice.

We are finalizing the provisions in subpart R with revisions (see Table 29). We discuss these changes in this section. For §§ 112.202, 112.209, 112.210, and 112.211, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions further.

TABLE 29—DESCRIPTION OF REVISIONS TO SUBPART R

Final provision	Description of revisions
§ 112.201(b)(2)	—Revision to allow 15 calendar days from the date of receipt of an order to withdraw a qualified exemption, for a farm to respond in writing to our notification.
§ 112.202	—Editorial change to insert the word “either” in § 112.202(a).
§ 112.203(c)	—Editorial changes to clarify that the order will specify which of two circumstances that may lead FDA to withdraw a qualified exemption apply, or whether both of these two circumstances apply.
§ 112.203(d)	—Revision to require that the contents of an order must include a statement that the farm must either comply with or appeal the order. —Revision to require compliance with an order to withdraw a qualified exemption within 120 days of the date of receipt of the order, consistent with the timeline in the PCHF regulation; and corresponding changes to §§ 112.204(a) and 112.205(b).
§ 112.203(e)	—Include a statement informing the farm that it may ask us to reinstate an exemption that was withdrawn by following the procedures in § 112.213.
§ 112.204(b)	—Revision to require that a farm may request an informal hearing by submitting a written appeal within 15 calendar days from the date of receipt of the order; and corresponding changes to §§ 112.206(a)(1) and 112.207(a)(2).
§ 112.205(b)(2)	—Specifies that a farm that loses its qualified exemption would no longer need to comply with the modified requirements in §§ 112.6 and 112.7.
§ 112.208(a)	—Revision to allow for the hearing to be held within 15 calendar days after the date the appeal is filed.
§ 112.213(a)	—Editorial change to replace the word “shall” with “will”.

A. Circumstances That May Lead FDA To Withdraw a Farm's Qualified Exemption (§ 112.201)

(Comment 423) Some comments agree with the proposed provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified exemption. For example, some comments agree that other regulatory actions should be considered before withdrawing a qualified exemption, and some comments agree that it is appropriate to assess corrective actions taken by a farm in response to a food safety problem when considering whether to withdraw its exemption. Some comments recommend revising the wording in § 112.201(b)(1) from “may consider” to “shall take” thus requiring FDA to take alternative actions prior to withdrawing a qualified exemption. Other comments agree that these provisions are reasonable and will provide farms due process and greater clarity on the withdrawal process, but suggest that we could issue guidance rather than include these provisions in the rule to allow us greater flexibility should we have to act quickly to protect the public health.

Other comments disagree with these proposed provisions and ask us to delete them from the final rule. These comments assert that FSMA does not require us to describe the actions that we may take prior to withdrawing a qualified exemption and that it is not necessary to do so because it is customary for us to work with regulated industry to address problems before taking enforcement actions. These comments also express concern that listing possible regulatory actions before we would issue an order to withdraw a qualified exemption could create an expectation that we will always exercise such regulatory actions before issuing the order. These comments also express concern that being bound by these provisions could prevent us from acting quickly to protect public health.

(Response) We are retaining the provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified exemption. We agree that it is customary for us to work with industry to address problems before taking enforcement actions but disagree that specifying this customary practice in the rule would prevent us from acting quickly to protect public health. We consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions such as those described in these provisions may

provide a more expeditious approach to correcting a problem than withdrawing an exemption. We also disagree that the rule binds us to take alternative regulatory action before issuing an order to withdraw a qualified exemption, other than to notify the farm in writing of circumstances that may lead us to withdraw the exemption, provide an opportunity for the farm to respond in writing, and consider the actions taken by the farm to address the circumstances we describe. The rule clearly specifies that regulatory actions such as a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction are actions that we “may” (not “must”) take before issuing an order to withdraw a qualified exemption. Providing the farm with an opportunity to correct the problems before we take steps to withdraw an exemption has the potential to save agency resources associated with preparing an order, responding to an appeal of the order and request for a hearing, and administering a hearing. Directing resources to help a farm to correct problems, rather than to administer a withdrawal process that could be resolved by the time of a hearing, is appropriate public health policy.

(Comment 424) Some comments ask us to specify that the notification of circumstances that may lead FDA to withdraw the exemption must include facts specific to the situation and information about how the farm can remedy the situation.

(Response) By specifying that we must notify the farm of circumstances that may lead us to withdraw an exemption, we mean that we would include facts specific to the situation. It is the responsibility of the farm, not FDA, to remedy the situation.

(Comment 425) Some comments recommend that both the initial notice of intent to withdraw and the withdrawal order itself should be based on an individualized, case-by-case determination, and should not apply to a group or class of farms.

(Response) The decision to withdraw a qualified exemption is an individualized determination and will not be applied to a class of farms or farmers.

(Comment 426) Some comments ask us to provide additional time for a farm to respond, in writing, to a notification of circumstances that may lead us to withdraw its qualified exemption. Some of these comments request timeframes such as 2 weeks or 90 days for a farm to compile information and

documentation of facts and to respond to FDA's notification.

(Response) We are revising § 112.201(b)(2) to provide for 15 calendar days, rather than 10 calendar days, for a farm to respond in writing to our notification. The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified exemption require prompt action on the part of a farm, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 427) Several comments request that FDA notify the appropriate State regulatory agency before a farm's qualified exemption is withdrawn or reinstated.

(Response) We decline this request. We are sensitive to the time required for various inspection activities and intend to communicate with States regarding our expectations for how to verify whether a farm meets the criteria for a qualified exemption. The qualified exemption status of a farm principally affects the requirements that it is subject to, and will be most useful to FDA and our food safety partners when preparing for inspection. At this time, we do not intend to establish a system notifying the applicable State authorities at a point in time when the qualified exemption status of a farm changes, whether as a result of withdrawal or reinstatement of the farm's qualified exemption or because the farm's business has grown to the point where it exceeds the criteria that must be met for a farm to be eligible for a qualified exemption.

B. Contents of an Order To Withdraw a Qualified Exemption (§ 112.203)

(Comment 428) Some comments recommend that the order specify which of the two circumstances (§ 112.201(a)(1) or § 112.201(a)(2)) that could lead us to issue the order apply.

(Response) We have made editorial changes to the regulatory text to make it more clear that the proposed provision to require us to include a brief, general statement of the reasons for the order, including information relevant to (1) an active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm, should specify which of these two circumstances apply, or whether both of these two circumstances apply. See the revised regulatory text for § 112.203(c).

(Comment 429) Several comments recommend that the written order withdrawing the qualified exemption should include a detailed description of the substantial, science-based evidence FDA has to support its finding for withdrawal of a qualified exemption, rather than a brief, general description, as described in § 112.203(c). Comments argue that a brief, general description supporting the order to withdraw a qualified exemption is not sufficient to allow the farmer to adequately respond to the order or prepare for an appeal hearing. Comments also contend that FDA must be required to clearly and specifically identify the “material conduct or conditions associated with the farm that are material to the safety of the food” regulated under this rule. In addition, some comments assert that “material conditions” should be based on scientifically measureable traits that can be clearly identified as occurring on the individual farm and/or should be limited to conditions within the farm’s control. Some comments recommend that we require FDA to meet an explicit evidentiary threshold to find that conduct or conditions exist on a farm sufficient to warrant withdrawal of the farm’s exemption.

(Response) We agree that the order must provide sufficient information to enable a farm to respond with particularity to specific evidence about the circumstances leading to the order. However, we disagree that the order must do so by including the specific information recommended by the comments, or that we should include an explicit evidentiary threshold, and we have not revised the proposed withdrawal provisions to incorporate the suggestions of these comments. A number of these comments appear to be more focused on whether the circumstances that lead us to issue an order meet an evidentiary standard than on explaining the problem so that a farm can both understand the problem and respond with particularity to the facts and issues contained in the order. The withdrawal provisions that we are establishing in this provision require the order to include a brief, general statement of the reasons for the order, including information relevant to: (1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm. The requirements that we are establishing in this provision would enable the farm to understand the

problem, have a dialogue with us as appropriate, and respond to the problem. In addition, we intend that the process of responding to the notification that we must send before issuing an order to withdraw a qualified exemption, including discussing the problems with FDA as warranted, would provide additional information to the farm to enable the farm to both understand the problem and respond to it. Also, as discussed in Comment 184 and Comment 186, conditions that are not within a farm’s control may be material to the safety of the produce grown on that farm, and this rule includes certain provisions requiring covered farms to consider certain conditions that may not be under the farm’s control as an important part of minimizing the risks presented by such conditions.

(Comment 430) Some comments suggest that FDA should require confirmation of the delivery and receipt of the withdrawal order by the farm, such as through certified mail.

(Response) We are not specifying that we send an order in a way that ensures its receipt. Although certified mail with confirmation of delivery is one way to ensure receipt, other methods are available, including delivery through private carriers that provide mechanisms to document receipt. FDA will likely use one of these methods to document receipt. In light of the provisions in §§ 112.203, 112.204, 112.205, 112.206, and 112.207 linking the timeframes for you to comply with, or appeal, an order to the date of receipt of the order (rather than to the date of the order) (see our responses to Comment 433 and Comment 434), it will be up to us to deliver the order in a way that provides us with evidence of receipt.

(Comment 431) Some comments ask us to include in the order a statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213.

(Response) We are revising the requirements for the contents of an order as requested by these comments (see § 112.203(e)).

(Comment 432) One comment recommends that the order specify the two options that a farm has upon receipt of the order, similar to the withdrawal provisions in proposed 117.257(d) in the proposed human preventive controls rule.

(Response) We agree that it would be useful for the order to itself specify the two options that a farm has upon receipt of the order, even though the order would otherwise include this

information (because the order will contain the full text of the withdrawal provisions under § 112.203(f)). In § 112.203(d), we are requiring that the contents of an order must include a statement that the farm must either comply with or appeal the order.

C. Compliance With, or Appeal of, an Order To Withdraw a Qualified Exemption (§§ 112.204, 112.205, and 112.206)

(Comment 433) Several comments express that 60 calendar days in proposed § 112.204(a) is not sufficient time for a farm to comply with an order withdrawing its qualified exemption. Several comments recommend revising proposed §§ 112.203(d) and 112.204(a) to require compliance within 120 days of the date of receipt of the order, consistent with the parallel timeline in part 117. Other comments ask for 1 or 2 years to comply. Some comments also suggest that the timelines in both rules should be based on working or business days rather than on calendar days. Other comments ask us to consider provisions that would require compliance with only those portions of the rule that formed the basis for the revocation.

(Response) As in the case of facilities subject to the PCHF regulation, we conclude that the nature of what a farm would need to do to comply with an order—*i.e.*, comply with the full requirements for minimum science-based standards established in the produce safety regulation—makes the 60-day timeframe in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the withdrawal provisions would only apply when a significant public health concern has been identified for a particular farm.

We are revising §§ 112.203(d), 112.204(a), and 112.205(b) to require compliance within 120 days of the date of receipt of the order, consistent with the parallel timeline in part 117. We believe that the 120-day timeframe is adequate, but we are adding flexibility such that a farm may request, with a justification in writing to FDA, a reasonable timeframe for compliance that exceeds 120 calendar days from the date of receipt of the order. FDA must grant the request for the farm to receive the extended timeframe. We are not generally extending the timeframe because circumstances that could lead us to withdraw a farm’s qualified exemption require prompt action on the part of the farm. A farm that receives an order to withdraw its qualified exemption would have received advance notification of the

circumstances leading to the order and would have had an opportunity to correct the problems rather than have us proceed to issue the order (see § 112.201(b)). If the farm requests a hearing, more than 40 days could elapse between the date that the farm receives the order and the date that the presiding officer for the hearing confirms the order to withdraw the exemption. Given that the circumstances that would lead us to issue the order involve either (1) an active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) a determination that withdrawal of the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm, a delay of one to two years to comply with the rule is not warranted.

We also do not believe that it would be appropriate to require a farm to come into compliance with only those provisions that formed the basis of the revocation. The provisions of subparts B through O are interrelated and operate as a system and, therefore, are not optimized through piecemeal implementation. However, FDA may consider staggered implementation as an option in granting a request for an extension of the timeframe to comply with an order to withdraw the qualified exemption for a farm.

We also conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (21 CFR 1.402).

In the supplemental notice, we acknowledged the difference in our proposed timelines for compliance when a qualified exemption is withdrawn between the PCHF and produce safety regulations (79 FR 58434 at 58467). We have made the administrative procedures associated with the withdrawal of a qualified exemption consistent to the extent practicable, and are revising the withdrawal provisions to require that a covered farm comply with an order to withdraw an exemption within 120 calendar days of the date of receipt of the order. See the revised regulatory text in provisions §§ 112.203(d), 112.204(a), and 112.205(b).

For clarification, we are specifying, in new § 112.205(b)(2), that a farm that

loses its qualified exemption would no longer need to comply with the modified requirements in §§ 112.6 and 112.7. This revision is also consistent with provisions in the PCHF regulation.

(Comment 434) Several comments request longer than the proposed 10 calendar days to file a written appeal of the order of withdrawal of the qualified exemption. Comments cite various reasons, including possible issues in mail delivery such that the farmer would have less than 10 calendar days, potential need for legal counsel, and time needed to gather evidence. Some comments ask us to provide 15 business days from date of receipt of the order for the farm to appeal the order.

(Response) We have revised the timeframe for compliance with the rule to the date of receipt of an order to withdraw a qualified exemption (see our response to Comment 433). Likewise, we conclude that it is appropriate to link the timeframe for submitting a written appeal of a withdrawal order to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (21 CFR 1.402). Accordingly, we are revising the withdrawal provisions to require that a covered farm may request an informal hearing by submitting a written appeal in accordance with § 112.206 within 15 calendar days from the date of receipt of the order. See the revised regulatory text in provisions §§ 112.204(b), 112.206(a)(1), and 112.207(a)(2). We are also revising § 112.201(b)(2) to provide for 15 calendar days from the date of receipt of the order for a farm to respond in writing to FDA's notification. We are also extending the timeframe for the hearing to be held within 15 calendar days, rather than the proposed 10 calendar days, after the date the appeal is filed to provide more time for the farm to prepare for the hearing (see § 112.208(a)). The timeframe for the hearing to be held continues to provide for an alternative timeframe agreed upon in writing by both the farm and FDA; a farm that would have preferred the proposed timeframe of 10 calendar days could request that the hearing be held more quickly than 15 calendar days.

The 15-day timeframe is the same as the timeframe for responding to a warning letter. As discussed in Comment 423, circumstances that could lead us to withdraw a qualified exemption require prompt action on the part of a farm, just as circumstances that lead us to issue a warning letter require prompt action.

D. Procedure for Requesting an Informal Hearing (§ 112.207)

(Comment 435) Some comments ask us to guarantee a hearing so that a farm can present its case in person before having its qualified exemption revoked.

(Response) We decline this request. We agree that a farm has a right to appeal an order to withdraw its qualified exemption, and we have provided for a right to appeal.

E. Informal Hearing (§ 112.208)

(Comment 436) One comment states that the two-day time period to review and respond to the presiding officer's report is not sufficient.

(Response) We decline this request. Circumstances that could lead us to withdraw a farm's qualified exemption require prompt action on the part of the farm, and we conclude that two calendar days is a reasonable timeframe, should the farm choose to review and comment on the presiding officer's report.

(Comment 437) Some comments object to our proposal that no party shall have the right, under 21 CFR 16.119, to petition FDA for reconsideration or a stay of the presiding officer's final decision, and ask us to revise proposed § 112.208(c)(6) to specify that a farm with a qualified exemption shall have the right to file a motion for reconsideration or stay. These comments find insufficient our rationale that the circumstances that would lead to a withdrawal merit prompt action and that a farm has the opportunity for judicial review in accordance with 21 CFR 10.45.

(Response) We decline this request. In § 112.201(b), we are providing an additional mechanism for a farm with a qualified exemption to present its view that its exemption should not be withdrawn—i.e., by providing advance written notification to the farm if we are considering withdrawing an exemption and providing an opportunity for the farm to respond before we issue an order to withdraw an exemption. In addition, in § 112.213, we are providing an opportunity for reinstatement of a qualified exemption that had been withdrawn. We believe the multiple opportunities now available to a farm provide adequate opportunities for the farm's views to be considered, and further mechanisms are not warranted.

F. Circumstances Related to Reinstatement of a Qualified Exemption That is Withdrawn (§ 112.213)

(Comment 438) Some comments agree with our tentative conclusion that the absence of a specific provision in

section 418 of the FD&C Act for the reinstatement of an exemption that is withdrawn does not preclude us from providing for such a process (79 FR 58434 at 58466). Other comments disagree with that tentative conclusion and assert that Congress crafted the withdrawal provision as a “one strike, you’re out” provision. These comments also assert that including the withdrawal provision as a “one strike, you’re out” provision was an essential part of the legislative agreement that allowed for adoption of the qualified exemption of a farm. These comments also assert that reinstatement would undermine the intent of the withdrawal provision, because it would reduce the incentive for small farms to ensure that the produce they sell is as safe as possible. These comments also assert that a recognized principle of statutory interpretation provides that exemptions to statutes should be strictly construed, particularly when the statute addresses public health and safety, and that FDA is giving the exemption an impermissibly broad construction.

Some comments ask why we believe that a farm deserves a “second bite of the apple” in light of the understanding (under proposed § 112.201(b)) that we will first seek to correct problems before considering withdrawal. These comments also question at what point a farm would apply for reinstatement, and ask why we would allow a farm that has already come into compliance with FSMA’s requirement to implement produce safety standards to abandon those measures in favor of reinstating its exempt status. These comments ask us to eliminate the proposed provisions allowing for reinstatement.

Some comments do not support the proposed reinstatement provisions when a farm has been directly linked to a foodborne illness outbreak. Some comments support the proposed reinstatement provisions only when we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm that had its exemption withdrawn.

(Response) We disagree that the proposed reinstatement provisions would give the exemption an impermissibly broad construction. The express statutory language of section 419(f) of the FD&C Act does not support the comments’ assertion that the withdrawal provision is a “one strike, you’re out” provision. We also disagree that reinstatement would undermine the intent of the withdrawal provision in that it would reduce the incentive for small farms to ensure that the produce they sell is as safe as possible. We

proposed that a farm would need to present data and information to demonstrate that it has adequately resolved the problems with the conduct or conditions that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak. In contrast to the assertion of the comments, we believe that the opportunity for reinstatement would be an incentive—not a disincentive—for farms that are eligible for a qualified exemption to ensure that the produce they sell is safe by continuing to adhere to procedures and practices that it develops to comply with the rule. For example, if a farm had to implement the provisions of the rule after having its exemption withdrawn and realized through testing to comply with the water provisions that it needed to apply a day of die-off in field before harvesting to come into compliance with the water standard, then the farm would likely continue to apply the die-off and delay harvesting by a day even after the exemption was reinstated. The farm would likely realize that if it did not continue to conduct activities that improve the safety of its produce that it might have a repeat food safety issue.

We disagree that we should categorically refuse to consider reinstating a qualified exemption if we had withdrawn the exemption because a farm had been directly linked to a foodborne illness outbreak. First, if information later comes to light to raise considerable doubt that a farm with a qualified exemption had, indeed, been directly linked to a foodborne illness outbreak, and conduct and conditions at the farm do not otherwise warrant withdrawing the farm’s exemption, it would be appropriate for us to reinstate the farm’s exemption. Second, as already discussed in this response, we consider the reinstatement provisions to be an incentive for a farm to continue adhering to procedures and practices that it develops to comply with the rule.

(Comment 439) Some comments that support the reinstatement of a withdrawn exemption ask us to establish a timeframe within which FDA will reinstate an exemption. Some comments ask us to specify in the regulatory text that the reinstatement would occur in a reasonable period of time, both in circumstances where FDA has decided on its own initiative to reinstate the exemption and in circumstances where a farm submits a request for reinstatement. Some comments suggest 10 days is a

reasonable period of time within which FDA should reinstate an exemption.

(Response) We decline the requests to establish a timeframe for reinstatement in the regulatory text. If we determine on our own initiative to reinstate an exemption (e.g., because we later determine, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm), our determination would be effective immediately. If we receive a request to reinstate a withdrawn exemption, we intend to respond in a reasonable time frame consistent with available resources. In some cases, we may respond that we need more information in order to evaluate your request.

(Comment 440) Some comments ask us to establish a 1-year probationary period before the withdrawn qualified exemption of a farm could be fully reinstated.

(Response) We decline this request. We intend to act on a request for reinstatement based on the merits of the data and information presented in the request, not after a pre-determined timeframe.

(Comment 441) One comment believes that the word “will” in proposed § 112.213(c) implies discretion where none is warranted, and suggests changing it to “shall” consistent with 112.213(a).

(Response) We decline this request. Instead, we are replacing the word “shall” with “will” in § 112.213(a) to be consistent with § 112.213(c), in the interest of using plain language in drafting regulations.

G. Other Comments

(Comment 442) Several comments ask us to provide clarification through guidance, issued for public comment, on a variety of topics associated with the withdrawal provisions, including on science-based standards that FDA would use when making the final decision to either approve or deny an order to withdraw a qualified exemption, and the conduct, conditions, or activities that would trigger FDA’s actions toward withdrawal.

(Response) We will consider the need for guidance in the future. At this time, we consider that withdrawing a qualified exemption of a farm would be both rare and dependent upon the circumstances. We need to direct our resources to developing guidance on issues that would apply more broadly, and more generally, than the withdrawal provisions.

H. Conforming Amendment to 21 CFR Part 16

We proposed to amend § 16.1(b)(2) to include part 112, subpart R, relating to the withdrawal of a qualified exemption applicable to a farm, to the list of regulatory provisions under which regulatory hearings are available. We received no comments that disagreed with this proposed provision, and we are finalizing it as proposed.

XXIV. Comments on Effective and Compliance Dates

A. Effective and Compliance Dates for Part 112

In the 2013 proposed rule, we proposed that any final rule based on proposed part 112 would become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates based on size of the farm. In addition, for certain specified proposed requirements related to agricultural water, we proposed the compliance dates would

be 2 years beyond the compliance date for the rest of the final rule applicable to the farm based on its size.

Most comments generally support our proposed staggered compliance periods based on farm size as well as the extended compliance period for the specified water provisions, although some comments suggest further extensions whereas others find the proposed compliance periods too long. In this section, we discuss comments that express concern with the proposed compliance periods, suggest extensions to the proposed compliance dates, and/or ask us to clarify how the compliance dates will apply.

After considering comments, we are finalizing the effective date as proposed, *i.e.*, 60 days after the publication of this rule. As shown in Table 30, we are establishing three sets of compliance dates, all of which vary based on size of the farm: one for covered activities involving sprouts covered under subpart M, which are subject to all of part 112; another for covered activities involving

all other produce, which are subject to part 112 except subpart M; and another for modified requirements relating to the qualified exemption. In the second set of compliance dates, we are also providing extended compliance dates for certain specified requirements related to agricultural water. In the compliance dates relating to the qualified exemption, the compliance date for the records that a farm is required by § 112.7(b) to maintain to support its eligibility for the qualified exemption (*e.g.*, sales receipts and other records as applicable) is the effective date of this rule, *i.e.*, January 26, 2016. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general compliance date, however. In addition, we are establishing January 1, 2020, as the compliance date for the modified requirement in § 112.6(b)(1).

TABLE 30—COMPLIANCE DATES

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
	Time periods starting from the effective date of this rule					
Very small business ...	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years. 3 years. N/A.
Small business	2 years	5 years	3 years			
All other businesses ...	1 year	4 years	2 years			

(Comment 443) Some comments state the proposed compliance periods are too long and fail to protect public health. One such comment suggests we increase efforts to provide technical assistance, particularly to small and very small farms to help implement the rule, and decrease the length of compliance periods. Another comment suggests not delaying compliance period for the standards directed to worker health and hygiene because the commenter believes farms already implement those provisions to comply with other government regulations.

Conversely, some other comments find the proposed compliance periods unrealistic given, according to these commenters, the significant scope and number of changes required and associated potential costs. One comment states implementation of the rule will require substantial investment and covered farms in its country will need additional time to comply with the rule. This comment suggests ten years as the

compliance period for the water provisions and a minimum of four to six years for the remaining provisions.

Still other comments maintain we should apply a uniform 5-year compliance period for all covered farms, instead of the proposed staggered compliance periods based on farm sizes. These comments argue having different compliance dates for different covered farms will be confusing and difficult to manage across different entities in the produce supply chain.

(Response) We intend to prioritize our compliance and enforcement efforts. The purpose of tiered compliance dates is to give businesses of various sizes time to come into compliance with the rule technically, financially, and operationally. FDA and food safety partners will be targeting education and outreach efforts to smaller businesses that may not be as familiar with our requirements as some of the larger farms.

We conducted extensive stakeholder outreach during the 10-month comment period for the 2013 proposed rule. We also provided public notice about proposed changes to the farm-related definitions that affect the determination of whether a farm is subject to this rule or the PCHF regulation, and about specific potential requirements for agricultural water. We conducted outreach activities to discuss the new and amended proposed provisions in the supplemental notice (see section I.E of this document). In addition, we have been collaborating with relevant stakeholders to support the development of necessary training materials (see section XI of this document) as well as research in the areas of agricultural water and raw manure (see sections XIII and XIV, respectively, of this document). In light of the extensive outreach associated with this rulemaking, we disagree that farms will need more than the established compliance periods

(including the extended compliance periods for certain water provisions for covered activities involving covered produce (except sprouts covered under subpart M)) to fully adapt their programs to the specific requirements of this rule.

We disagree that we should establish a uniform compliance period across all farm sizes. Rather, these compliance periods provide an appropriate balance between public health protection and flexibility, in light of practical considerations for small and very small businesses. Moreover, the extended compliance periods for certain specified water provisions are intended to help businesses to develop the necessary expertise to implement the specified water requirements, and to consider appropriate alternatives and develop adequate scientific data or information necessary to support the use of that alternative.

1. Effective Date

Under this rule, the effective date is 60 days after the date of publication of this rule in the **Federal Register**.

2. Compliance Dates for Covered Activities Involving Sprouts Covered Under Subpart M

For covered activities involving sprouts covered under subpart M (*i.e.*, all requirements of part 112 apply), the compliance dates are as follows: (1) 3 years from the effective date for covered farms that are very small businesses; (2) 2 years from the effective date for covered farms that are small businesses; and (3) 1 year from the effective date for all other covered farms. As discussed in section XVIII.J of this document, we conclude these compliance periods are appropriate for covered activities involving sprouts covered under subpart M, to protect public health. We are also not providing extended compliance dates related to certain water requirements. Therefore, the one-to-three year compliance period applicable to the farm based on its size applies for compliance with all requirements of part 112.

3. Compliance Dates for Covered Activities Involving All Other Covered Produce

For covered activities involving all other covered produce (*i.e.*, except sprouts covered under subpart M) (*i.e.*, requirements of part 112 except those of subpart M apply), the compliance dates are as follows: (1) 4 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow) for covered

farms that are very small businesses; (2) 3 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow) for covered farms that are small businesses; and (3) 2 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow) for all other covered farms. In addition, for covered activities involving covered produce (except sprouts covered under subpart M), we are providing the additional flexibility of extended compliance dates for certain water-related requirements. As discussed in section XIII.K of this document, the compliance period for the following requirements is 2 years beyond the compliance date for the rest of this rule applicable to the farm based on its size: §§ 112.44, 112.45, 112.46 (except § 112.46(a) and (b)(1)), 112.50(b)(5), 112.50(b)(6), 112.50(b)(7), and 112.50(b)(8). Accordingly, for these specified requirements, the compliance period is 6 years from the effective date for covered farms that are very small businesses, 5 years from the effective date for covered farms that are small businesses, and 4 years from the effective date for all other covered farms.

4. Compliance Dates for Farms Engaged in Covered Activities Involving Sprouts Covered Under Subpart M as Well as Other Covered Produce

For those covered farms that may be engaged in covered activities involving both sprouts covered under subpart M as well as other covered produce, both sets of compliance dates will apply depending on the produce involved in the covered activity. For those aspects of your operation relating to covered activities involving sprouts covered under subpart M, the compliance dates ranging from 1 to 3 years (based on size of your farm) will apply, and for other aspects of your operation relating to covered activities involving all other covered produce, the compliance dates ranging from 2 to 4 years (based on size of the farm) as well as the extended compliance dates ranging from 4 to 6 years (based on size of the farm) for certain specified water requirements will apply.

5. Compliance Dates Applicable to Farms Eligible for a Qualified Exemption

We are establishing three additional compliance dates applicable to farms eligible for a qualified exemption. First, as explained in section IX.C.7 of this document, the compliance date for the

records that a farm maintains to support its eligibility for a qualified exemption in accordance with §§ 112.5 and 112.7 is the effective date of this rule, *i.e.*, January 26, 2016. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general compliance date, however. Second, we are establishing January 1, 2020, as the compliance date for the modified requirement of § 112.6(b)(1). A farm that is eligible for a qualified exemption must notify consumers as to the name and complete business address of the farm where the food is grown, harvested, packed, and held (see § 112.6(b)). If a food packaging label is required, the required notification must appear prominently and conspicuously on the label of the food (see § 112.6(b)(1)). This modified requirement may require some farms to update the labels of their packaged food products. For many labeling requirements, the time frame for a food establishment to comply with new or revised labeling requirements is governed by a uniform compliance date (see, *e.g.*, 79 FR 73201, December 10, 2014 and 77 FR 70885, November 28, 2012). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices. We generally announce a uniform compliance date during November or December of even-numbered calendar years, and establish the uniform compliance date to be January 1 of an upcoming even-numbered calendar year. For example, in December, 2014, we issued a final rule establishing January 1, 2018, as the uniform compliance date for food labeling regulations that are issued between January 1, 2015, and December 31, 2016 (79 FR 73201). Likewise, in November, 2012, we issued a final rule establishing January 1, 2016, as the uniform compliance date for food labeling regulations that are issued between January 1, 2013, and December 31, 2014 (77 FR 70885, November 28, 2012). These uniform compliance dates provide a minimum of 1 year between the date when a food labeling regulation is issued and the date when a food

establishment must comply with that regulation. Following this pattern, we intend that the next uniform compliance date will be January 1, 2020 for food labeling regulations that are issued between January 1, 2017 and December 31, 2018. A farm that is eligible for a qualified exemption would become subject to the modified requirement in § 112.6(b)(1) during this timeframe—*i.e.*, by December 31, 2018. The compliance date that we are establishing for the modified requirement of § 112.6(b)(1) (*i.e.*, January 1, 2020) is consistent with the approach of a uniform compliance date and will provide such farms with more than 1 year from the applicable general compliance date to comply with this modified requirement. This compliance date also will provide such a farm with more than 4 years to comply with the modified requirement relative to the date of publication of this rule. Third, we are establishing the compliance dates for all other requirements in §§ 112.6 and 112.7. As explained under Comment 120, because of the difference in the bases for monetary cut-offs established in § 112.3 and in § 112.5, farms that are eligible for the qualified exemption may be either small businesses or very small businesses (as defined in § 112.3). Farms eligible for a qualified exemption (in accordance with § 112.5) must comply with all other modified requirements of §§ 112.6 and 112.7 within the compliance periods established for either a small business or a very small business, whichever is applicable. Based on the monetary cut-offs and definitions in § 112.3 and in § 112.5, a farm eligible for a qualified exemption must either be a small business or a very small business for purposes of this rule.

(Comment 444) Some comments further request clarification regarding the beginning of the compliance period. One comment asks us to account for the seasonal nature of farming operations and suggests the compliance period should begin on the date of the beginning of the first harvest period following the effective date of the rule.

(Response) See our response to Comment 443 for compliance dates, which are based on the size of a covered farm. Setting the compliance date for a farm based on the time of harvest, as the comment suggested, is challenging because harvest periods will vary greatly based on commodity, region, and the farm's practices, which would result in widely variable compliance dates. Therefore, we decline this request.

B. Effective Dates for Conforming Changes

The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 112 are not subject to part 11. The conforming amendment to part 16 adds a reference to the scope of part 16 for new procedures in part 112, subpart R that provide a person with an opportunity for a hearing under part 16. These conforming amendments are effective on January 26, 2016, the same date as the effective date of part 112. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance will be implemented by compliance with part 112.

C. Effective Date for Certain Provisions in the PCHF Regulation

The final human preventive controls rule established six new provisions (§§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13)) that refer to provisions in part 112. We announced our intent to publish a document in the **Federal Register** announcing the effective dates of these provisions (80 FR 55908). These provisions are effective on January 26, 2016, the same date as the effective date of part 112.

D. Effective Date for Certain Provisions in the PCAF Regulation

The final animal preventive controls rule established five new provisions (§§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13)) that refer to provisions in part 112. We announced our intent to publish a document in the **Federal Register** announcing the effective dates of these provisions (80 FR 56170). These provisions are effective on January 26, 2016, the same date as the effective date of part 112.

XXV. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 257). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> or at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

XXVI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (Ref. 142). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA believes this rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small farms will bear a large portion of the costs, FDA concludes that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that will exceed this amount.

The final analysis conducted in accordance with these Executive Orders and statutes is available in the docket for this rulemaking (Ref. 142) and at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>.

XXVII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this action. FDA determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)) and, therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). The Draft EIS was released for public comment (80 FR 1852, January 14, 2015). FDA considered the comments received on

the Draft EIS when preparing the Final EIS (see (Ref. 258)). Table 31 lists Federal Register publications regarding the EIS related to this rule.

FDA's Final EIS and record of decision (Ref. 126) (Ref. 150) may be seen in the Division of Dockets Management (see ADDRESSES) between 9

a.m. and 4 p.m., Monday through Friday.

TABLE 31—LIST OF FEDERAL REGISTER PUBLICATIONS REGARDING THE EIS

Description	Publication
Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Note: The categorical exclusion statement was cited as a reference in this document).	78 FR 3504; January 16, 2013.
Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule.	78 FR 50358; August 19, 2013.
Extension of Comment Period for the Environmental Impact Statement	78 FR 69006; November 18, 2013.
Public Meeting on Scoping of Environmental Impact Statement and Extension of Comment Period for the Environmental Impact Statement.	79 FR 13593; March 11, 2014.
Draft Environmental Impact Statement Notice of Availability	80 FR 1852; January 14, 2015.

XXVIII. Paperwork Reduction Act of 1995

This rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.

Description: Section 105 of FSMA adds section 419 to the FD&C Act (21 U.S.C. 350h) requiring FDA to adopt a final regulation to provide for minimum science-based standards for fruits and vegetables that are RACs based on known safety risks, and directing FDA to set forth in the final regulation those procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

Description of Respondents: The regulation applies to farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. There are 37,404 farms in the United States, excluding sprouting operations (Ref. 259), that would be covered by the rule. We estimate that there are approximately 285 sprouting operations covered by this rule. One section of the regulation also applies to some non-farm entities as described in

the Third-Party Disclosure Burden subsection of this section.

Exemptions or Eligibility for Exemptions

The rule includes provisions under which certain farms and produce are either not covered or eligible for an exemption and, instead, subject to certain modified requirements (see §§ 112.2 through 112.7).

Information Collection Burden Estimate

The estimated hourly burden is 20,484 one-time hours, and 1,112,641 annual hours. Furthermore, the estimated one-time third-party disclosure burden is 247 hours and the estimated annual third-party disclosure burden is 379,705 hours. FDA estimates the burden for this information collection as follows:

One-Time Hourly Burden

Agricultural Water—Documentation of Scientific Data

Section 112.50(b)(3) requires documentation of scientific data or information relied on to support the adequacy of a method used to satisfy the requirements of §§ 112.43(a)(1) and (a)(2). All covered farms that would treat their water to achieve a water quality requirement in the rule will be required to keep these records. Consequently, we estimate that 5,547 farms ([17,840 farms from table 18 of the RIA × 20 percent that do not rely on die-off] + [3,958 farms from table 19 of the RIA × 50 percent that do not re-inspect and correct]) would rely on documentation of scientific data or information to support the adequacy of a method used to satisfy these requirements. It is estimated that one recordkeeper for each of 5,547 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and

information. Therefore, 5,547 × 0.5 = 2,773 one-time hours to meet the requirement of § 112.50(b)(3).

Section 112.50(b)(5) requires farms that rely on a microbial die-off or removal rate to determine a time interval between harvest and end of storage, including other activities such as commercial washing, to achieve a calculated log reduction of generic *E. coli* in accordance with § 112.45(b)(1)(ii) to have documentation of the scientific data or information they rely on to support that rate. We estimate that 25 percent of all farms that rely on die-off, 3,661 (17,840 farms from table 18 of the RIA × 80 percent that rely on die-off × 25 percent) would generate these records for postharvest die-off intervals. It is estimated that two recordkeepers for each of 3,661 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, 3,661 × 2 × 0.5 = 3,661 one-time hours to meet the requirement of § 112.50(b)(5).

Section 112.50(b)(8) requires all farms that choose to rely on an alternative under § 112.49 to have documentation of the scientific data or information they rely on to support that alternative. There are four types of alternatives that may be employed according to § 112.49(a)–(d).

Section 112.49(a) provides for an alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b). We estimate that approximately 8,757 farms that irrigate (35,029 total farms × 25 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 8,757 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining

the documentation of scientific data and information. Therefore, $8,757 \times 0.5 = 4,376$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(a).

Section 112.49(b) provides for an alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i). We estimate that approximately 3,661 farms that rely on die-off (14,643 farms that rely on die-off \times 25 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 3,661 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $3,661 \times 0.5 = 1,830$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(b).

Section 112.49(c) provides for an alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources \times 20 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 2,511 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $2,511 \times 0.5 = 1,255$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(c).

Section 112.49(d) provides for an alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources \times 20 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 2,511 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $2,511 \times 0.5 = 1,255$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(c).

Section 112.50(b)(9) requires all farms that are required to test their agricultural water in compliance with § 112.46 to have documentation of any analytical methods that they choose to use for such testing in lieu of the method that is incorporated by reference in § 112.151(a). It is not known how many farms will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement, estimated as the time needed to search for and collect the documentation of the alternative analytical methods.

Sprouts—Establishment of Environmental Monitoring Plan

Section 112.150(b)(2) requires sprout operations to establish and keep a written environmental monitoring plan in accordance with § 112.145. There is a one-time burden estimated for the establishment of this plan and an annual burden estimated for the maintenance of this plan. For 74 very small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) record is a one-time burden of 7 hours. Therefore, $46 \text{ farms} \times 7 \text{ hours} = 321$ one-time hours to comply with § 112.150(b)(2). For 60 small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) is a one-time burden of 12 hours. Therefore, $37 \text{ farms} \times 12 \text{ hours} = 446$ one-time hours to comply with § 112.150(b)(2). For 94 large farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) is a one-time burden of 17 hours. Therefore, $94 \text{ farms} \times 17 \text{ hours} = 1,592$ one-time hours to comply with § 112.150(b)(2).

Sprouts—Establishment of Sampling Plan

Section 112.150(b)(3) requires the documentation of the written sampling plan for each production batch of sprouts in accordance with § 112.147(a). It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan, including a corrective action plan, and

developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For each of 177 sprout farms, it is estimated that the one-time burden to establish a written sampling plan is 8 hours. Therefore, $8 \text{ hours} \times 177 \text{ sprout farms} = 1,414$ one-time burden hours for sprout farms to comply with § 112.150(b)(3).

Sprouts—Documentation of Scientific Data

Section 112.150(b)(5) requires sprout operations to have documentation of any analytical methods used in lieu of the methods for both environmental testing and batch testing that are incorporated by reference in §§ 112.152 and 112.153. It is not known how many sprout operations will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement, estimated as the time needed to search for and collect the documentation of the alternative analytical methods.

In addition, § 112.144(c) requires sprout operations to conduct testing for additional pathogens when certain conditions are met, and § 112.150(b)(5) requires sprouting operations to have documentation of any analytical methods used for such testing because there is no specific method for such testing incorporated by reference in § 112.152 or 112.153. It is not known if or when there will be a pathogen(s) meeting the relevant criteria; however, it is estimated that one recordkeeper will work a total of 2 hours one-time to fulfill this requirement, estimated as the time needed to establish a new testing routine. Therefore, we estimate it will take 177 sprouters 353 records (177×2) to fulfill this requirement. At two hours per record, this represents a total hourly burden of 707 (353×2) to fulfill the requirements of §§ 112.150(b)(5) and § 112.144(c).

Variances

Section 112.171 of this rule allows States, tribes, and foreign countries to petition FDA for a variance from one or more requirements of the rule. Section 112.172 requires the competent authority (*i.e.*, the regulatory authority for food safety) for a State, tribe, or a foreign country to submit a petition to seek a variance, and § 112.173 describes what must be included in the Statement of Grounds in a petition requesting a variance.

Data on the number of hours needed to assemble the information required for a petition are not available. However, it is estimated that it will take one

recordkeeper 80 hours to compile the relevant information and submit the petition to FDA. Furthermore, it is estimated that an additional recordkeeper (for example, a supervisor) will evaluate and review the petition before it is submitted. We estimate that it will take an additional 40 hours for the additional recordkeeper to review the submission. Therefore, it is estimated that a State, tribe, or foreign government would spend a total of 120 hours on a petition, and this would be a one-time burden. Data do not exist to estimate how many petitions FDA may get in a year; however, for the purposes of this analysis, it is estimated that FDA may receive seven petitions. Therefore, 120 hours \times 7 petitions = 840 hours to comply with the requirements of § 112.173.

Annual Hourly Burden

Qualified Exempt Farms—Documenting Eligibility

Section 112.7(b) requires farms eligible for the qualified exemption in accordance with § 112.5 to establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that the owner, operator, or agent in charge of the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. We calculate that there are a total of 3,285 farms that will incur the costs of recordkeeping associated with demonstrating qualified exempt status. Therefore, it is estimated that one recordkeeper on each of 3,285 farms will spend an average of 0.5 hours per year on recordkeeping related to documenting eligibility for the qualified exemption. Therefore, 3,285 recordkeepers \times 0.5 average hours per recordkeeper = 1,643 hours to meet the requirements of § 112.7(b).

Training Records

Section 112.30(b)(1) requires the establishment and maintenance of records of training documenting required training of personnel, including the date of training, topics covered, and the persons(s) trained. We calculate that there are a total of 24,420 farms (37,404 total farms \times 0.65 not currently keeping training records) that will incur the costs of worker training recordkeeping. Therefore, it is estimated that one recordkeeper on each of 24,420 farms will spend an average of 7.25 hours per year on recordkeeping related to training requirements (recording and maintaining the dates and topics of training, and person(s) trained) of this

final rule. Therefore, 24,420 recordkeepers \times 7.25 average hours per recordkeeper = 177,045 hours to meet the requirements of § 112.30(b)(1).

Water Testing

Water Testing for Zero Detectable Generic *E. coli*. Section 112.46(c) requires testing untreated groundwater for the purposes that are subject to the requirements of § 112.44(a). We calculate there are a total of 26,038 farms (all farms with activities during and after harvest, and sprout farms using untreated ground water for growing sprouts) that will incur these costs. Therefore, it is estimated that two recordkeepers on each of 26,038 farms will spend an average of 0.66 hours per year on testing water for zero detectable generic *E. coli* of this final rule. Therefore, 26,038 farms \times 2 recordkeepers \times 0.66 average hours per recordkeeper = 34,371 hours to meet the requirements of §§ 112.44(a) and 112.46(c).

Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic *E. coli*—Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce. Section 112.46(b) requires testing each such source of water used for the purposes that are subject to the requirements of § 112.44(b). We calculate that there are a total of 12,554 farms (all irrigated farms using surface water less the percentage estimated on public water sources) that will incur these costs. Therefore, it is estimated that 6.29 recordkeepers on each of 12,554 farms will spend an average of 0.92 hours per year on Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic *E. coli*—Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce of this final rule. Therefore, 12,554 farms \times 6.29 recordkeepers \times 0.92 average hours per recordkeeper = 72,648 hours to meet the requirements of §§ 112.44(b) and 112.46(b).

Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic *E. coli*—Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce. Section 112.46(b) requires testing each such source of water used for the purposes that are subject to the requirements of § 112.44(b). We calculate that there are a total of 9,471 farms (all irrigated farms using ground water less the percentage estimated on public water sources) that will incur these costs. Therefore, it is estimated that 1.4 recordkeepers on each of 9,471 farms will spend an average of 0.92 hours per year on Testing for GM of 126 CFU/100 mL and

STV of 410 CFU/100 mL Generic *E. coli*—Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce of this final rule. Therefore, 9,471 farms \times 1.4 recordkeepers \times 0.92 average hours per recordkeeper = 12,198 hours to meet the requirements of §§ 112.44(b) and 112.46(b).

Section 112.45 requires water testing as part of certain options for corrective steps when the water quality requirements of §§ 112.41 or 112.44 are not met (see §§ 112.45(a)(1)(i) and 112.45(b)(2)). We calculate approximately one percent of all irrigated farms will need to conduct these tests; therefore 298 farms (29,763 \times 1 percent) will incur these costs. Therefore, it is estimated that 1 recordkeeper on each of the 298 farms will spend an average of 0.33 hours per year on these actions taken when requirements in subpart E are not met. Therefore, 298 farms \times 1 recordkeeper \times 0.33 average hours per recordkeeper = 98 hours to meet the requirements of § 112.45.

Recordkeeping Related to Water

Section 112.50(b)(1) requires the establishment and maintenance of records of the Findings of Water System Inspections. We calculate that there are 34,369 (all covered farms not currently keeping these records) that will incur the costs of water inspection recordkeeping. Therefore, it is estimated that 4 recordkeepers on each of 34,369 farms will spend an average of 0.8 hours per year on recordkeeping related to the Findings of Water System Inspections. Therefore, 34,369 farms \times 4 recordkeepers \times 0.8 average hours per recordkeeper = 110,066 hours to meet the requirement of § 112.50(b)(1).

Section 112.50(b)(2) requires the establishment and maintenance of Records of Testing for 0 Detectable Generic *E. coli*. We calculate that 26,038 farms (see testing discussion) will incur the costs of recordkeeping of testing for 0 detectable generic *E. coli*. Therefore, it is estimated that 2 recordkeepers on each of the 26,038 farms will spend an average of 0.33 hours per year on recordkeeping related to Records of Testing for 0 Detectable Generic *E. coli*. Therefore, 26,038 farms \times 2 recordkeepers \times 0.33 average hours per recordkeeper = 17,185 hours to meet the requirements of § 112.50(b)(2).

Section 112.50(b)(2) requires the establishment and maintenance of Records of Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic *E. coli* for Untreated Surface Water Used for Direct Application Irrigation of Non-Sprout Covered

Produce. We calculate that 12,554 farms (see previous testing discussion) will incur the costs of establishing these records. Therefore, it is estimated that 6.29 recordkeepers on each of the 12,554 farms will spend an average of 0.08 hours per year on this recordkeeping. Therefore, 12,554 farms \times 6.29 recordkeepers \times 0.08 average hours per recordkeeper = 6,317 hours to meet the requirements of § 112.50(b)(2). As noted in response to Comment 229, we are exploring the development of an online tool to allow covered farms to derive their GM and STV values and appropriate time intervals between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that farms would not need to perform the necessary calculations themselves. We expect such a tool to reduce the recordkeeping burden associated with testing of untreated surface and untreated ground water (§§ 112.46(b) and 112.50(b)(2)) and time intervals applied between last irrigation and harvest (§§ 112.45(b)(1) and 112.50(b)(6)). Moreover, FDA will not be collecting, storing, or otherwise using any water testing sample data that farms enter into the online tool to calculate the GM and STV values and develop or update their microbial water quality profiles.

Section 112.50(b)(2) also requires the establishment and maintenance of Records of Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic *E. coli* for Untreated Ground Water Used for Direct Application Irrigation of Non-Sprout Covered Produce. We calculate that 9,471 farms (see previous testing discussion) will incur the costs of establishing these records. Therefore, it is estimated that 1.4 recordkeepers on each of the 9,471 farms will spend an average of 0.08 hours per year on this recordkeeping. Therefore, 9,471 farms \times 1.4 recordkeepers \times 0.08 average hours per recordkeeper = 1,061 hours to meet the requirements of § 112.50(b)(2). As noted previously, we expect development of an online tool to reduce the recordkeeping burden associated with testing of untreated surface and untreated ground water required under §§ 112.46(b) and 112.50(b)(2).

Section 112.50(b)(4) requires Documentation of Results of Monitoring Water Treatment under § 112.43(b). We calculate that 5,547 farms (the proportion of covered farms that do not use municipal water sources and who are not able to use other options to otherwise meet quality criteria) will incur the costs of documentation of monitoring water treatment. Therefore, it is estimated that 1 recordkeeper on

each of the 5,547 farms will spend an average of 0.98 hours per year on recordkeeping related to Monitoring Water Treatment. Therefore, 5,547 farms \times 1 recordkeeper \times 0.98 average hours per recordkeeper = 5,436 hours to meet the requirements of § 112.50(b)(4).

Section 112.50(b)(6) requires documentation of any corrective actions taken in accordance with § 112.45. Further, where time intervals or (calculated) log reductions are applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing. We calculate that 14,643 farms will incur the costs of documentation of any corrective actions taken in accordance with § 112.45, including any time intervals or calculated log reductions applied. Therefore, it is estimated that 1 recordkeeper on each of the 14,643 farms will spend an average of 0.5 hours per year on recordkeeping related to corrective actions applied. Therefore, 14,643 farms \times 1 recordkeeper \times 0.5 average hours per recordkeeper = 7,322 hours to meet the requirements of § 112.50(b)(6). As noted previously, we expect development of an online tool to reduce the recordkeeping burden associated with time intervals applied between last irrigation and harvest as required under §§ 112.45(b)(1) and 112.50(b)(6).

Section 112.50(b)(7) requires annual documentation of the results or certificates of compliance from a Public Water System required under § 112.46(a)(1) or (a)(2), if applicable. We calculate that 9,108 farms (the number of farms using public water systems such as municipal water sources) will incur the costs of getting this annual documentation from their public water systems. Therefore, it is estimated that 1 recordkeeper on each of the 9,108 farms will spend an average of 0.33 hours per year on recordkeeping related to Documentation from Public Water Systems. Therefore, 9,108 farms \times 1 recordkeeper \times 0.33 average hours per recordkeeper = 3,005 hours to meet the requirements of § 112.50(b)(7).

Recordkeeping Related to Biological Soil Amendments of Animal Origin

Section 112.60(b) of this rule specifies the records that covered produce farms must establish and keep regarding biological soil amendments of animal origin.

For treated soil amendments acquired from a third party, § 112.60(b)(1) requires documentation, at least annually, that certain criteria have been met, namely that: (1) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and (2) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin. It is estimated that, for any covered produce farm already using treated biological soil amendments from a third party, this requirement does not represent a new recordkeeping burden. Furthermore, to account for the possibility that this may still be a new recordkeeping burden for farms using soil amendments acquired from a third party, it is estimated that this requirement will be a new recordkeeping burden for an additional 10 percent of remaining covered farms (35,029 \times 0.10 = 3,503). Therefore, for the purposes of this analysis, it is estimated that one recordkeeper for each of a maximum of 3,503 farms will spend 0.25 hour annually to meet this requirement, estimated to consist of the act of acquiring and maintaining documentation. Therefore, 3,503 recordkeepers \times 0.25 hour = 876 annual hours.

Section 112.60(b)(2) of this rule requires covered farms to document, for a treated biological soil amendment of animal origin produced by the covered farm, documentation that process controls (for example, time, temperature, and turnings) were achieved. NASS data do not exist that would make it possible to estimate how many covered farms would choose to produce treated biological soil amendments of animal origin for use on their own farms. However, using the USDA's 1999 Fruit and Vegetable Survey (Ref. 260), it is estimated that 15 percent of farms that claim to use manure also claim that the manure is composted on farm. Furthermore, using data from NASS, the RIA estimates that a total of 2,802 covered produce farms use manure (either as a component of stabilized compost or raw). For the purposes of this analysis, we assume, as an upper bound, that 420 covered farms (2,802 \times 0.15 = 420) choose to produce treated biological soil amendments of animal origin for their own farms, and that one recordkeeper for each of the 420 farms will spend 0.5 hour annually on this requirement, estimated to

consist of recording confirmation of process control achievement. Therefore, 420 recordkeepers \times 0.5 hour = 210 annual hours.

Recordkeeping Related to Cleaning and Sanitation

Section 112.140(b)(1) requires establishment and maintenance of records related to cleaning and sanitation, including cleaning worker tools and machinery. We calculate that 16,061 very small farms (farms that are not currently cleaning and sanitizing tools plus 50 percent of farms that are currently cleaning and sanitizing tools) will incur the costs of recordkeeping related to cleaning and sanitizing worker tools. Therefore, it is estimated that 1 recordkeeper on each of the 16,061 very small farms will spend an average of 8 hours per year on recordkeeping related to cleaning and sanitizing worker tools. Therefore, 16,061 very small farms \times 1 recordkeeper \times 8 average hours per recordkeeper = 128,485 hours to meet the requirements of § 112.140(b)(1). We calculate that 8,635 small and large farms (farms that are not currently cleaning and sanitizing tools plus 50 percent of farms that are currently cleaning and sanitizing tools) will incur the costs of recordkeeping related to cleaning and sanitizing worker tools. Therefore, it is estimated that 1 recordkeeper on each of the 8,635 small and large farms will spend an average of 25 hours per year on recordkeeping related to cleaning and sanitizing worker tools. Therefore, 8,635 small and large farms \times 1 recordkeeper \times 25 average hours per recordkeeper = 215,871 hours to meet the requirements of § 112.140(b)(1).

Section 112.140(b)(1) also requires establishment and maintenance of records related to the cleaning and sanitizing machinery. We calculate that 13,156 very small farms (farms that are not currently cleaning and sanitizing machinery plus 50 percent of farms that are currently cleaning and sanitizing machinery) will incur the costs of recordkeeping related to cleaning and sanitizing machinery. Therefore, it is estimated that 1 recordkeeper on each of the 13,156 very small farms will spend an average of 8 hours per year on recordkeeping related to cleaning and sanitizing machinery. Therefore, 13,156 very small farms \times 1 recordkeeper \times 8 average hours per recordkeeper = 105,248 hours to meet the requirements of § 112.140(b)(1). We calculate that 7,073 small and large farms (farms that are not currently cleaning and sanitizing machinery plus 50 percent of farms that are currently cleaning and sanitizing

machinery) will incur the costs of recordkeeping related to cleaning and sanitizing machinery. Therefore, it is estimated that 1 recordkeeper on each of the 7,073 small and large farms will spend an average of 25 hours per year on recordkeeping related to cleaning and sanitizing machinery. Therefore, 7,073 small and large farms \times 1 recordkeeper \times 25 average hours per farm = 176,831 hours to meet the requirements of § 112.140(b)(1).

Testing Requirements Related to Sprouts

Sections 112.144(b) and (c), and 112.147 requires testing spent sprout irrigation water from each production batch of sprouts, or if such testing is not practicable, each production batch of sprouts at the in-process stage for certain pathogens, and § 112.150(b)(4) requires recordkeeping related to those tests. This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is an average of 0.5 hour per test. This time burden is estimated to include collecting and preparing the sample. We estimate that 33 very small sprout farms produce 3,710 batches, 27 small sprout farms produce 2,976 batches, and 68 large sprout farms produce 33,623 batches. Each farm will have one recordkeeper for each test. Small and very small farms will average 125 (50 \times 2.5 one each for *E. coli* and *Salmonella* and 0.5 to reflect the uncertainty associated with applicability of testing requirements for additional pathogens) tests per farm; large farms will average 558 (223 \times 2.5) tests.

It is estimated that a total of 4,163 batches of sprouts will be tested annually for *E. coli* and *Salmonella* and, if certain criteria are met, emerging pathogens across 33 very small farms. Therefore, 4,163 tests \times 0.5 hour per test = 2,081 annual hours for very small farms to comply with §§ 112.144(b) and (c) and 112.147. It is estimated that a total of 3,375 batches of sprouts will be tested annually across 27 small farms. Therefore 3,375 tests \times 0.5 hour per test = 1,688 annual hours for small farms to comply with §§ 112.144(b) and (c) and 112.147. It is estimated that 37,882 batches of sprouts will be tested annually across 68 large farms. Therefore, 37,882 test \times 0.5 hour per = 18,941 annual hours for large farms to comply with §§ 112.144(b) and (c) and 112.147.

Sections 112.144(a) and 112.145 require testing the sprout growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes*, and § 112.150(b)(4) requires recordkeeping related to those

tests. This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is 0.15 hour to collect and prepare each sample. We expect that all firms will sample on a monthly basis; it is also expected that the number of samples will vary with the size of the farm. We expect very small farms to average five samples for each test; small farms to average ten samples per test; and large farms to average 15 samples. More samples are expected as the size of the farm increases because we estimate that the number and location of sampling sites, including appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces would increase as the farm size increases. It is estimated that one recordkeeper from each of the farms will be responsible for collecting samples. Therefore, to comply with the requirements of §§ 112.144(a) and 112.145, 33 very small farms will incur a total of 300 hours of burden annually (33 farms \times 5 samples \times 12 annual tests \times 0.15 hour per sample); 27 small farms will incur a total of 486 hours annually, (27 farms \times 10 samples \times 12 annual tests \times 0.15 hour per sample); and 68 large farms will incur a total of 1,835 hours (68 farms \times 15 samples \times 12 annual tests \times 0.15 hour per sample).

Recordkeeping Requirements Related to Sprouts

Section 112.150(b)(1) requires documentation of treatment of seeds or beans or documentation of previous seed treatment by a third party. This burden is expected to vary across farms; however, this documentation burden is estimated to be 0.2 hour per activity, estimated to consist of the time needed to record the treatment of seeds or beans. It is estimated that one recordkeeper per very small farm will document this activity 50 times annually. Therefore, 33 very small farms \times 50 records = 1,665 records \times 0.2 hours per record = 333 hours for very small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per small farm will document this activity 50 times annually. Therefore, 27 small farms \times 50 records = 1,350 records \times 0.2 hours per record = 270 hours for small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per large farm will document this activity about 223 times annually. Therefore, 68 large farms \times 223 records = 15,153 records \times 0.2 hours per record = 3,031 hours for large farms to comply with § 112.150(b)(1).

Section 112.150(b)(2) requires sprout operations to establish and keep a written environmental monitoring plan

in accordance with § 112.145. It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan and developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For annual burdens, it is estimated that each record will require one recordkeeper to work 0.15 hour to maintain the environmental monitoring plan (such as updating or making needed changes to the plan), across all farm sizes. For 46 very small farms, it is estimated that one record will be generated annually. Therefore, $46 \text{ records} \times 0.15 \text{ hour per record} = 7$ total annual hours for very small farms to comply with § 112.150(b)(2). For 37 small farms, it is estimated that 37 total records will be generated annually. Therefore, $37 \text{ records} \times 0.15 \text{ hour per record} = 6$ total annual hours for small farms to comply with § 112.150(b)(2). For 94 large farms, it is estimated that 94 total records will be generated annually. Therefore, $94 \text{ records} \times 0.15 \text{ hour per record} = 14$ total annual hours for very small farms to comply with § 112.150(b)(2).

Section 112.150(b)(3) requires the documentation of the written sampling plan for each production batch of sprouts in accordance with § 112.147(a). It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan and developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For each of 177 sprout farms, it is estimated that there will be an annual burden of 1 hour per farm to update and make needed changes to the plans. Therefore, $177 \text{ sprout farms} \times 1 \text{ hour} = 177$ annual hours for sprout farms to comply with § 112.150(b)(3).

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of § 112.144 for sprouting operations. To comply with this, records of testing for *E. coli* O157:H7 and *Salmonella* spp. and any pathogen meeting the criteria in § 112.144(c) will be kept, and it is estimated that each such record will represent a burden of 0.15 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across farm sizes.

For 33 very small sprouting operations testing for *E. coli* O157:H7 and *Salmonella* and other pathogens as applicable, it is estimated that 2,498 total records will be generated annually (or an average of 50.13 per firm \times 1.5 to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, $2,498 \times 0.15 = 375$ annual hours for very small sprouting operations to comply with § 112.150(b)(4). For 27 small sprouting operations it is estimated that 2,025 total records will be generated annually (or an average of about 49.6 per sprouting operation \times 1.5 to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, $2,025 \text{ records} \times 0.15 \text{ hour per record} = 304$ annual hours for small sprouting operations to comply with § 112.150(b)(4) with respect to testing for *E. coli* O157:H7 and *Salmonella* and other pathogens as applicable. For 68 large sprouting operations it is estimated that 22,689 total records will be generated annually (or an average of about 222.6 per sprouting operation \times 1.5 to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, $22,689 \text{ records} \times 0.15 \text{ hour per record} = 3,403$ annual hours for large sprouting operations to comply with § 112.150(b)(4) with respect to testing for *E. coli* O157:H7 and *Salmonella*, and other pathogens as applicable.

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of §§ 112.144 and 112.145 for sprouting operations. To comply with this, records of testing for *Listeria* spp. or *L. monocytogenes* will be kept, and it is estimated that each such record will represent a burden of 0.17 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across sprouting operation sizes. For 33 very small sprouting operations, it is estimated that a total of 1,998 records will be kept annually (or an average of 60 per sprouting operation) with respect to testing for *Listeria* spp. or *L. monocytogenes*. Therefore, $1,998 \text{ records} \times 0.17 \text{ hour per record} = 340$ total annual hours for small sprouting operations to comply with § 112.150(b)(4) with respect to testing for *Listeria* spp. or *L. monocytogenes*.

For 27 small farms, it is estimated that a total of 3,240 records will be kept annually (or an average of 120 per sprouting operation). Therefore, $3,240 \text{ records} \times 0.17 \text{ hour per record} = 551$ total annual hours for small farms to comply with § 112.150(b)(4) with respect to testing for *Listeria* spp. or *L. monocytogenes*. For 68 large sprouting operations, it is estimated that a total of 12,231 records will be kept annually (or an average of 180 per sprouting operation). Therefore, $12,231 \text{ records} \times 0.17 \text{ hour per record} = 2,079$ total annual hours for large sprouting operations to comply with § 112.150(b)(4) with respect to testing for *Listeria* spp. or *L. monocytogenes*.

Section 112.150(b)(6) requires records of corrective actions conducted in accordance with the requirements of §§ 112.142(b)(2), 112.146, and 112.148 for sprouting operations. It is estimated that all sprouting operations may collectively perform approximately 285 corrective actions annually. For each of 285 sprout operations, it is estimated that there will be an annual burden of 0.5 hour per operation to make the required record documenting these corrective actions. Therefore, $285 \text{ sprout farms} \times 0.5 \text{ hour} = 143$ annual hours for sprout farms to comply with § 112.150(b)(6).

Commercial Processing Exemption Recordkeeping

Under § 112.2(b)(4), farms relying on the commercial processing exemption must establish and maintain records of their required disclosures to customers regarding produce that has not been commercially processed and the annual written assurances obtained from customers regarding such commercial processing. It is estimated that § 112.2(b)(4) represents a recordkeeping requirement for 4,568 entities (4,153 farms that only grow produce exempt from the rule due to commercial processing, who would otherwise be subject to the rule \times an additional 10 percent to account for covered farms relying on this exemption for only some of their produce, and other entities that will be required to make these records). We estimate that it will take approximately 5 minutes to make these records each year. Therefore, $4,568 \text{ entities} \times 0.08 \text{ hour per entity} = 365$ annual hours to comply with § 112.2(b)(4).

TABLE 32—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[One-time hourly burden]

21 CFR	Number of recordkeepers	Number of records	Total records	Average hourly burden	Total hours	Operating costs in millions (related to testing burdens)
Agricultural Water—Documentation of Scientific Data:						
112.50(b)(3)	5,547	1	5,547	0.5	2,773
112.50(b)(5)	3,661	2	7,322	0.5	3,661
112.50(b)(8); 112.49(a)	8,757	1	8,757	0.5	4,379
112.50(b)(8); 112.49(b)	3,661	1	3,661	0.5	1,830
112.50(b)(8); 112.49(c)	2,511	1	2,511	0.5	1,255
112.50(b)(8); 112.49(d)	2,511	1	2,511	0.5	1,255
112.50(b)(9)	1	1	1	5.0	5
Sprouts—Establishment of Environmental Monitoring Plan:						
112.150(b)(2), Very Small Farms	46	1	46	7.0	321
112.150(b)(2), Small farms	37	1	37	12.0	446
112.150(b)(2), Large farms	94	1	94	17.0	1,592
Sprouts—Establishment of Sampling Plan:						
112.150(b)(3)	177	1	177	8.0	1,414
Sprouts—Documentation of Scientific Data:						
112.150(b)(5)	1	1	1	5.0	5
112.150(b)(5); 112.144(c)	177	2	353	2.0	707
Variations:						
112.173	7	1	7	120.0	840
Total One-Time Hourly Burden	20,484	N/A

ANNUAL HOURLY BURDEN

21 CFR	Number of recordkeepers	Number of records	Total annual records	Average hourly burden	Total hours	Operating costs (in millions)
Qualified Exempt Farms—Documenting Eligibility for Exemption						
112.7(b)	3,285	1	3,285	0.5	1,643
Training						
112.30(b)(1)	24,420	1	24,420	7.25	177,045
Testing Requirements for Agricultural Water						
Records of Testing for 0 Detectable Generic <i>E. coli</i>:						
112.44(a), 112.46(c)	26,038	2	52,077	0.7	34,371	\$2.48
Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic <i>E. coli</i>—Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce:						
112.44(b), 112.46(b)	12,554	6.29	78,965	0.92	72,647	5.24
Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic <i>E. coli</i>—Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce:						
112.44(b), 112.46(b)	9,471	1	13,259	0.9	12,198	0.88
Records of Analytical Test Results as Part of Corrective Steps:						
112.45	298	1	298	0.33	98
Recordkeeping Related to Agricultural Water						
Findings of Water System Inspection:						
112.50(b)(1)	34,396	4	137,583	0.8	110,066
Records of Testing for 0 Detectable Generic <i>E. coli</i>:						
112.50(b)(2)	26,038	2	52,077	0.33	17,185

ANNUAL HOURLY BURDEN—Continued

21 CFR	Number of recordkeepers	Number of records	Total annual records	Average hourly burden	Total hours	Operating costs (in millions)
Records of Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic <i>E. coli</i> —Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce: 112.50(b)(2)	12,554	6.29	78,965	0.08	6,317
Records of Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic <i>E. coli</i> —Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce: 112.50(b)(2)	9,471	1	13,259	0.08	1,061
Documentation of Monitoring Water Treatment 112.50(b)(4)	5,547	1	5,547	0.98	5,436
Documentation of corrective actions applied: 112.50(b)(6)	14,643	1	14,643	0.5	7,322
Documentation from Public Water Systems: 112.50(b)(7)	9,108	1	9,108	0.33	3,005
Recordkeeping Related to Soil Amendments: 112.60(b)(1)	3,503	1	3,503	0.25	876
112.60(b)(2)	420	1	420	0.50	210
Recordkeeping Related to Cleaning and Sanitation: 112.140(b)(1) Cleaning worker tools, very small farms	16,061	1	16,061	8.0	128,485
112.140(b)(1) Cleaning worker tools, small and large farms	8,635	1	8,635	25.0	215,871
112.140(b)(1) Cleaning machinery, very small farms	13,156	1	13,156	8.0	105,248
112.140(b)(1) Cleaning machinery, small and large farms	7,073	1	7,073	25.0	176,831
Testing Requirements for Sprouts						
Testing for <i>E. coli</i> and <i>Salmonella</i> and additional pathogens as applicable 112.144(b) and (c), 112.147, very small farms	33	125	4,163	0.50	2,081	0.15
112.144(b) and (c), 112.147, small farms	27	125	3,375	0.50	1,688	\$0.12
112.144(b) and (c), 112.147, large farms	68	558	37,882	0.50	18,941	1.37
Testing for <i>Listeria</i> spp. or <i>L. monocytogenes</i> : 112.144(a), 112.145, very small farms	33	60	1,998	0.15	300	0.02
112.144(a), 112.145, small farms	27	120	3,240	0.15	486	0.04
112.144(a), 112.145, large farms	68	180	12,231	0.15	1,835	0.13
Recordkeeping Related to Sprouts						
Documentation of Treatment of Seeds or Beans: 112.150(b)(1), very small farms	33	50	1,665	0.20	333
112.150(b)(1), small farms	27	50	1,350	0.20	270
112.150(b)(1), large farms	68	223	15,153	0.20	3,031
Environmental Monitoring Plan—Updating: 112.150(b)(2), very small farms	46	1	46	0.15	7
112.150(b)(2), small farms	37	1	37	0.15	6
112.150(b)(2), large farms	94	1	94	0.15	14
Sampling Plan—Updating: 112.150(b)(3)	177	1	177	1.00	177
Records of Testing for <i>E. coli</i> and <i>Salmonella</i> and additional pathogens as applicable: 112.150(b)(4), very small farms	33	75	2,498	0.15	375
112.150(b)(4), small farms	27	75	2,025	0.15	304
112.150(b)(4), large farms	68	334	22,689	0.15	3,403
Records of Testing for <i>Listeria</i> spp. or <i>L. monocytogenes</i> : 112.150(b)(4), very small farms	33	60	1,998	0.17	340
112.150(b)(4), small farms	27	120	3,240	0.17	551
112.150(b)(4), large farms	68	180	12,231	0.17	2,079
Records of corrective actions: 112.150(b)(6)	285	1	285	0.50	143
Commercial processing exemption recordkeeping						
Records of disclosures to customers and annual written assurances obtained from customers:						

ANNUAL HOURLY BURDEN—Continued

21 CFR	Number of recordkeepers	Number of records	Total annual records	Average hourly burden	Total hours	Operating costs (in millions)
112.2(b)(4)	4568	1	4,568	0.08	365
Annual Hourly Burden	1,112,641
Operating Costs	10.42

Third-Party Disclosure Burden

Under § 112.6(b) certain qualified exempt farms (those that would otherwise be covered by the rule but that meet the criteria in § 112.5) must comply with certain food labeling or disclosure requirements. A total of 21,666 non-sprout farms are estimated to be eligible for the qualified exemption in § 112.5. After subtracting the number of farms that are not covered by the rule because they have annual monetary value of produce sold of \$25,000 or less, 3,285 farms remain that must comply with § 112.6(b). It is estimated that it will take the farm operator approximately 5 minutes to buy and prepare one poster board. It is also estimated that the operator will buy posters bi-weekly. The total annual time required to buy and prepare a poster board is 24 hours [(60 minutes × 24)/60]. Therefore, 3,285 farms × 24 annual hours = 78,840 annual hours for these farms to comply with the requirement of § 112.6(b).

It is estimated that farms with other marketing channels will provide their name and complete business address on an invoice or receipt that accompanies their product. We estimate that a total of 3,083 farms will incur a cost to comply with this provision. It is estimated that it will take a farm operator 5 minutes (0.08 hour) to change this template for new invoices, and that this is a one-time burden. Therefore, 3,083 × 0.08 hour = about 247 hours to comply with § 112.6(b).

Under § 112.31(b)(2), covered farms are required to instruct personnel to notify their supervisor(s) if they are have, or if there is a reasonable possibility that they have an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea). The number of farms that will need to implement this disclosure

is based on the estimated number of farms that are not currently implementing the requirements imposed by the rule in the RIA. It is estimated that one worker from each of 29,175 farms will spend 5 minutes annually to comply with § 112.31(b)(2), which will consist of the employer giving verbal instructions to employees. Therefore, 29,175 × 5 minutes = 2,334 hours to comply with § 112.31(b)(2).

Under § 112.33(a), covered farms must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. It is estimated that farms with voluntary food safety programs in place will already have practices aligned with this provision; therefore no burden is estimated for those farms. After subtracting these farms, it is estimated that § 112.33(a) represents a third-party disclosure requirement for 35,556 farms. We estimate that it will take 8 hours annually for the operator to inform visitors of the farm policies, including showing them where the restrooms are, and to take reasonable steps to ensure their compliance, such as monitoring visitors to ensure they are following the policies and procedures. Therefore, 35,556 farms × 8 hours per farm = 284,448 annual hours to comply with § 112.33(a).

Under § 112.2(b)(2), farms must disclose in documents accompanying produce that is eligible for the commercial processing exemption that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” It is estimated that § 112.2(b)(2) represents a third-party disclosure requirement for 4,568 entities (4,153 farms that only grow produce exempt from the rule due to commercial processing, who would otherwise be subject to the rule × an

additional 10 percent to account for covered farms relying on this exemption for only some of their produce, and other entities that will be required to make these disclosures). We estimate that it will take 0.08 hours to provide this statement, and the statement will occur on average about 26 times per year (or once a week for half of the year). Therefore, 4,568 entities × 0.08 hours per entity × 26 shipments = 9,502 annual hours to comply with § 112.2(b)(2).

Under § 112.2(b)(3), farms relying on the commercial processing exemption must receive certain annual documentation from their buyers ensuring that the relevant produce will receive the required processing. It is estimated that § 112.2(b)(3) represents a third-party disclosure requirement for 4,568 entities (the same entities described previously regarding § 112.2(b)(2)). We estimate that it will take 1 hour to provide this documentation each year. Therefore, 4,568 entities × 1 hour per entity = 4,568 annual hours to comply with § 112.2(b)(3).

Under § 112.142(b)(2), with certain limited exceptions, if a sprouting operation knows or has reason to believe that a lot of seeds or beans may be contaminated with a pathogen, the sprouting operation must report that information to the seed grower, distributor, supplier, or other entity from whom the sprouting operation received the seeds or beans. We estimate that this requirement will apply to only a small percentage of sprouting operations; therefore this requirement represents a burden to 13 sprouting operations (128 × 10 percent). We estimate that it will take 1 hour to provide this documentation each year. Therefore, 13 sprouting operations × 1 hour per sprouting operations = 13 annual hours to comply with § 112.2(b)(3).

TABLE 33—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

21 CFR Section (or FDA Form #)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total hours
One Time Third-Party Disclosure Burden					
112.6(b) Documentation	3,083	1	3,083	0.08	247
Total One-Time Burden					247
Annual Third-Party Disclosure Burden					
112.6(b) Posting signage	3,285	24	78,840	1	78,840
112.31(b)(2)	29,175	1	29,175	0.08	2,334
112.33(a)	35,556	1	35,556	8	284,448
112.2(b)(2)	4,568	26	118,776	0.08	9,502
112.2(b)(3)	4,568	1	4,568	1	4,568
112.142(b)(2)	13	1	13	1	13
Total annual burden hours					379,705

XXIX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. These references are also available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

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List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11, 16, and 112 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (k) to read as follows:

§ 11.1 Scope.

* * * * *

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 4. Amend § 16.1 by:

■ a. In paragraph (b)(1), adding an entry in numerical order.

■ b. In paragraph (b)(2), adding an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *
(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

* * * * *

(2) * * *

§§ 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.

* * * * *

■ 5. Add part 112 to read as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**Subpart A—General Provisions**

Sec.

112.1 What food is covered by this part?

112.2 What produce is not covered by this part?

112.3 What definitions apply to this part?

112.4 Which farms are subject to the requirements of this part?

112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

Subpart B—General Requirements

112.11 What general requirements apply to persons who are subject to this part?

112.12 Are there any alternatives to the requirements established in this part?

Subpart C—Personnel Qualifications and Training

112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

112.22 What minimum requirements apply for training personnel who conduct a covered activity?

112.23 What requirements apply regarding supervisors?

112.30 Under this subpart, what requirements apply regarding records?

Subpart D—Health and Hygiene

112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

112.32 What hygienic practices must personnel use?

112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

Subpart E—Agricultural Water

112.41 What requirements apply to the quality of agricultural water?

112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

112.43 What requirements apply to treating agricultural water?

112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

112.47 Who must perform the tests required under § 112.46 and what methods must be used?

112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

112.50 Under this subpart, what requirements apply regarding records?

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

112.52 How must I handle, convey, and store biological soil amendments of animal origin?

112.53 What prohibitions apply regarding use of human waste?

112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

112.55 What microbial standards apply to the treatment processes in § 112.54?

112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

112.60 Under this subpart, what requirements apply regarding records?

Subpart G—H—[Reserved]**Subpart I—Domesticated and Wild Animals**

112.81 How do the requirements of this subpart apply to areas where covered activities take place?

112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

Subpart J—[Reserved]**Subpart K—Growing, Harvesting, Packing, and Holding Activities**

112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

112.112 What measures must I take immediately prior to and during harvest activities?

112.113 How must I handle harvested covered produce during covered activities?

112.114 What requirements apply to dropped covered produce?

112.115 What measures must I take when packaging covered produce?

112.116 What measures must I take when using food-packing (including food packaging) material?

Subpart L—Equipment, Tools, Buildings, and Sanitation

- 112.121 What equipment and tools are subject to the requirements of this subpart?
- 112.122 What buildings are subject to the requirements of this subpart?
- 112.123 What requirements apply regarding equipment and tools subject to this subpart?
- 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?
- 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?
- 112.126 What requirements apply to my buildings?
- 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?
- 112.128 What requirements apply regarding pest control in buildings?
- 112.129 What requirements apply to toilet facilities?
- 112.130 What requirements apply for hand-washing facilities?
- 112.131 What must I do to control and dispose of sewage?
- 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?
- 112.133 What requirements apply to plumbing?
- 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?
- 112.140 Under this subpart, what requirements apply regarding records?

Subpart M—Sprouts

- 112.141 What commodities are subject to this subpart?
- 112.142 What requirements apply to seeds or beans used to grow sprouts?
- 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?
- 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?
- 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?
- 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?
- 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?
- 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?
- 112.150 Under this subpart, what requirements apply regarding records?

Subpart N—Analytical Methods

- 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?
- 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

- 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

Subpart O—Records

- 112.161 What general requirements apply to records required under this part?
- 112.162 Where must I store records?
- 112.163 May I use existing records to satisfy the requirements of this part?
- 112.164 How long must I keep records?
- 112.165 What formats are acceptable for the records I keep?
- 112.166 What requirements apply for making records available and accessible to FDA?
- 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Subpart P—Variances

- 112.171 Who may request a variance from the requirements of this part?
- 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?
- 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?
- 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?
- 112.175 Who responds to a petition requesting a variance?
- 112.176 What process applies to a petition requesting a variance?
- 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?
- 112.178 Under what circumstances may FDA deny a petition requesting a variance?
- 112.179 When does a variance approved by FDA become effective?
- 112.180 Under what circumstances may FDA modify or revoke an approved variance?
- 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?
- 112.182 What are the permissible types of variances that may be granted?

Subpart Q—Compliance and Enforcement

- 112.192 What is the applicability and status of this part?
- 112.193 What are the provisions for coordination of education and enforcement?

Subpart R—Withdrawal of Qualified Exemption

- 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?
- 112.202 What procedure will FDA use to withdraw an exemption?
- 112.203 What information must FDA include in an order to withdraw a qualified exemption?
- 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

- 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?
- 112.206 What is the procedure for submitting an appeal?
- 112.207 What is the procedure for requesting an informal hearing?
- 112.208 What requirements are applicable to an informal hearing?
- 112.209 Who is the presiding officer for an appeal and for an informal hearing?
- 112.210 What is the timeframe for issuing a decision on an appeal?
- 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?
- 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions**§ 112.1 What food is covered by this part?**

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell

and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of

microorganisms of public health significance;” and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal

Food, Drug, and Cosmetic Act apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term "biological soil amendment of animal origin" does not include any form of human waste.

Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may

or may not involve insulation, depending on environmental conditions.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(i) *Primary Production Farm.* A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and

(C) Manufacture/process food, provided that:

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) *Secondary Activities Farm.* A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary

Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food contact surfaces" includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw

agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health

significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or

corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State or the same Indian reservation as the farm that produced the food; or

(ii) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means "raw agricultural commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is

effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of "sewage sludge" in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (*i.e.*, finished) biological soil amendment produced through a controlled composting process.

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce stabilized compost in which

air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You, for purposes of this part, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a "covered farm" subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

(b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users

(as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

(a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

- (1) This subpart (General Provisions);
- (2) Subpart O of this part (Records);
- (3) Subpart Q of this part (Compliance and Enforcement); and
- (4) Subpart R of this part (Withdrawal of Qualified Exemption).

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

(a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).

(b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B—General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.

(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a)

of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C—Personnel Qualifications and Training

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is

reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D—Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an

applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

- (1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and
- (2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:

- (1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;
- (2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;
- (3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:
 - (i) Before starting work;
 - (ii) Before putting on gloves;
 - (iii) After using the toilet;
 - (iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;

(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

- (1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent and nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:

- (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet

the relevant microbial quality criteria in § 112.44, as applicable.

(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

- (1) Used as sprout irrigation water;
- (2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;
- (3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and
- (4) Used for washing hands during and after harvest activities.

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):

- (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and
- (2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

- (1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or
- (2) Treat the water in accordance with the requirements of § 112.43.

(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:

- (1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:
 - (i) Applying a time interval between last irrigation and harvest using either:
 - (A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or
 - (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or
 - (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate

supporting scientific data and information;

(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or

(3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):

(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.

(i) The initial survey must be conducted:

(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.

(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).

(iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.

(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.

(i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:

(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).

(B) For an untreated ground water source, a minimum of one sample per year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which

you believe your microbial water quality profile changed.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).

(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and

food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);

(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and

(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;

(3) Scientific data or information you rely on to support the adequacy of a

method used to satisfy the requirements of § 112.43(a)(1) and (2);

(4) Documentation of the results of water treatment monitoring under § 112.43(b);

(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *Escherichia coli* (*E. coli*), in accordance with § 112.45(b)(1)(ii);

(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);

(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;

(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and

(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable

generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in

accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph (a); or

For the microorganism—	The microbial standard is—
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.

For the microorganism—	The microbial standard is—
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this

paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.	[Reserved].
(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (<i>i.e.</i> , no restrictions)	0 days.

(b) [Reserved]

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and

(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you

produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G–H [Reserved]

Subpart I—Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply:

(1) When a covered activity takes place in a fully-enclosed building; or

(2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

(a) You must take the steps set forth in paragraph (b) of this section if under

the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.

(b) You must:

(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and

(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.*, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J—[Reserved]

Subpart K—Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (*i.e.*, excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and

(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the

growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

(1) Cleanable or designed for single use; and

(2) Unlikely to support growth or transfer of bacteria.

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L—Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment,

palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and

(b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and

(b) Equipment and tools must be:

(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and

(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must

do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) Accurate and precise as necessary and appropriate in keeping with their purpose;
- (b) Adequately maintained; and
- (c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and
- (b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:

(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:

- (i) Provide sufficient space for placement of equipment and storage of materials;
- (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and

(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in

your buildings, as appropriate, considering the potential for such contamination through:

- (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and
- (2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

- (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or
- (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

- (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
- (2) Be directly accessible for servicing,

be serviced and cleaned at a frequency

sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

- (1) Soap (or other effective surfactant);
- (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and
- (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of

covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities;

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

(1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

(1) Growing operations for sprouts; and

(2) Covered harvesting, packing, or holding activities.

Subpart M—Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:

(1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and

(2) Report the information (association with illness and/or findings of microbial testing) to the seed grower,

distributor, supplier, or other entity from whom you received the seeds or beans.

(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:

(1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or

(2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

(e) You must either:

(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or

(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:

(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and

(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before

contact with sprouts or seeds or beans used to grow sprouts.

(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.

(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.

(e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in § 112.146.

(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.145.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or

(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (*i.e.*, while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.

(c) In addition to *E. coli* O157:H7 and *Salmonella* species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:

(1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and

(2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (*i.e.*, *Listeria* species or *L. monocytogenes*);

(2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in § 112.152.

(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?

You must, at a minimum, take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;

(d) Conduct finished product testing when appropriate;

(e) Perform any other actions necessary to prevent recurrence of the contamination; and

(f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).

(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c):

(a) Take appropriate action to prevent any food that is adulterated under

section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;

(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));

(c) Clean and sanitize the affected surfaces and surrounding areas; and

(d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);

(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and

(6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or

(b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or

(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* using:

(a) The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:

(a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O—Records

§ 112.161 What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

(a) Existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

(a)(1) You must keep records required by this part for at least 2 years past the date the record was created.

(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.

(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P—Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure

that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the competent authority (*i.e.*, the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (*e.g.*, because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the **Federal Register**. This notice will establish a

public docket so that interested parties may submit written comments on our determination.

(3) When applicable, we will:

(i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

(iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.

(ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O of this part. Examples of permissible types of variances include:

(a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);

(b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and

(c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q—Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

(a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

or

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including

information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must either:

(1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

(e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213;

(f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a

timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:

(1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented

at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5) of this chapter and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the

presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order

within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office

of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 11, and 16

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, and 16

[Docket No. FDA-2011-N-0146]

RIN 0910-AG66

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is adopting regulations to provide for accreditation of third-party certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications, under the FDA Food Safety Modernization Act (FSMA). These certifications will be required for participation in the voluntary qualified importer program (VQIP) established under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, when the Agency has determined that an imported food is subject to certification under FSMA, the Agency may require a certification under this rule as a condition for admitting the food into the United States. FDA also expects that these regulations will increase efficiency by reducing the number of redundant food safety audits.

DATES: This rule is effective January 26, 2016.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Christin, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7526.

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Executive Summary

Purpose and Coverage of the Final Rule

This rule is part of FDA's implementation of FSMA, which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. In this document, we establish a program for accreditation of third-party certification bodies¹ to conduct food safety audits and issue certifications of

¹ As explained more fully in Response 1, in response to comments and for clarity, this final rule uses the term "third-party certification body" rather than either the term "third-party auditor" or the term, "third party auditor/certification body" (except that we will use the term "third-party auditor" in the definitions of "accredited third-party certification body" and "third-party certification body" in 21 CFR 1.600(c) and in the preamble discussion of those definitions in section III.A).

foreign food facilities and foods for humans and animals for purposes of sections 801(q) and 806 of the FD&C Act. We are also codifying certain limited exemptions to mandatory import certification under 801(q) of the FD&C Act (21 U.S.C. 381).

FSMA added section 808 to the FD&C Act (21 U.S.C. 384d), which directs FDA to establish a new program for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q) and 806 of the FD&C Act. This rulemaking implements section 808 of the FD&C Act; we will recognize accreditation bodies to accredit third-party certification bodies, except for limited circumstances in which we may directly accredit third-party certification bodies.

FSMA specifies two uses for the food and facility certifications issued by accredited third-party certification bodies under this program. First, facility certifications will be used by importers to establish eligibility for VQIP under section 806 of the FD&C Act (21 U.S.C. 384b(a)). VQIP offers participating importers expedited review and entry of food that is part of VQIP. One condition of participation is importation of food from facilities audited and certified by third-party certification bodies accredited under this subpart. FDA issued draft guidance on VQIP on June 5, 2015 (80 FR 32136); the draft guidance may be accessed at <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM448558.pdf>.

Second, section 801(q) of the FD&C Act gives FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act. The authority to mandate import certification for food, based on risk, is one of the tools we can use to help prevent potentially harmful food from reaching U.S. consumers. When FDA has determined that a food import is subject to such certification under section 801(q) of the FD&C Act, FDA will require, as a condition of entry, a certification issued either by an accredited third-party certification body under this rule or by an agency or representative of the government of the country from which the food at issue originated, as designated by FDA.

In addition, facilities and importers may choose to use onsite audits conducted by third-party certification bodies accredited under the program set out in this rule in connection with meeting supplier verification requirements under FDA's final rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (final human preventive controls regulation) (80 FR 55907, September 17, 2015); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (final animal preventive controls regulation) (80 FR 56169, September 17, 2015); and the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (published elsewhere in this edition of the **Federal Register**) (implementing sections 418 and 805 of the FD&C Act, respectively). Under those rules, in circumstances where an onsite audit is the appropriate supplier verification activity, such audit must be conducted by a "qualified auditor." The definitions of "qualified auditor" in those rules make clear that an example of a potential qualified auditor includes, but is not limited to, an audit agent of a certification body that has been accredited in accordance with regulations in part 1, subpart M of this chapter (*i.e.*, this rule implementing section 808 of the FD&C Act).

Summary of Major Provisions of the Final Rule

This rule establishes the framework, procedures, and requirements for accreditation bodies and third-party certification bodies for purposes of section 808 of the FD&C Act. The rule sets requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that accreditation bodies must demonstrate to be eligible for recognition. Accreditation bodies also must demonstrate capability to meet the FDA requirements that would apply upon recognition. Additionally, the rule establishes requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that third-party certification bodies must demonstrate to be eligible for accreditation. Third-party certification bodies also must demonstrate capability to meet the applicable requirements of the rule that would apply upon accreditation.

Pursuant to FSMA section 307 (21 U.S.C. 384d), the rule requires accredited third-party certification

bodies to perform unannounced facility audits, to notify FDA upon discovering a condition that could cause or contribute to a serious risk to the public health, and to submit to FDA reports of regulatory audits conducted for certification purposes. The rule includes stringent requirements to prevent conflicts of interest from influencing the decisions of recognized accreditation

bodies and accredited third-party certification bodies. The rule does not, however, establish the audit criteria that accredited third-party certification bodies will use in examining eligible entities for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, because those criteria appear elsewhere in FDA regulations and the FD&C Act.

Costs and Benefits

Costs of the Third-Party final rule include compliance costs of accreditation bodies and certification bodies that choose to participate in our third-party program, and user fees imposed by FDA on accreditation bodies and certification bodies for application review and monitoring of program participants.

TABLE 1—SUMMARY USER FEE, COMPLIANCE, UNDISCOUNTED AND ANNUALIZED COSTS OF THE THIRD-PARTY (TP) PROGRAM PER PARTICIPANT

Eligible entity	Audited by		Total
	Certification bodies (CBs) currently accredited under other programs	CBs not accredited under any program	
SCENARIO 1			
Number of section 801(q) Entities	10	65	75
Cost of Compliance with Program Requirements (TP Compliance Cost)	\$694	\$2,569
Section 801(q) Compliance Cost	\$6,940	\$166,985	\$173,925
Number of section 806 Entities	145	971	1,116
TP Compliance Cost	\$694	\$2,569
Section 806 Compliance Cost	\$100,630	\$2,494,499	\$2,595,129
Total TP Compliance Cost—Scenario 1	\$2,769,054
SCENARIO 2			
Number of section 801(q) Entities	10	65	75
TP Compliance Cost	\$322	\$2,197
Section 801(q) Compliance Cost	\$3,220	\$142,805	\$146,025
Number of § 806 Entities	459	3,068	3,527
TP Compliance Cost	\$322	\$2,197
Section 806 Compliance Cost	\$147,798	\$6,740,396	\$6,888,194
Total TP Compliance Cost—Scenario 2	\$7,034,219
SCENARIO 3			
Number of section 801(q) Entities	10	65	75
TP Compliance Cost	\$227	\$2,102
Section 801(q) Compliance Cost	\$2,270	\$136,630	\$138,900
Number of section 806 Entities	801	5,359	6,160
TP Compliance Cost	\$227	\$2,102
Section 806 Compliance Cost	\$181,827	\$11,264,618	\$11,446,445
Total TP Compliance Cost—Scenario 3	\$11,585,345

The costs that accreditation bodies and certification bodies incur in complying with the regulation are necessarily less than the private benefits they accrue by becoming recognized or accredited, respectively. Through the third-party accreditation program more effective regulatory oversight is achieved. FDA will recoup resources in managing its third-party accreditation program through user fees that FDA intends to impose on participating accreditation bodies and third-party certification bodies.

I. Introduction and Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain

problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities and international collaborations with foreign regulatory counterparts. A top priority for FDA are those FSMA-required regulations that provide the framework for industry’s implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in table 2 and

requested comments on all aspects of these proposed rules.

TABLE 2—PUBLISHED FOUNDATIONAL PROPOSED RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls regulation.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety regulation	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls regulation.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP regulation	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification regulation (also referred to in this document as the proposed rule).	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration regulation.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation regulation.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice listed in table 3 and requested in each supplemental notice of proposed rulemaking for the rules comments on specific issues identified proposed rulemaking.

TABLE 3—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
FSVP for Importers of Food for Humans and Animals	2014 supplemental FSVP notice	79 FR 58574, September 29, 2014.

We finalized two of the foundational rulemakings listed in table 4 in September 2015.

TABLE 4—PUBLISHED FOUNDATIONAL FINAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	final human preventive controls regulation	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	final animal preventive controls regulation	80 FR 56170, September 17, 2015.

As FDA finalizes these seven foundational rulemakings, we are putting in place a modern, risk-based framework for food safety that is based on the most recent science, that focuses efforts where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a significant amount of outreach to the stakeholder community to find the right balance between flexibility and accountability in these regulations.

After FSMA was enacted in 2011, we have been involved in approximately 600 stakeholder engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 1, 2, 3). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA

implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that stakeholders understand and engage in their respective roles in food safety. FDA believes these seven foundational final rules, when implemented, will affect the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

B. Purpose of This Rulemaking

FSMA added section 808 to the FD&C Act which directs FDA to establish a new voluntary program for accreditation of third-party certification bodies to conduct food safety audits and to issue food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements for purposes of sections 801(q) and 806 of the FD&C Act. This rulemaking implements section 808 of the FD&C Act; we will recognize accreditation bodies to accredit third-party certification bodies, except for limited circumstances in which we may directly accredit third-party certification bodies.

FSMA specifies two uses for the food and facility certifications issued by accredited third-party certification bodies under this program. First, facility certifications will be used by importers to establish eligibility for VQIP under section 806 of the FD&C Act. VQIP offers participating importers expedited review and importation for food from facilities audited and certified by third-party certification bodies accredited under this subpart. FDA issued draft guidance on VQIP on June 5, 2015 (80 FR 32136); the draft guidance may be accessed at <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM448558.pdf>.

Second, section 801(q) of the FD&C Act gives FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act. The authority to mandate import certification for food, based on risk, is one of the tools we can use to help prevent potentially harmful food from reaching U.S. consumers. When FDA has determined that a food import is subject to such certification under section 801(q) of the FD&C Act, FDA will require, as a condition of entry, a certification issued either by an accredited third-party certification body under this rule or by an agency or representative of the government of the country from which the food at issue originated, as designated by FDA.

This final rule will help FDA ensure the competence and independence of third-party certification bodies who are accredited to conduct foreign food safety audits to examine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, among other things. The document also will help ensure the

validity and reliability of certifications offered to FDA for purposes of VQIP eligibility under section 806 of the FD&C Act and admissibility of an imported food subject to an FDA risk determination under section 801(q) of the FD&C Act.

The third-party certification program is part of FSMA's paradigm shift toward a modern, preventive, and risk-based approach to food safety regulation and new programs to facilitate global trade in safe food. Specifically, FSMA requires FDA to issue new preventive controls and produce safety standards that apply to domestic and foreign processors and producers. In addition, FSMA directs FDA to issue an FSVP regulation requiring importers to implement FSVPs that provide adequate assurances that their foreign suppliers produce food that is in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the FD&C Act, as appropriate, and that is in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act. We emphasize that facilities and importers are not required to use third-party certification bodies accredited under this rule in meeting their supplier verification requirements under the final human or animal preventive controls or FSVP regulations. See section XIII.G.

By contrast, the third-party certification program established under section 808 of the FD&C Act focuses on food safety audits to certify that eligible foreign entities and the food produced by such entities meet applicable FDA requirements for purposes of sections 801(q) and 806 of the FD&C Act. Although importers must obtain facility certifications from accredited third-party certification bodies under this rule in order to be eligible for VQIP, we note that importers seeking to satisfy a requirement for certification as a condition of admissibility for an article of food under section 801(q) of the FD&C Act may offer a certification issued either by foreign governments designated by FDA to issue such certifications or by third-party certification bodies accredited under this rule.

Through FSMA we are transforming our role in the global food safety system, by building ever stronger partnerships with our foreign regulatory counterparts and by exploring opportunities to

leverage private food safety activities to benefit of our system of public food safety assurances. We value the role that private audits can play in enhancing food safety when done properly, and we share common purpose with the food industry in ensuring the rigor and objectivity of those audits.

The final rule on accreditation of third-party certification bodies reflects the results of significant stakeholder engagement to help ensure that the rule achieves its public health goal, reflects industry best practices, and strikes the right balance between flexibility and accountability.

C. The Proposed Rule

FDA published a proposed rule for "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (the proposed rule) on July 29, 2013. The proposed rule included eligibility requirements for accreditation bodies to qualify for recognition and requirements that accreditation bodies choosing to participate in the FDA program must meet, once recognized. We also proposed eligibility requirements for third-party certification bodies to qualify for accreditation and requirements that third-party certification bodies choosing to participate in the FDA program must meet, once accredited. We intended the proposed requirements to ensure the competency and independence of the accreditation bodies and third-party certification bodies participating in the program.

We also proposed procedures for recognition and accreditation, as well as requirements relating to monitoring and oversight of participating accreditation bodies and third-party certification bodies. These included procedures that we would follow when removing a third-party certification body or an accreditation body from the program. Further, we proposed requirements relating to auditing and certification of foreign eligible entities under the program, and for notifying us of conditions in an audited facility that could cause or contribute to a serious risk to the public health. In response to several requests, we extended the proposed rule comment period until January 27, 2014.

D. Public Comments

We received over 150 comments from accreditation bodies, certification bodies, members of the food industry, industry associations, foreign governments, State governments, public health organizations, public advocacy

groups, individual consumers, consumer groups, and others. Some submissions included signatures and statements from multiple individuals. Taken as a whole, the comments address virtually every provision of the proposed rule. In the remainder of this document, we describe the comments that are within the scope of this rulemaking, respond to them, and explain any revisions we made from the proposed rule.

A number of comments focus on the overarching issues of: (1) Alignment with voluntary consensus standards; (2) the use of private food safety schemes; (3) the relationship between the third-party certification program, foreign competent authorities, and FDA's international activities; and (4) the possible implications of the lack of qualified auditors on the third-party certification program. We address these comments generally below.

We received several comments on the overarching issue of the use of voluntary international consensus standards issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), including the following ISO/IEC standards: ISO/IEC 17000:2004 Conformity assessment—Vocabulary and general principles (ISO/IEC 17000:2004) (Ref. 4); ISO/IEC 17011:2004, Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2004) (Ref. 5); ISO/IEC 17021:2011, Conformity assessment—Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2011) (Ref. 6); ISO/IEC 17065:2012, Conformity assessment—Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012) (Ref. 7); and ISO/IEC 19011:2011, Guidelines for auditing management systems (ISO/IEC 19011:2011) (Ref. 8).

Some comments support the approach to ISO/IEC standards that we used when developing the proposed rule; some comments state that the process for developing these standards makes them unbiased. Other comments suggest we should place greater reliance on ISO/IEC standards, including some comments asserting that we should incorporate ISO/IEC standards by reference into the final rule. These comments encourage us to follow the example of a proposed rule issued by the Environmental Protection Agency and entitled, "Formaldehyde; Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products" (78 FR 34795, June 10,

2013), which proposed to incorporate by reference certain international standards. These comments assert that by placing greater reliance on ISO standards, we could allow ISO's broader oversight program to complement FDA's management of these bodies.

Implementation of section 808 of the FD&C Act occurs against the backdrop of the broader Federal policies on consensus standards and conformity assessment under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113). The NTTAA, together with the Office of Management and Budget (OMB) Circular A–119, revised February 10, 1998 (63 FR 8546, February 19, 1998), directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. OMB Circular A–119 states that the use of voluntary standards, whenever practicable and appropriate, is intended to eliminate the cost to government of developing its own standards and decrease the cost of goods procured and the burden of complying with Agency regulation; provide incentives and opportunities to establish standards that serve national needs; encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and further the policy of reliance upon the private sector to supply government needs for goods and services.

As directed by OMB in Circular A–119, the National Institute of Standards and Technology (NIST), in the **Federal Register** of August 10, 2000 (65 FR 48894), issued policy guidance on Federal conformity assessment activities (defined as activities concerned with determining directly or indirectly that requirements for products, services, systems, and organizations are fulfilled) (15 CFR 287.2). The Federal conformity assessment guidance is codified at 15 CFR part 287 and applies to all Federal Agencies that set policy for, manage, operate, or use conformity assessment activities or results, domestically and internationally (except for activities conducted pursuant to treaties) and is intended to eliminate unnecessary duplication and complexity in conformity assessment requirements. (We note that OMB has announced it is currently revising Circular A–119, and NIST is revising the Federal conformity assessment guidance.)

We agree with comments on the value of promoting international consistency and tapping into an existing framework of consensus standards that is familiar

to industry, which may make it easier for accreditation bodies, third-party certification bodies, and eligible entities to comply with this rule. Therefore, we are revising the rule to allow for accreditation bodies and third-party certification bodies to use documentation of their conformance with ISO/IEC standards in meeting the program requirements under this rule, supplemented as necessary. We are not, however, incorporating these standards by reference into the rule as further discussed in our responses to comments in sections III. to XIII., except that we are not further responding to comments citing specific requirements of ISO/IEC Guide 65:1996, Conformity assessment—Requirements for bodies providing audit and certification of management systems (ISO/IEC Guide 65:1996) (Ref. 9) in sections III. to XIII., because that standard has been withdrawn and replaced by ISO/IEC 17065:2012 (Ref. 7) in September 2015. Comments referring to ISO/IEC 17020:2012, Conformity assessment—Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012) (Ref. 10) are outside the scope of this rulemaking, because that standard relates to inspections and not the auditing and certification activities that will be performed under this rule. Therefore, we are not responding to comments citing to ISO/IEC 17020:2012, Conformity assessment—Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012) (Ref. 10) in sections III. to XIII.

We also received several comments on the overarching issue of using private food safety schemes as audit criteria for regulatory audits conducted under the third-party certification program. Some comments suggest that FDA should rely on private food safety schemes, particularly those that have been benchmarked by the Global Food Safety Initiative (GFSI), as the audit criteria for regulatory audits of eligible entities under the third-party certification program. Other comments suggest that FDA should establish requirements for accreditation bodies and third-party certification bodies that are similar to those required by GFSI, such as GFSI requirements relating to accreditation under relevant ISO/IEC product certification or management system standards.

By way of background, a group of international retailers established GFSI in 2000 with the goal of reducing the need for duplicative third-party audits by benchmarking private food safety schemes against a harmonized set of

criteria for food safety and management systems (see 78 FR 45782 at 45788; July 29, 2013). Under current GFSI criteria, a food safety scheme must have a commitment with one or more accreditation bodies for certification bodies that operate in conformance with either the product certification standard, ISO/IEC Guide 65, or the management system standard, ISO/IEC 17021:2006 (supplemented by ISO/TS 22003). GFSI describes these standards as having similar requirements for how a certification body must operate—*e.g.*, in addressing issues of preventing conflict of interest, managing customer information, properly qualifying personnel, auditor calibration, and many other aspects involved with the certification process. However, as GFSI noted in a 2011 White Paper (Ref. 11), there is a distinct difference between the two. ISO 17021/ISO 22003 is not product specific. ISO/IEC Guide 65, on the other hand, is concerned with verifying that particular products or services meet specified requirements. The type and scope of GFSI benchmarked scheme selected, determines the accreditation standard which applies. The majority of GFSI recognized schemes fall under ISO/IEC Guide 65 accreditation requirements, whereas only two currently recognized schemes are management system schemes accredited to ISO 17021/ISO 22003.

Comments suggesting that we should rely on GFSI-benchmarked food safety schemes or other private food safety schemes as the criteria for certification under the third-party program are outside the scope of this rulemaking. This rule establishes the framework for the third-party certification program, and not the food safety standards that accredited third-party certification bodies will use to determine an eligible entity's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. We are however responding to relevant comments that address audit quality and auditor competency, consistency, and capacity, including comments referencing GFSI's work in these areas.

Other overarching comments ask how the FSMA third-party certification program relates to the roles of foreign competent authorities and to FDA's international activities. Some comments assert that competent authorities should be allowed to participate in the third-party certification program purely by administrative procedures without a formal review process. Other comments suggest that government agencies with both regulatory and trade promotion

missions face inherent conflicts of interest.

Some comments recommend that we should establish a different structure for accrediting third-party certification bodies that already have been approved by a foreign government accreditation body. Other comments suggest that FDA should reserve the role of accreditation body or third-party certification body for a national competent authority that requests it. The comments argue that the responsibility for monitoring the safety of food exports should remain with the national competent authorities in each country.

Some comments ask whether a national competent authority has a role in auditing and certification activities occurring in the country, including in countries where an FDA foreign office is located. Other comments ask whether the competent authority may perform other activities in the third-party certification program, such as authentication of audit information before it is submitted to FDA. Still other comments suggest that FDA require accredited third-party certification bodies to review correspondence between an audited eligible entity and the competent authorities in the country where the eligible entity is located.

Section 808 of the FD&C Act expressly provides for both public and private accredited third-party certification bodies. Public accreditation bodies and third-party certification bodies, as well as private accreditation bodies and third-party certification bodies that meet the eligibility requirements for recognition and accreditation under section 808 of the FD&C Act and this rule are equally eligible to participate in the third-party certification program. This includes government accreditation bodies and certification bodies in countries where FDA has a foreign office, as well as government agencies with the dual missions of food safety and trade promotion. We believe that both public and private third-party certification bodies and accreditation bodies are capable of exhibiting the competency, capacity, and impartiality necessary to meet the letter and spirit of the law and this regulation.

By becoming an accredited third-party certification body or a recognized accreditation body, a competent authority for food safety or a foreign accreditation body would establish a role in the third-party certification program. Only if competent authorities are accredited under this rule, may they issue food and facility certifications under section 808 of the FD&C Act. (We note, however, that FDA may require

certifications from competent authorities under section 801(q) of the FD&C Act for foods that FDA determines meet the criteria set forth in that section (see 801(q)(3)(A) of the FD&C Act), regardless of whether the competent authorities are accredited.) We acknowledge that the third-party certification program that is the subject of this rule is narrowly tailored and only a small piece of the much larger modernized, prevention-oriented food safety system we are establishing under FSMA. Broader FSMA activities are outside the scope of this rulemaking, as are matters covered by FDA's information sharing arrangements with foreign competent authorities.

We received other comments on the overarching issue of how the third-party certification program fits into FDA's international activities. Some comments assert that, for countries with a systems recognition agreement with FDA, there should be no need for a (direct or indirect) role for FDA in monitoring accredited third-party certification bodies. Other comments encourage us to recognize their national food safety system as equivalent to that of the United States.

The systems recognition initiative is a food safety regulatory cooperation program that allows FDA to take into account the role of food safety systems of exporting countries in our risk-based decisionmaking. We are using systems recognition as a tool to determine when we can rely on the implementation of science-based food safety programs by foreign regulatory authorities and take action based on information provided by such authorities.

We note that a competent authority with whom FDA has a systems recognition agreement must apply for recognition to make accreditation decisions and apply for accreditation to issue certifications under section 808 of the FD&C Act. If the competent authority applies for recognition or direct accreditation by FDA (assuming that the statutory criteria have been met for FDA to begin direct accreditation), FDA's review will be informed by the data, experiences, and insights into the foreign system that FDA gained through the systems recognition review. Except as described above, systems recognition activities are outside the scope of this rulemaking, as are equivalency determinations.

We also received several overarching comments noting that the lack of qualified food safety auditors is a problem in many countries. Some comments suggest that we may face similar problems with the availability of accredited third-party certification

bodies in our program. The comments assert that we should prioritize the review of applications from foreign countries with significant volumes of exports to the United States because of the cost and inconvenience to foreign suppliers and the likely trade disruption that would result if the only accredited third-party certification bodies were located in other countries. Some comments predict that rapid expansion in the field of food safety auditing may result in shortcuts in auditing. Other comments contend that because of the limited availability of qualified auditors we should adjust the timeframes for accredited third-party certification bodies to submit information to FDA under the regulations. The comments specifically request that we lengthen the 45-day timeframe for submitting regulatory audit reports.

We acknowledge the concerns about cost, inconvenience, and disruption resulting from auditor capacity issues. We are encouraging broad program participation to minimize the likelihood that capacity issues might emerge, because certifications issued by accredited third-party certification bodies under this program are intended to facilitate trade. The certifications are used in meeting the eligibility requirements of VQIP for expedited entry of food under section 806 of the FD&C Act and in satisfying a condition of admissibility for a food subject to an FDA determination under section 801(q) of the FD&C Act.

Revisions have been made to this rule made in response to comments, such as allowing accreditation bodies and third-party certification bodies to use documentation of their conformance with ISO/IEC standards in support of their applications. We also are modifying our “first in, first out” approach to processing applications, as comments request, to allow for prioritizing specific applications and requests based on program needs. We are unable to accommodate the request to lengthen the timeframe for submission of regulatory audit reports to FDA, because the 45-day deadline for submission is established in section 808(c)(3)(A) of the FD&C Act. Audit protocols and other requirements of the rule are designed to prevent audit agents (auditors) and third-party certification bodies from taking shortcuts that would jeopardize audit results.

Some comments addressed the Model Accreditation Standards that FDA is required to develop under section 808(b)(2) of the FD&C Act for use in qualifying third-party certification bodies for accreditation. Some of these comments suggest various criteria to be

included in the model standards. Other comments suggest the proposed rule was ambiguous with respect to the form of, and manner by which, FDA will establish the Model Accreditation Standards.

While the substance of the Model Accreditation Standards is outside the scope of this rulemaking, we note that on July 24, 2015, FDA published a draft guidance on Model Accreditation Standards. The draft guidance can be accessed at: <http://www.fda.gov/Food/GuidanceRegulation/Guidance/ucm455328.htm>. Additionally, a notice was published in the **Federal Register** (80 FR 44137, July 24, 2015) of the availability of the draft guidance and of the opening of a docket for public comments on the document. As explained in the draft guidance, section 808(b)(2) of the FD&C Act requires FDA to develop Model Accreditation Standards that recognized accreditation bodies shall use to qualify third-party certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. The draft guidance contains FDA recommendations on third-party certification body qualifications, including recommendations based on relevant provisions in the proposed rule. This final rule will serve as a framework for the Model Accreditation Standards final guidance, which will include more detailed recommendations on third-party certification body qualifications.

Some comments respond to our request for input on the question about the value of, and possible need for, FDA to establish a program for use of accredited third-party certification bodies to conduct domestic food safety audits (78 FR 45782 at 45823). We received comments on all sides, expressing various views. We are taking these comments under advisement at this time, as the focus of this final rule is on establishing and implementing the third-party certification program set forth in section 808 of the FD&C Act.

Other comments addressed the substance of VQIP, import certification, laboratory accreditation, and provisions in the proposed FSVP rule and/or other FSMA rules that are outside the scope of this rulemaking; accordingly we will not be responding to those comments here. Other comments that fall outside the scope of this rulemaking, and to which we will therefore not be responding, include comments on the value of a universal, mandatory food safety system; comments advocating for

policies promoting locally grown produce; comments addressing the information technology infrastructure needs of the third-party certification program; comments suggesting the value of student interns to the food safety system; and comments on factors beyond the use of third-party audits that FDA should consider in setting inspection priorities.

We also received a few comments concerning the rulemaking process. Comments suggest that we devise a new process for regularly updating the rule; they state that FDA has cumbersome requirements for modifying rules. FDA's current rulemaking process is consistent with FDA's obligations under the Administrative Procedure Act (5 U.S.C. 551–559).

II. Legal Authority

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name. Section 808(b)(1)(A) of the FD&C Act requires us to establish a system, within 2 years of the enactment of FSMA, for the recognition of accreditation bodies that accredit third-party certification bodies to conduct food safety audits and to issue certifications for eligible foreign food entities and their products for purposes of sections 801(q) and 806 of the FD&C Act.

Section 808(c)(5)(C) of the FD&C Act directs us to issue implementing regulations for section 808 of the FD&C Act. The regulations must require audits to be unannounced and must contain protections against conflicts of interest between accredited third-party certification bodies (and their audit agents) and the entities they audit or certify, including requirements on timing and public disclosure of fees and appropriate limits on financial affiliations (21 U.S.C. 384d(c)(5)(C)(i), (ii), and (iii)).

This final rule establishes regulations implementing section 808 of the FD&C Act. The authority for the requirements in this rule comes primarily from section 808 of the FD&C Act. However, FDA also derives authority for this final rule from other sections of the FD&C Act, including section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which authorizes us to issue regulations for the efficient enforcement of the FD&C Act. The regulations in this final rule ensure the competency and independence of recognized accreditation bodies and of accredited third-party certification bodies, which will help ensure the validity and reliability of certifications and other information resulting from the food safety audits conducted by

accredited third-party certification bodies. These features of the final rule are essential to the operation of the third-party program. This rule also is consistent with section 404 of FSMA (21 U.S.C. 2252), which states that nothing in FSMA should be construed in a manner that is inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

This rule establishes requirements for accreditation bodies and third-party certification bodies seeking recognition and accreditation, respectively. These requirements will help ensure that any accreditation bodies that we recognize, and any certification bodies that are accredited, are capable of meeting all of the requirements of this program. This includes requirements, for example, for legal authority and competency and capacity. It also includes provisions for the direct accreditation of third-party certification bodies by FDA in accordance with section 808(b)(1)(A)(ii) of the FD&C Act. This rule also establishes requirements for accreditation bodies that have been recognized, and third-party certification bodies that have been accredited. This includes requirements designed to decrease the potential for conflicts of interest in accordance with section 808(c)(5)(C)(ii) of the FD&C Act. Additionally, this rule establishes requirements for eligible entities that want to be certified under this program. This includes requirements for onsite audits by FDA for the purpose of monitoring in accordance with section 808(f)(3) of the FD&C Act. Finally, this rule establishes general requirements related to the operation of this program. These include requirements for requesting a regulatory hearing on revocation of recognition or withdrawal of accreditation.

Some of the requirements under this final rule are also established, in part, under the authority in sections 806 and 801(q) of the FD&C Act. Section 806 of the FD&C Act describes a voluntary program to provide for the expedited review and importation of food offered for importation from certified facilities (VQIP). Section 801(q) of the FD&C Act gives FDA authority to require certifications for imported food in certain situations. This final rule does not set up the framework for participation in the program described under section 806 of the FD&C Act, nor does it describe the circumstances under which FDA might require certification under section 801(q) of the FD&C Act. However, this rule does describe circumstances under which

FDA might refuse to consider a certification issued under this program in determining the admissibility of an article of food for which the certification was offered under section 801(q) of the FD&C Act, or in determining eligibility for participation in VQIP under section 806 of the FD&C Act. Additionally, this rule creates limited exemptions from the certification requirements of section 801(q) of the FD&C Act for certain alcoholic beverages, including certain raw materials and ingredients that are used to manufacture/process alcoholic beverages. The exemptions are being promulgated consistent with section 116 of FSMA (21 U.S.C. 2206). Section 116(a) of FSMA states that, except as provided by certain listed sections in FSMA, nothing in FSMA, or the amendments made by FSMA, will be construed to apply to a facility that: (1) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States and (2) under section 415 of the FD&C Act (21 U.S.C. 350d) is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages (with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages). This rule also creates exemptions from the certification requirements of section 801(q) of the FD&C Act for products subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) at the time of importation. We conclude that this provision is consistent with section 403 of FSMA, entitled "Rule of Construction," which states that nothing in FSMA shall be construed to alter or limit the jurisdiction of the Secretary of the Department of Agriculture.

III. Comments on What Definitions Apply to This Subpart (§ 1.600)

We proposed to codify definitions of several terms used in the third-party certification regulations. We received several comments on this section. As discussed in the following paragraphs, we have revised many of the proposed definitions in response to comments as well as on our own initiative. Where we disagree with comments or decline a

suggested revision, we offer an explanation in response. Some definitions were finalized as proposed.

The definitions for terms used in the third-party certification regulations are codified in 21 CFR 1.600.

A. Definitions, Generally

(Comment 1) Several comments encourage us to more closely align the definitions in § 1.600 with international standards to promote consistency and common understanding of the rule. The comments explain that the terms and definitions used in section 808 of the FD&C Act and in the proposed rule convey a different meaning for accreditation bodies, certification bodies, and the standards community. To that end, some comments encourage us to avoid using the term "third-party auditor" synonymously with "certification body," to be consistent with international standards, which use the term "certification body" (*e.g.*, ISO/IEC 17065:2012 (Ref.7)).

Similarly, some comments indicate that, the language of the statute notwithstanding, it is not correct to use the term "third-party auditor" when describing the activities of a "third-party certification body." The comments explain that auditors are individuals contracted or employed by certification bodies to conduct audits, and they urge us to clarify the rule by substituting "certification body" for "third-party auditor."

(Response 1) We agree that alignment with the terminology used in international standards is preferable, wherever possible. Congress recognized the value of international standards in accreditation and certification, having instructed us in section 808(b)(2) of the FD&C Act to look to existing standards in developing our model accreditation standards to avoid unnecessary duplication of efforts and costs. We believe it is particularly useful to rely on definitions and terminology from international consensus standards when possible where, as here, the rule is establishing a voluntary program with an international focus. In addition, we agree that, notwithstanding the use of the term "third-party auditor" in the statute, the use of the term "third-party certification body" instead of the term "third-party auditor" provides some clarity for purposes of referring to bodies that employ or contract individuals to perform audits.

Therefore, in response to the comments suggesting the term "third-party auditor" is confusing and inconsistent with international standards, we are using the term "third-party certification body" in the

remainder of the preamble and in the codified of this final rule, except in the definitions of “Accredited third-party certification body” and “Third-party certification body” in § 1.600(c) and in the preamble discussion of those definitions.

On our own initiative, we are including the descriptor “third-party” before “certification body” throughout this final rule. We did not use that descriptor in the proposed rule when referring to a third-party auditor/certification body once accredited. We are doing so now in order that the term accurately reflects that, under this subpart, only third-party certification bodies are eligible for accreditation. We are making corresponding changes to the term “accredited auditor/certification body;” and in this final rule we will instead use the term, “accredited third-party certification body.”

Accordingly, we have revised the proposed definitions of “accreditation,” “accreditation body,” “accredited auditor/certification body,” “audit,” “audit agent,” “certification body,” “direct accreditation,” “eligible entity,” “facility certification,” “food certification,” “recognized accreditation body,” “relinquishment,” and “self-assessment,” to replace the term “third-party auditor” with the term “third-party certification body,” or “third-party certification bodies,” and to remove “auditor/” from in the term “third-party auditor/certification body” or “third-party auditors/certification bodies” that was used in the proposed rule.

On our own initiative, we added a sentence to the definition of “accredited third-party certification body” in § 1.600 of this final rule to explain that the term has the same meaning as “accredited third-party auditor” as defined in section 808(a)(4) of the FD&C Act. Similarly, we added language to the definition of “third-party certification body” in § 1.600 of this final rule explaining that the term has the same meaning as “third-party auditor” as defined in section 808(a)(3) of the FD&C Act.

(Comment 2) Some comments encourage us to make the definitions in this rule consistent with the definitions in other FSMA proposed rules, such as the 2013 proposed FSVP regulation, the 2013 proposed human preventive controls regulation, the 2013 proposed animal preventive controls regulation, and the 2012 proposed produce safety regulation, where feasible.

(Response 2) We agree with the comments on the overarching goal of alignment across regulations and accepted suggested revisions, where

feasible and appropriate. However, it is not always possible to develop uniform definitions due to the distinct statutory requirements and the framework of each program. In such cases where it was not feasible or appropriate, we declined the suggested revisions from comments. We discuss such comments and our responses under each relevant term.

B. Assessment

We did not define “assessment” in the proposed rule.

(Comment 3) Some comments recommend adding a definition of “assessment” based on ISO/IEC 17011:2004 (Ref. 5), clause 3.7, which describes the process for evaluating certification bodies. The comments explain that defining such evaluations as “audits,” as we had proposed, is inconsistent with international standards. The comments suggest consulting with other ISO/IEC standards for relevant terminology.

(Response 3) We agree that the term “assessment” should be used, in part, to refer to the activity undertaken to assess the competency and capacity of a third-party certification body under the rule. We reviewed ISO/IEC 17011:2004 (Ref. 5) (clause 3.7 and NOTE) and ISO/IEC 17000:2004 (Ref. 4), ISO/IEC 17040:2005 Conformity assessment—General requirements for peer assessment of conformity assessment bodies and accreditation bodies (ISO/IEC 17040:2005) (Ref. 12), and an International Accreditation Forum (IAF) document entitled, “IAF Endorsed Normative Documents” (Ref. 13).

After considering the comments and reviewing the referenced documents, we developed a definition of “assessment” that describes, with respect to accreditation bodies, the activity undertaken by FDA to evaluate the competency and capacity of the accreditation body under the applicable requirements of this rule. With respect to certification bodies, “assessment” describes the activity undertaken by a recognized accreditation body (or, in the case of direct accreditation, FDA) to evaluate the competency and capacity of a certification body under the applicable requirements of this rule. We also made corresponding changes to the definition of “audit” from proposed § 1.600(c) by removing clauses (1) and (2).

C. Audit

We proposed a definition of “audit” describing the examination of accreditation bodies, third-party certification bodies, and eligible entities. We proposed to define an audit of an accreditation body as an examination by FDA of the accreditation

body’s authority, qualifications, resources, policies, procedures, and performance, as well as of its capability to meet the requirements of the proposed rule. We proposed to define an audit of a third-party certification body as an examination by a recognized accreditation body (or, by FDA, for direct accreditation) of the third-party certification body’s authority, qualifications, resources, policies, procedures, and performance, as well as of its capability to meet the requirements of the proposed rule. We proposed to define an eligible entity as an examination by an accredited third-party certification body of the eligible entity to assess the entity, its facility, system(s), and food using audit criteria for consultative or regulatory audits, and, for consultative audits, also including an assessment of compliance with applicable industry standards and practices.

We received some comments on the proposed definition of “audit,” and the related definitions of “consultative audit” and “regulatory audit.” Comments specific to the definition of “consultative audit” are discussed in section III.E., and comments on the definition of “regulatory audit” are discussed in section III.L. As described in Response 3, we also removed clauses (1) and (2) from the proposed definition of “audit” because those evaluations are “assessments” as the term is defined in § 1.600(c).

On our own initiative, we are revising the definition of “audit” to clarify that an audit conducted under this subpart is not an inspection under section 704 of the FD&C Act (21 U.S.C. 374).

(Comment 4) Several comments encourage us to align our definition of audit with relevant international standards, and some comments request that we use the definition of “audit” from the Codex “Principles for Food Import and Export Inspection and Certification” (CAC/GL 20–1995) (Ref. 14), which defines “audit” as a “systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.”

(Response 4) We agree with the general principle of creating consistency with international standards and have revised the definition of “audit” in § 1.600(c) accordingly. Rather than describing the determination of whether activities comply with “planned objectives” that appears in the Codex definition of “audit” (Ref. 14), we inserted a brief description of the objectives of consultative and regulatory audits from the definitions in section 808(a)(5) and (7) of the FD&C Act (*i.e.*,

the examination of an eligible entity under this rule).

(Comment 5) Some comments encourage us to remove the proposed definition of “audit” in § 1.600(c) and substitute the FSVP definition of “audit” instead, to promote consistency and a common understanding of terminology.

(Response 5) We disagree. We believe that it is more important for the definition in this rule to reflect international standards that are generally well known to the parties subject to this rule than it is for the definition to mirror the definition in FSVP, which has different applicability. FSVP applies to importers; this rule applies to accreditation bodies, third-party certification bodies, and eligible entities. Therefore, we are rejecting the suggestion to use the FSVP definition of “audit” as the definition of “audit” in § 1.600(c).

(Comment 6) We received some comments on the definition of “audit” regarding its relationship to the related definitions of “consultative audit” and “regulatory audit” in § 1.600(c). Some comments recommend that we revise the definition of “audit” to mean only regulatory audits, and not consultative audits, asserting that is how the word “audit” is used in the statute. These comments contend that the statute must be interpreted in light of the fact that section 808 of the FD&C Act is directed to food and facility certifications, which are only accomplished through regulatory audits. Other comments ask us to clarify that the services of an accredited third-party certification body that fall short of the definition of an “audit” (e.g., informal consulting, continuous improvement programs, and limited purpose audits) under this rule, are not subject to the requirements of the rule.

(Response 6) We decline the suggestion to interpret section 808 of the FD&C Act in a manner that would equate “audit” with “regulatory audit.” Section 808 of the FD&C Act defines two types of audits used under the program, consultative audits and regulatory audits, and contains requirements relating to each. (See, e.g., section 808(a)(5), (7), and (c)(3)(A) of the FD&C Act). In addition, section 808(c)(4)(B) of the FD&C Act expressly allows an accredited third-party certification body or an audit agent of such auditor to perform consultative and regulatory audits of eligible entities.

To the extent that other comments suggest creating a list of exceptions from the definition of “audit” in the codified for this rule, we decline to do so. To the extent that these comments were

seeking clarification of the definition of “consultative audit” in § 1.600(c), and what types of activities might fall outside of that definition as well as outside of this program, please see the discussion in Response 9 in section III.E.

(Comment 7) Some comments express confusion about the criteria that accredited third-party certification bodies will be using in conducting audits under subpart M and ask us to more clearly describe the “applicable requirements” against which compliance will be evaluated. Some comments are concerned that eligible entities might be audited against requirements that do not apply to their operations. For example, some comments note that firms subject to the final animal preventive controls regulation should not be assessed for compliance with the allergen cross contamination requirements of the final human preventive controls regulation. Other comments ask us to clarify whether the “applicable requirements” are limited to requirements that appear in the FD&C Act or FDA regulations, or both.

(Response 7) During regulatory and consultative audits, accredited third-party certification bodies will examine compliance with applicable food safety requirements of the FD&C Act and FDA regulations within the scope of the audit. In consultative audits, the third-party certification bodies also may be conducting an examination to determine conformance with applicable industry standards and practices.

The applicable requirements that accredited third-party certification bodies and their audit agents will use relate to the food safety standards under the FD&C Act, such as the adulterated food provisions in section 402 of the FD&C Act and the provisions on the misbranding of food allergens in section 403(w) of the FD&C Act. The applicable requirements of the FD&C Act and FDA regulations would depend on the type of eligible entity being audited. To use the example given by one of the comments, an eligible entity that is subject to the requirements of the final animal preventive controls regulation, but not the final human preventive controls regulation, would not be subject to an audit examining its practices relating to cross-contamination by food allergens under the final human preventive controls regulation because those are not “applicable food safety requirements” for such an entity.

To help clarify this rule for eligible entities, third-party certification bodies, and accreditation bodies who may be interested in participating in the

program and who may not yet be familiar with U.S. laws and regulations, we are using the phrase “applicable food safety requirements of the FD&C Act and FDA regulations” in place of the phrase “applicable requirements” in the definition of “audit” in § 1.600(c) and elsewhere throughout the rule where we are discussing the requirements that will be used in auditing eligible entities.²

D. Audit Agent

We proposed to define an “audit agent” as an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. Under the proposed rule we also defined an audit agent to include a contractor of the accredited third-party certification body.

(Comment 8) Some comments express concern about our proposal to allow a contractor of an accredited third-party certification body to serve as an audit agent, asserting that “[w]ith each step that is further removed in this process, institutional control is lost exponentially.” The comments point out that a subcontractor conducted the audit and gave a passing audit score to a cantaloupe farm and packing facility that used “improper and unsafe processing equipment” and subsequently was linked to a deadly outbreak caused by *Listeria monocytogenes*. Other comments mentioning the incident cite to an article in Bloomberg News explaining that auditors often outsource to independent contractors over whom they do not have direct management control (Ref. 15). Still other comments offer the cantaloupe outbreak as an example of why auditors must be competent and accountable for their activities.

(Response 8) We understand that third-party certification bodies currently work with individual auditors under many different types of arrangements. We acknowledge concerns raised by comments about recent outbreaks at some domestic facilities that had received satisfactory scores in food safety audits. Further, we agree with the comments on the importance of an accredited third-party certification body exercising adequate control over an audit agent conducting audits on its

² Although we have elected to cite to both the FD&C Act and FDA regulations in this definition, we otherwise will follow the conventional practice of using the words “applicable requirements” to refer to the applicable requirements of the FD&C Act and FDA regulations.

behalf. We believe that principle is equally true whether the audit agent is an employee or a contract auditor.

International standards, such as ISO/IEC 17021:2011 (Ref. 6), specifically allow accredited third-party certification bodies to use contractors to perform audits if certain conditions are met. Among other conditions, contract auditors must meet the same level of qualifications (*e.g.*, knowledge, skills, and experience) and the same requirements for impartiality and objectivity as do the auditors the third-party certification body employs. The third-party certification body must exercise adequate control and oversight over a contractor such that the third-party certification body accepts the result of the contractor's audit as its own.

When we proposed to define "audit agent" to include a contractor, we were contemplating arrangements such as those described in ISO/IEC 17021:2011 (Ref. 6) that involve a direct relationship between the accredited third-party certification body and its auditors. We are revising the definition of "audit agent" to clarify that we are excluding subcontractors and other types of outsourcing arrangements; we have concluded that such arrangements fail to provide the degree of control and oversight necessary for an accredited third-party certification body to ensure that its audit agents are competent and objective. An accredited third-party certification body exercises direct supervision over the activities of its employees, and has a direct relationship with a contractor; but the relationship between the third-party certification body and a subcontractor or other type of outsourced staff is attenuated—the third-party certification body may not even choose such persons and may not have any direct authority over them. We do not believe such diminished oversight is appropriate, given the important role of audit agents in this program.

By revising the definition of "audit agent" we are not preventing an accredited third-party certification body from subcontracting for services in areas other than the conduct of audits. For example, an accredited third-party certification body may use subcontractors or other outsourcing arrangements to deliver annual training to its audit agents under § 1.650 or may use subcontractors or other outsourcing arrangements to investigate and decide on appeals of adverse regulatory audit results under § 1.651. However, we are limiting the role of "audit agent" to employees and contractors of the

accredited third-party certification body.

E. Consultative Audit

We proposed to define a "consultative audit" as an audit of an eligible entity: (1) To determine whether such entity is in compliance with applicable requirements of the FD&C Act and industry standards and practices and (2) the results of which are for internal purposes only and cannot be used to determine eligibility for a food or facility certification issued under this subpart or in meeting the requirements for an onsite audit of a foreign supplier under subpart L of this part.

(Comment 9) We received several comments on the definition of "consultative audit." Many comments express concern that the definition of "consultative audit" is overly broad and that some of the requirements that would apply to consultative audits under the proposed rule might create a disincentive to using accredited third-party certification bodies. Some comments urge FDA to remove all requirements associated with consultative audits from the rule. Other comments identify two requirements of particular concern: (1) Proposed § 1.656, requiring an accredited third-party certification body conducting a consultative audit or regulatory audit under the rule to notify FDA immediately upon discovering a condition that could cause or contribute to a serious risk to public health (the notification requirement) and (2) proposed § 1.652, requiring an accredited third-party certification body to provide FDA access to a consultative audit report when the criteria for records access under section 414 of the FD&C Act (21 U.S.C. 350c) are met (the records access requirement). The comments explain that many firms use certification bodies (and/or their consulting divisions) to help establish, maintain, and improve their food safety practices. For example, some firms use certification bodies (and/or their consulting divisions) to help in identifying root causes and remediating food safety problems. Comments also note that certification bodies (and/or their consulting divisions) provide informal counseling, perform preliminary evaluations, limited purpose audits, and activities in support of firms' continuous improvement programs.

Comments express concern that if these types of activities are subject to notification, records access, and other requirements of the rule, firms located outside the United States might not use accredited third-party certification

bodies, instead choosing unaccredited third-party certification bodies to avoid the requirements of this rule. The comments assert that unaccredited third-party certification bodies are less likely to have qualified auditors and their independence and objectivity is less certain, than third-party certification bodies that have been evaluated and issued accreditation.

Comments also argue that the definition of "consultative audit," which states that the results of such an audit are "for internal purposes only," is inconsistent with the requirements for notification and records access that would apply to consultative audits under the proposed rule. Other comments ask us to clarify that audits conducted for external purposes—for example, an audit for purposes of compliance with FSVP—do not satisfy the definition of a consultative audit because consultative audits are for internal purposes only.

Some comments suggest that the proposed definition of "consultative audit," taken together with the proposed definitions of "food safety audit" and "regulatory audit," could preclude third-party certification bodies from conducting any audits that are outside the scope of subpart M, once accredited. Based on that interpretation, the comments predict that few if any third-party certification bodies would want to participate in the program.

Many of the comments that express concern about disincentives also suggest that Congress intended the third-party program to be much narrower than our proposed definition of "consultative audit" would suggest. These comments suggest that the FSMA third-party certification program was intended to be focused on regulatory audits and the issuance of certifications to be used for two limited purposes: *i.e.*, in establishing an importer's eligibility for VQIP and in satisfying a condition of admissibility for a food subject to an FDA safety determination under section 801(q) of the FD&C Act. These comments argue further that Congress inserted the term "consultative audit" in the statute to be used only in reference to the conflicts of interest provisions in section 808(c)(4)(C) and (c)(5) of the FD&C Act; therefore, a broad interpretation of "consultative audit" is inconsistent with Congressional intent. The comments urge us to construe the term "consultative audit" as narrowly as possible.

(Response 9) We recognize that food firms use accredited third-party certification bodies (and their consulting divisions) in various

capacities that serve the ultimate goal of improving food safety. We do not want, nor do we believe Congress intended, for our third-party certification program to create disincentives for food firms seeking to use accredited third-party certification bodies for various purposes to improve food safety practices in their operations. Nevertheless, we decline the request to remove all requirements relating to consultative audits from this final rule. Section 808(c)(5)(C) of the FD&C Act directs us to issue implementing regulations for section 808 of the FD&C Act, which includes some specific provisions relating to consultative audits (e.g., section 808(c)(3)(A) and (C) on consultative audit reports and section 808 (c)(4)(C) of the FD&C Act on audit agents performing regulatory audits of eligible entities of which they performed consultative or regulatory audits within the preceding 13 months). We have, however, revised the definition of “consultative audit” as explained below and have made other revisions to the rule to clarify the scope of such audits and help mitigate possible disincentives to conduct consultative audits, while fulfilling the letter and spirit of the law.

With regard to the comments expressing concerns about an overly broad interpretation of “consultative audit,” we remind readers that the statute endows both regulatory and consultative audits with certain characteristics. For example, section 808(a)(6) of the FD&C Act indicates that an eligible entity must choose to be audited by an accredited third-party certification body, and section 808(c)(5)(C)(i) of the FD&C Act states that audits under this program must be unannounced. We understand these provisions to mean that, at the time the audit services are arranged, an eligible entity must specifically request from an accredited third-party certification body a food safety audit under this rule—that is the only way the accredited third-party certification body would know that the eligible entity is requesting an unannounced subpart M audit to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. Further, the eligible entity would need to specify whether it is seeking a regulatory or consultative audit. (In addition to determining whether the eligible entity is in compliance with the food safety requirements of the FD&C Act, consultative audits under section 808 of the FD&C Act also determine whether the eligible entity is in compliance with applicable industry standards and practices). Audits that fall

outside the purview of this rule—for example, audits that are conducted by third-party certification bodies that are not accredited under this program, audits that determine compliance with standards other than the food safety requirements of the FD&C Act and FDA regulations (e.g., audits that determine compliance with private standards), audits that are announced, and audits conducted solely for the purposes of supplier verification under the final human or animal preventive controls regulations or the final FSVP regulations—are not covered by, or subject to, the requirements of this rule.

It is impossible to describe or predict all of the audit scenarios that may occur. We emphasize that an accredited third-party certification body can continue to offer auditing and certification services that are outside the scope of this rule, such as on-site supplier verification audits under the final human or animal food preventive controls regulations or the final FSVP regulation. Such audits would not be subject to the requirements of this rule, including the reporting and notification requirements.

In response to comments, we revised the proposed definition of “consultative audit” to clarify that it is an audit conducted in preparation for a regulatory audit under the third-party certification program. A consultative audit would thus be a pre-examination or pre-assessment type of activity imbued with certain characteristics. We further clarify the characteristics of a consultative audit, as well as of a regulatory audit (the results of which can form the basis for issuance of certification under the rule), in the definition of “food safety audit” discussed in section III.J.

F. Eligible Entity

We proposed to define an “eligible entity” as a foreign entity that chooses to be subject to a food safety audit by an accredited third-party certification body. We further proposed that eligible entities include foreign facilities subject to the registration requirements in FDA regulations.

(Comment 10) We received several comments on the definition of “eligible entity.” Some comments request that we provide examples of specific types of entities that satisfy the definition. Some comments offer examples of “eligible entities,” including orchards or farms, packing houses, processing plants, and storage facilities. Other comments suggest we add “and foreign farms” to the end of the definition, to clarify that such entities are eligible to receive audits under subpart M. Some comments encourage us to adjust the

definition of “eligible entity” to make it mandatory for foreign food facilities to undergo food safety audits by accredited third-party certification bodies.

(Response 10) The proposed definition of “eligible entity” was based on the statutory definition, which includes facilities subject to the registration requirements in section 415 of the FD&C Act that choose to be audited under the program. At our own initiative we are revising the definition of “eligible entity” in the codified to more accurately track the statute, and we decline the suggestion to add specific examples, such as orchards or farms, that are not included in the statutory definition of “eligible entity.” However, as explained in Response 12 we are revising the definition of “facility” in § 1.600(c) to clarify that entities that grow, harvest, or raise animals for food for consumption in the United States are facilities that are eligible for auditing and certification under this subpart.

We disagree with the comment suggesting that we should make audits under this program mandatory for all foreign food firms by modifying the definition of “eligible entity.” The statute clearly indicates that participation in this program is intended to be voluntary, and only entities that choose to be audited under the program are subject to its requirements (see section 808(a)(6) of the FD&C Act).

(Comment 11) In the proposed rule, we specifically asked for comment on whether to allow for food or facility certification to be issued to a producer group, offering as an example the criteria for groups under the National Organic Program (NOP)—*i.e.*, having multiple sites operating under a single management system and whose farms are “uniform in most ways.” Several comments responded to this inquiry in relation to the definition of “eligible entity.”

Comments in support of certification of a group (e.g., a cooperative being audited as a single eligible entity) note that some producers are very small and might find it difficult on their own to obtain third-party certification, but taken as a group the task would likely be more manageable. Other comments note that treating multiples sites with a single management system as a single eligible entity could be particularly helpful in sectors or regions where there is a scarcity of accredited third-party certification bodies. Some comments argue in support of groups functioning as a single eligible entity as long as the central management system functions effectively, providing oversight to the

members. Comments also note that some multisite sampling protocols have been developed by international organizations, such as ISO.

Other comments encourage us to ensure that cooperatives are subject to this rule, so that all the links in a foreign supply chain are appropriately inspected, and so that they are subject to any applicable regulations before their product is exported to the United States.

Comments not in support of cooperatives being classified as eligible entities note that food safety practices and conditions are site-specific and can vary significantly even if the individual farms are located in the same geographic area (for example, due to soil composition, agricultural water runoff, or the manner in which the land was used in the past). They also note that organic production standards and scientifically-based food safety standards are not the same, so what works for the NOP may not be appropriate here.

Some comments encourage us to provide guidance on the acceptable parameters of a cooperative. Some comments encourage us to consider guidance available from other sources beyond the NOP, such as the International Federation of Organic Agriculture Movements.

(Response 11) We decline to revise the definition of eligible entities to include a group. We acknowledge that some very small producers might be daunted by the prospect of working individually with an accredited third-party certification body, and there would be obvious economies in banding together with other very small producers to gain certification. We also acknowledge that some sets of producers do currently function as a unit under a centralized management system, and that group certification may make it easier for entities to access accredited third-party certification bodies in areas or regions where they may be scarce. Nevertheless, after reviewing the NOP, the International Federation of Organic Agricultural Movements, the Canada Organic Office Operation Manual, the USDA Agricultural Marketing Service pilot program on group certification, and other recommended sources, we conclude that it would not be appropriate to allow groups to be certified under this program. Group certification raises a myriad of complicated issues such as establishing who may act as a group, determining the requisites of a central management system, and delineating the minimum

requirements for accredited third-party certification body audits of a group.

With regard to the comments contending that certifications from individual eligible entities that might otherwise act as a group would create redundant and unnecessary paperwork for FDA, we will take that sort of information into account as we gain experience with the program. Finally, with regard to the comments encouraging us to define “eligible entity” to include groups to ensure that all their members are examined for compliance with applicable food safety regulations before their food is exported to the United States, we note that this rule does not create audit obligations for all foreign suppliers or for all importers. The third-party certification program created by this rule is a voluntary program for eligible entities who wish to participate.

G. Facility

We proposed to define “facility” as any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, which manufactures/ processes, packs, or holds food for consumption in the United States. The definition went on to state that: (1) Transport vehicles are not facilities if they hold food only in the usual course of business as carriers; (2) a facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership; (3) the private residence of an individual is not a facility; and (4) non-bottled water drinking water collection and distribution establishments and their structures are not facilities.

On our own initiative, we are clarifying that facilities for the purposes of this subpart are not limited to facilities required to be registered under Subpart H.

(Comment 12) Some comments encourage us to align the proposed definition of “facility” to the definition of “facility” in the human and animal preventive controls, produce safety, and FSVP regulations, to promote consistency and common understanding of the rules.

(Response 12) As previously noted, we agree with the comments on the importance of consistency across regulations, where feasible and appropriate. We reviewed the definitions of “facility” in the final FSVP and final human preventive controls regulations, and found those definitions to be too narrow in light of

the purpose of this rule to establish a voluntary program for certification of foods and facilities and the broad definition of “eligible entity” in section 808(a)(6) of the FD&C Act. Of our own initiative, in order to preserve the option for broad participation in the third-party program, we are expressly including in the definition of “facility” those entities that grow, harvest, or raise animals for food for consumption in the United States.

H. Facility Certification and Food Certification

We proposed to define “facility certification” as an attestation, issued for purposes of section 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish that a facility meets the applicable requirements of the FD&C Act. We proposed to define “food certification” as an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish that a food meets the applicable requirements of the FD&C Act.

(Comment 13) We received some comments on the definitions of “facility certification” and “food certification.” Some of these comments raise group certification issues which we address above, in connection with the definition of “foreign cooperative.” Some comments state that “food certification” is improper terminology, because it implies a product certification model, whereas audits of eligible entities—particularly in the produce sector—generally assess processes and/or management systems.

(Response 13) The term “food certification” appears in the statute and is specifically discussed in the statute as a type of certification that may be used in meeting a condition of admissibility under section 801(q) of the FD&C Act. Under section 808(c)(2)(C) of the FD&C Act, food certifications may only issue upon conduct of a regulatory audit. In light of the statutory language, we decline to revise the term “food certification” in response to the comments on this rule.

We also note that section 801(q)(1) of the FD&C Act allows for FDA to accept “a listing of certified facilities that manufacture, process, pack, or hold food, or other assurances deemed appropriate by FDA” to satisfy the condition of admissibility. Of our own initiative, in light of this statutory language, we are clarifying in the definition of “facility certification” that

a facility certification may be issued for purposes of 801(q) of the FD&C Act.

I. Food

In proposed § 1.600(b), we stated unless otherwise defined in § 1.600(c) of the proposed rule, definitions of terms in section 201 of the FD&C Act would apply to terms used in this subpart. Section 201 of the FD&C Act defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” Proposed § 1.600(c) did not define the term “food.”

(Comment 14) Some comments request that we define “food” consistent with how it was defined in the FSVP proposed rule for consistency and to indicate that producers of food contact substances are eligible entities.

(Response 14) The proposed definition of “food” under § 1.600 would include pesticides when they meet the definition of “food” under section 201 of the FD&C Act. By contrast, the FSVP rule’s proposed definition of food explicitly does not include pesticides, as defined in 7 U.S.C. 136(u), consistent with the definition of “food” used in the rulemaking on the Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Act of 2002 (prior notice rule). FDA received comments during that rulemaking questioning the applicability of the rule to pesticides, so FDA clarified that “food” for the purposes of that rule did not include pesticides.

The final FSVP regulation, which is publishing elsewhere in this issue of the **Federal Register**, retains the exclusion of pesticides from the definition of “food.”

In response to comments suggesting revision of the definition of “food” in this rule to be consistent with the final FSVP regulation, we considered the purposes that certifications serve under this program and the nature of comments we received on the third-party proposed rule, including general comments requesting alignment across the FSMA rules and comments specifically requesting that we use the FSVP definition of “food.” Certifications issued by accredited third-party certification bodies may be used in establishing an importer’s eligibility to participate in VQIP and in satisfying a condition of admissibility for an imported food that we determine poses a safety risk under section 801(q) of the FD&C Act.

While certifications may be useful in addressing pesticide contamination of

food (e.g., pesticide levels in food that exceed established tolerances), we have not identified a need for certifications to address pesticides as articles of food, nor do we anticipate a role for food safety audits in pesticide manufacturing facilities. Accordingly, we are revising the final rule by adding to § 1.600(c) a definition of “food” that excludes pesticides.

We also agree with the comment that producers of food contact substances could be eligible entities under this rule and that food contact substances should be considered food for the purposes of this rule. Third-party food safety audits and certifications for food contact substances could potentially be useful given the possibility of migration of harmful food contact substances into food or contamination of food contact materials that directly contact food. Accordingly, we are revising the proposed definition of “food” to exclude pesticides and retain “food contact substances” in the definition of “food” in this final rule, consistent with the definition of “food” in the final FSVP regulation.

J. Food Safety Audit

We proposed to define “food safety audit” as a regulatory audit or a consultative audit.

(Comment 15) We received a few comments on the definition of “food safety audit.” Some comments request that we remove consultative audits from the definition of “food safety audit,” asserting that consultative audits should not be subject to the reporting and notification requirements associated with “food safety audits.” Other comments say we should replace the term “food safety audit” with “regulatory audit,” as a matter of statutory construction and sound policy. Finally, some comments suggest that we delete the definition of “food safety audit” altogether.

(Response 15) We are retaining the definition of “food safety audit” as a useful definition to describe regulatory and consultative audits that fall under the requirements of this rule. As described in Response 9, we have revised the definition of “consultative audit” to clarify that it is an audit conducted in preparation for a regulatory audit under the third-party certification program. Although an audit meeting that definition would be subject to certain reporting and notification requirements, there are many types of audits/arrangements that would not fall within the definition of “consultative audit” or “regulatory audit,” and would therefore not be subject to the requirements of this rule, including the

reporting and notification requirements. Therefore, including consultative audits in the definition of “food safety audit” will not prevent eligible entities from using accredited third-party certification bodies for auditing arrangements that fall outside of the scope of this rule and do not trigger the requirements of this rule. To further address comments’ concerns, we are modifying the definition of “food safety audit” to provide clarification regarding what types of audits/activities would fall outside of the scope of this rule. Specifically, we clarify that a food safety audit must be declared by an eligible entity at the time of audit planning and must be conducted on an unannounced basis consistent with sections 808(b)(6) and 808(c)(5)(C) of the FD&C Act.

K. Foreign Cooperative

We proposed to define “foreign cooperative” as an entity that aggregates food from growers or processors that is intended for export to the United States.

On our own initiative, we are replacing the phrase “entity that aggregates” with “autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate” for clarification purposes.

(Comment 16) Some comments suggest that we add a definition for “consolidator.” The comments contrast consolidators with cooperatives and argue that consolidators act essentially as brokers that purchase products from several sources and then export the total set to the United States. According to these comments, consolidators do not own or manage the individual sites and generally do not have control over or even knowledge of the processing procedures.

(Response 16) We agree with the comment that an entity without a single management system that exercises control over the manner in which individual sites meet the applicable food safety requirements of the FD&C Act and FDA regulations would not be an eligible entity. However, we disagree that adding a definition of “consolidator” would be helpful because whether an entity is a “consolidator” has no bearing on the requirements of this rule.

(Comment 17) Some comments point out that while the proposed rule indicates a foreign cooperative could be an accreditation body or a third-party certification body, in their countries the government is the accreditation body. Also, in some places the government authorizes certain parties to conduct audit activities and those parties are under the control and supervision of the

government. Accordingly, the comments suggest that we indicate in which countries and in which cases a foreign cooperative could be an accreditation body or a third-party certification body. Other comments recommend more detail on how cooperatives are defined, and how they would conform to FDA requirements for third-party certification bodies.

(Response 17) We currently are not in a position to be able to determine which countries or which foreign cooperatives may be adequately qualified to become accredited under the third-party certification program. We note that section 808 of the FD&C Act expressly allows foreign cooperatives to serve as accredited third-party certification bodies if they are adequately qualified and independent of the eligible entities they audit or certify under the third-party certification program. Therefore, we are not categorically excluding foreign cooperatives from the third-party certification program, nor are we making any categorical decisions on whether governmental accreditation bodies have conflicts that would preclude them from accrediting such foreign cooperatives under the program.

L. Regulatory Audit

We proposed to define a “regulatory audit” as an audit of an eligible entity to determine whether such entity is in compliance with the provisions of the FD&C Act and the results of which are used in determining eligibility for food certification under section 801(q) of the FD&C Act or facility certification under section 806 of the FD&C Act, and may be used by an importer in meeting the requirements for an onsite audit of a foreign supplier under the FSVP program.

(Comment 18) Some comments request that we clarify the definition of “regulatory audit.”

(Response 18) The comments requesting clarification failed to mention specific characteristics in the definition needing clarification and did not offer suggestions for clarification. Therefore, we decline to modify the definition based on these comments. However, on our own initiative we have revised the definition of “regulatory audit” by removing the clause “, and may be used by an importer in meeting the requirements for an onsite audit of a foreign supplier under subpart L of this part” that does not appear in the statute. We did this in part to avoid confusion. We emphasize that an audit conducted for the purposes of FSVP would not need to be conducted by a third-party certification body under this subpart. See section XIII.G. Nor are

facilities required to use third-party certification bodies accredited under this rule in meeting their supplier verification requirements under the final human or animal preventive controls regulations. On our own initiative, we are revising the definition of “regulatory audit” to clarify that the results of a regulatory audit may be used to determine eligibility for any certifications that may be used for purposes of section 801(q) or section 806 of the FD&C Act.

M. Self-Assessment

We proposed to define “self-assessment” as a systematic assessment conducted by an accreditation body or by a third-party certification body to determine whether it meets the applicable requirements of this subpart.

We received no adverse comments about our proposed definition. However, on our own initiative, we are revising the definition of “self-assessment” to improve clarity and to specify what is required of a recognized accreditation body and an accredited third-party certification body when performing these evaluations.

N. Third-Party Auditor

We proposed to define a “third-party auditor” as a foreign government, agency of a foreign government, foreign cooperative, or any other third-party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable requirements of the FD&C Act. We further proposed that a third-party auditor may be a single individual or an organization and may use audit agents to conduct food safety audits. Finally, we proposed that “third-party auditor” has the same meaning as “certification body” as that term was defined in the proposed rule.

(Comment 19) As described in Comment 1, we received several comments urging us to align our definitions and terminology with international standards. Some comments state that the term “third-party auditor,” the language of the statute notwithstanding, is not correct terminology to use interchangeably with “third-party certification body.”

(Response 19) As discussed previously, we agree that it is beneficial to use terminology in this rule that is consistent with terminology used in international standards when feasible and appropriate. Therefore, we are deleting the definition of “third-party auditor” in the final rule and will use the term “third-party certification body” in this rule except that we will use the term “third-party auditor” in the

definitions of “Accredited third-party certification body” and “Third-party certification body” in § 1.600(c) and in the preamble discussion of those definitions in section III.A. We are clarifying in the definition of “third-party certification body” in § 1.600(c) that the term has the same meaning as “third-party auditor” as defined in section 808(a)(3) of the FD&C Act.

IV. Comments on Who Is Subject to This Subpart (§ 1.601)

We proposed in § 1.601 that this rule would apply to those accreditation bodies, third-party certification bodies, and eligible entities that seek to participate in this voluntary third-party certification program. We proposed two limited exemptions from section 801(q) of the FD&C Act: One related to alcoholic beverages from an eligible entity that is a facility that meets certain conditions, and another related to certain food constituting not more than 5 percent of the overall sales of a facility meeting the conditions of the first exemption.

A. Limiting the Scope of the Rule to Regulatory Audits and Certifications

Under proposed § 1.601(b), we proposed that subpart M would apply to third-party certification bodies seeking accreditation to conduct food safety audits and issue certifications for purposes of sections 801(q) and 806 of the FD&C Act.

(Comment 20) Some comments suggest we modify the language in § 1.601(b) regarding third-party certification bodies seeking accreditation to clarify that requirements of the rule apply only to imported foods that are subject to a condition of admissibility under section 801(q) of the FD&C Act and imported foods offered by an importer seeking to establish eligibility to participate in VQIP. In this view, the requirements of the rule (e.g., the notification requirements) should not apply to audits other than regulatory audits that are conducted for certification purposes.

(Response 20) We decline to make the suggested revisions to § 1.601(b) because § 1.601(b)(2) already describes the two types of certifications that may be issued by accredited third-party certification bodies under the final rule and the types of audits that they would conduct under this program (i.e., food safety audits, which include both consultative and regulatory audits). Audits conducted by third-party certification bodies that are outside of the scope of this program, and eligible entities receiving audits outside of the scope of this program, would not be

subject to the requirements of this final rule. With respect to the suggestion that the final rule should apply only to regulatory audits, and therefore not to consultative audits, we note, as previously discussed, that section 808 of the FD&C Act specifically defines “consultative audit” and contains requirements for the conduct of both regulatory and consultative audits (see, e.g., section 808(a)(5) and (c)(4)(B) of the FD&C Act). Therefore, this final rule establishes requirements for consultative audits that are consistent with the provisions on consultative audits in the statute.

B. Exemption for Alcoholic Beverages

Under proposed § 1.601(d), we proposed to exempt from the certification requirements under section 801(q) of the FD&C Act alcoholic beverages that are imported from an eligible entity that is a facility that meets the following two conditions:

- Under the Federal Alcohol Administration Act or chapter 51 of subtitle E of the Internal Revenue Code of 1986, the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and
- Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

We also proposed that the certification requirements under section 801(q) of the FD&C Act would not apply to food other than alcoholic beverages that is imported from a facility described in § 1.601(d)(1) provided that such food:

- (i) Is in prepackaged form that prevents any direct human contact with such food; and
- (ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

We tentatively concluded that these provisions were consistent with the provisions on alcohol-related facilities in section 116 of FSMA.

(Comment 21) Some comments support the proposed exemption of imported beverage alcohol products, but encourage us to clarify and amplify the exemption to cover the raw materials and ingredients (e.g., grapes, grains, hops, flavors) used to produce alcoholic beverages. The comments assert that the requested exemption would provide for

consistency between domestic and foreign facilities and would be consistent with Congressional intent regarding section 116 of FSMA. The comments assert that the expanded exemption would be consistent with the regulations on preventive controls for human food. The comments urge us to consult their comments on the FSVP proposed rule.

(Response 21) As requested, we consulted comments submitted on proposed § 1.501(e) in the FSVP proposed rule, requesting an exemption from the FSVP requirements for the importation of the raw materials and ingredients (e.g., grapes, grains, hops, flavors) used to produce alcoholic beverages, and asserting that such an exemption would be consistent with Congressional intent regarding section 116 of FSMA.

We considered the comments’ request in light of the risk-based public health principles generally underlying FSMA and have concluded that Congress did not intend for FSMA’s core requirements to apply to the manufacture/processing, packing, and holding of alcoholic beverages. Congress may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau. In light of this context, we have concluded that section 116 of FSMA should be interpreted to mean that the manufacturing, processing, packing, or holding of alcoholic beverages at most alcohol-related facilities should not be subject to this rule.

We believe the same rationale supports the comments’ request. Accordingly, and consistent with the final FSVP regulation, we are expanding the exemption from certification under section 801(q) of the FD&C Act in § 1.601(d) to cover raw materials or other ingredients that are used to manufacture/process, pack or hold alcoholic beverages by an importer required to be registered under section 415 of the FD&C Act, when such facilities are exempt from the preventive controls regulations under 21 CFR 117.5(i).

Also in this final rule, we are replacing the term “food other than alcoholic beverages,” to describe the applicability of the exemption, with the term “food that is not an alcoholic beverage.”

C. USDA Regulated Products

(Comment 22) Some comments suggest we explicitly exempt products

under USDA jurisdiction from the requirements of this rule.

(Response 22) We agree that an exemption to 801(q) is appropriate with respect to meat, poultry, and egg products regulated by USDA at the time of importation. The final rule adds a new § 1.601(d)(2) which states that any certification under 801(q) does not apply to meat, poultry, and egg products that at the time of importation are subject to the requirements of the USDA under FMIA (21 U.S.C. 601 *et seq.*), PPIA (21 U.S.C. 451 *et seq.*), or EPIA (21 U.S.C. 1031 *et seq.*). We conclude that this provision is consistent with section 403 of FSMA, entitled “Rule of Construction,” which states that nothing in FSMA shall be construed to alter or limit the jurisdiction of the Secretary of the Department of Agriculture. For many decades, USDA has exercised authority and responsibility over the import of such meat, poultry, and egg products, and has detailed regulations and procedures implementing this authority. In light of USDA’s role with respect to the importation of these products, and also in light of section 403 of FSMA, we believe that Congress did not intend for an FDA determination under section 801(q) of the FD&C Act to apply to meat, poultry, and egg products that at the time of importation are subject to USDA requirements under the MPIA, PPIA, and EPIA, respectively. We therefore conclude that final § 1.601(d)(2) is consistent with Congress’s intent in promulgating section 403 of FSMA.

With respect to the third-party program, we note that the program establishes a voluntary system of certification by accredited third-party certification bodies that food and facilities meet applicable requirements of the FD&C Act and FDA regulations. Certifications issued under this program will not be used to facilitate entry of meat, poultry, and egg products that are regulated by USDA at the time of importation, as defined above.

V. Comments on Recognition of Accreditation Bodies Under This Subpart

A. Who is eligible to seek recognition? (§ 1.610)

Proposed § 1.610 states that an accreditation body would be eligible for recognition if it could demonstrate that it meets the requirements related to legal authority, competency, capacity, conflicts of interest, quality assurance, and records in §§ 1.611 through 1.615. In our discussion of this section in the preamble of the proposed rule we stated our tentative conclusions that key

elements of ISO/IEC 17011:2004 (Ref. 5) would form a basis for our requirements, and that documented conformance to that standard would be relevant in demonstrating that an accreditation body is qualified for recognition.

(Comment 23) Some comments recommend that we require accreditation bodies to be signatories to IAF multilateral recognition agreements (IAF-MLAs) (which requires signatories, among other things, to conform to ISO/IEC 17011:2004) as a condition of recognition, and some contend it should be the sole criterion. Comments in favor of including signatory status as a requirement note that the process of becoming a signatory involves a thorough peer-review process, which helps ensure quality outcomes (e.g., signatories have to demonstrate conformance to ISO/IEC 17011:2004 as part of the peer review process). Comments note other aspects of IAF-MLA signatory status that would be beneficial to the program, such as periodic reevaluation by peer signatories to ensure continued compliance. These comments argue that when a foreign government is the accreditation body, it may be difficult for FDA to regulate a peer agency, so reliance on IAF-MLA signatory status would be helpful, in part because it would give an independent organization (IAF) a role in managing the accreditation body.

Some comments discourage us from requiring IAF-MLA signatory status as a condition of recognition. Some comments suggest that we consider signatory status as a factor in favor of recognition, noting many of the same advantages touted by proponents of requiring signatory status, but suggest that we not make IAF-MLA signatory status a condition of program participation.

Other comments explain that it would be premature to make IAF signatory status the sole requirement. The comments note that at the time of these comments the IAF-MLA does not yet include subsopes for specific food safety standards or schemes. Still other comments recommend that FDA study the issues surrounding signatory status further before making it a requirement, pointing out that some countries may not have signatory IAF-MLA members representing them.

Some comments cite to third-party food safety audit programs administered by other governments, noting those programs do not require IAF-MLA status as a condition for program participation. These comments argue

that it is more important to require conformance to ISO/IEC 17011:2004.

(Response 23) The comments uniformly agree on the value of an accreditation body's conformance to ISO/IEC 17011:2004 in establishing its qualifications for recognition. As discussed in section I.D., we agree that an accreditation body may use its documented conformance to ISO/IEC 17011:2004 to support its eligibility for recognition under this rule, supplemented as necessary (for example, to demonstrate capability to meet FDA requirements for reporting and notification under § 1.623, if recognized). We also agree that additional documentation relating to IAF-MLA signatory status may be useful in supporting an accreditation body's application for recognition under this program. However, we disagree with comments suggesting that we require IAF-MLA signatory status as the sole criterion or one of several criteria for recognition to accredit third-party certification bodies to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations at this time. We currently lack (and the comments did not provide) adequate information to conclude that IAF-MLA signatory status should be the sole factual basis or one of several criteria for determining whether an accreditation body can fulfill the roles and responsibilities of a recognized accreditation body under this subpart. Further, we also want to allow accreditation bodies that are not signatories to participate in the program if they meet the statutory and regulatory criteria.

(Comment 24) As explained in section I.D., several comments support FDA's reliance on ISO/IEC 17011:2004 (Ref. 5) in developing the proposed rule. Other comments suggest FDA should place greater reliance on ISO/IEC 17011:2004 (Ref. 5), including some comments recommending that we incorporate the standard by reference into the rule.

(Response 24) We agree with comments on the value of promoting international consistency and tapping into an existing framework that is familiar to accreditation bodies, third-party certification bodies, and the food industry. Accordingly, in § 1.610 we are adding new language to state that an accreditation body may use documentation of conformance with ISO/IEC 17011:2004 (Ref. 5), supplemented as necessary, to demonstrate that it is eligible for recognition. This new language may make it easier for accreditation bodies that already conform to ISO/IEC

17011:2004 (Ref. 5) to apply for the program. We are also making conforming changes to §§ 1.622(d) and 1.623(b), 1.640(a), and 1.655(e).

We decline to incorporate ISO/IEC 17011:2004 (Ref. 5) by reference as the sole criterion or one of several criteria for recognition, because the standard contains some provisions that are inconsistent with section 808 of the FD&C Act or impractical for use in our program. For example, ISO/IEC 17011:2004 (Ref. 5), clause 4.3.7, allows an accreditation body to have "related bodies" that provide conformity assessment services (e.g., auditing and certification) in areas the accreditation body accredits. (A "related body" is linked to the accreditation body by common ownership or contractual arrangement, under clause 4.3.7 NOTE 1.) The only safeguards that a related body is expressly required to meet are as follows: (1) It must have different top management than the accreditation body's top management; (2) different personnel from those involved in the accreditation decisionmaking processes; (3) no possibility to influence the outcome of an assessment for accreditation; and (4) distinctly different names, logos, and symbols. While clause 4.3.7 of ISO/IEC 17011 (Ref. 5) speaks to issues of common management and control of the accreditation body and its related body, the standard does not expressly prohibit the accreditation body from accrediting its related body with which it shares common ownership or financial interests. For example, an accreditation body that provides financial support (directly or indirectly) to a related body could be viewed as lacking the impartiality necessary to make an objective decision about whether the related body it supports is appropriately qualified. The impartiality provisions in ISO/IEC 17011:2004 (Ref. 5) are impractical for our purposes because they fail to address the range of possible conflicts associated with shared financial interests and ownership between a recognized accreditation body and a "related" third-party certification body under this rule. To help ensure the credibility of our program, § 1.624 requires a recognized accreditation body to implement a program to ensure that the accreditation body and its officers, employees, and other agents involved in accreditation activities do not own or have a financial interest in a third-party certification body seeking its accreditation. Accordingly, it would be inappropriate for us to rely on the conflict of interest safeguards contained in ISO/IEC

17011:2004 (Ref. 5), in the third-party certification program we are establishing.

For the foregoing reasons, we decline the suggestion to incorporate ISO/IEC 17011:2004 (Ref. 5) by reference into this rule.

(Comment 25) Several comments express concern about our proposal to allow both public and private accreditation bodies to seek recognition. Some comments discourage us from allowing private entities to be accreditation bodies because of the concern that allowing for private accreditation bodies may cause conflicts of interest. Similarly, some comments contend that accreditation bodies must uphold public confidence and perform their duties objectively, which is the purview of governmental entities.

Other comments take a contrary view, suggesting that some government agencies have missions that may undermine the objectivity and independence required of a recognized accreditation body. Some comments encourage us to consider which government agency/ministry in a given country may be eligible for recognition, and to solicit input from stakeholders as to which agencies/ministries are best positioned to perform this function.

Still other comments assert that private and government entities are sufficiently different such that we should establish different conflict of interest provisions and requirements for each.

(Response 25) Comments on both sides of this issue express concern that any accreditation body we recognize must be independent and objective in the performance of its duties. We share that concern. However, none of the comments offered substantiation that would lead us to bar public or private accreditation bodies, as a class, from seeking recognition because of conflicts of interest inherent in the class.

Section 808 of the FD&C Act defines an “accreditation body” as an authority that accredits third-party certification bodies and makes no distinction between public and private accreditation bodies. We have concluded that both public and private accreditation bodies are potentially capable of exhibiting the impartiality necessary for recognition under this rule. Therefore in light of the broad definition of “accreditation body” and to maximize the opportunities for qualified accreditation bodies to participate in the program, FDA does not consider it to be appropriate to limit the program to only certain types of accreditation bodies.

With respect to the comments that suggest we apply different conflict of interest requirements to different types of accreditation bodies, none of these comments offered an adequate explanation to justify different requirements for public and private accreditation bodies. Again, we note that section 808 of the FD&C Act does not make distinctions for different types of accreditation bodies.

(Comment 26) Some comments request that we provide additional explanation regarding how an accreditation body that does not have experience accrediting third-party certification bodies for food safety scopes would become eligible for recognition under this program.

(Response 26) An accreditation body of the type described in the comments’ hypothetical might face practical difficulties in providing adequate substantiation demonstrating that it meets the requirements described in § 1.610. However, we will consider each application on its own merits and do not foreclose the possibility for such an accreditation body to make the showing necessary to be granted recognition under this rule.

B. What legal authority must an accreditation body have to qualify for recognition? (§ 1.611)

We proposed to require an accreditation body seeking recognition to demonstrate that it has adequate legal authority (as a governmental entity or through contractual rights) to assess a third-party certification body for accreditation, including authority to review records and conduct performance assessments (e.g., authority to witness the performance of a statistically significant number of employees and other agents conducting assessments). We proposed to require that the accreditation body have adequate authority to remove or modify an accreditation status, once granted. We also proposed to require the accreditation body to demonstrate that it would be capable of exercising the legal authority necessary to meet the program requirements, if we granted recognition.

On our own initiative, in § 1.611(a)(2) we replaced, “personnel and other agents,” with, “audit agents, or the third-party certification body in the case of a third-party certification body that is an individual” for clarity and consistency with section 808(a)(4) of the FD&C Act. We have also made corresponding changes throughout this subpart.

(Comment 27) Some comments provide support for this provision, and others encourage us to ensure that a

private accreditation body seeking recognition could have adequate legal authority to operate.

(Response 27) We agree with the comment urging us to ensure that a private accreditation body could have the necessary authority to act as a recognized accreditation body under this rule. As noted previously, we see no inherent reason why private entities could not theoretically meet the eligibility requirements for accreditation bodies under this rule. Therefore, we are revising § 1.611(a) and (b) to clarify that an accreditation body can be a legal entity with contractual rights. By the words “legal entity,” we mean that the accreditation body must be duly authorized to operate as an accreditation body by governmental authorities responsible for such authorizations in any country or countries in which the accreditation body seeks to perform accreditation of third-party certification bodies under this rule.

(Comment 28) Some comments ask us to clarify what we mean by “statistically significant” as used in § 1.611(a)(2) and elsewhere in the proposed rule to provide adequate confidence in the results of an analysis of the sample. The comments encourage us to abandon the phrase “statistically significant” in favor of the language of ISO/IEC 17011:2004 (Ref. 5), which requires an accreditation body to witness the performance of a representative number of third-party certification body staff.

(Response 28) We understand from the comments that a body of knowledge and experience has developed among accreditation bodies conforming to ISO/IEC 17011:2004 (Ref. 5) on the meaning of “representative” numbers of observations and that no similar body of knowledge or experience exists on the meaning of “statistically significant” numbers of observations in this context. Accordingly, we are revising § 1.611 to require observations of a “representative sample” of audit agents and food safety audits. We are making similar revisions to other sections of the rule that require onsite observations.

For purposes of an accreditation body’s observations of a third-party certification body under this rule, what constitutes a “representative sample” will be decided on a case-by-case basis, depending on various factors. These factors include the scope of accreditation, whether the third-party certification body is an individual who will conduct audits and make certification decisions, or whether the third-party certification body uses agents to conduct audits and, if so, whether such agents are centrally managed, conducting similar types of

audits, under a single set of operating procedures or whether the agents are managed from various locations, perform different types of audits, or follow different procedures such that these various locations, activities, or practices must be observed to ensure that the sample is sufficiently representative. A representative sample also must provide adequate confidence in the results of an analysis of the sample.

C. What competency and capacity must an accreditation body have to qualify for recognition? (§ 1.612)

We proposed to require an accreditation body seeking recognition to demonstrate that it has the resources required to adequately implement its accreditation program, including adequate numbers of qualified employees and other agents, adequate financial resources for its operations, and the capability to meet the resource demands of a recognized accreditation body, in the event the accreditation body is recognized.

(Comment 29) We received some comments on this provision, which also support the proposed rule's requirement that accreditation bodies demonstrate their competence and capacity based on the requirements of ISO/IEC 17011:2004 (Ref. 5). However, these comments disagree with our statement in the preamble that liability coverage requirements should not apply to this rule. The comments argue that we should include a requirement for accreditation bodies to carry liability coverage, noting that it is one of the requirements in ISO/IEC 17011:2004 (Ref. 5) and describing it as especially important because of the risks associated with food safety.

(Response 29) We agree with the comments that liability insurance may be useful in demonstrating the adequacy of an accreditation body's resources, for example, under ISO/IEC 17011:2004 (Ref. 5); however, FDA lacks experience in evaluating the adequacy of liability coverage for accreditation activities and we do not believe it would be appropriate for FDA to make recognition decisions primarily on this basis. We believe an accreditation body can demonstrate that it is adequately resourced in a number of different ways, including providing documentation of liability coverage as part of the information submitted to help to demonstrate that accreditation body is adequately resourced.

D. What protections against conflict of interest must an accreditation body have to qualify for recognition? (§ 1.613)

Proposed § 1.613 requires accreditation bodies to demonstrate that they have written measures to protect against conflicts of interest with third-party certification bodies and the capability to meet the rule's other conflict of interest requirements.

On our own initiative, we are clarifying that the scope of conflict of interest provisions in § 1.613(a) is limited to individuals involved in accreditation, auditing, and certification activities and not, for example, employees involved in purely administrative functions, such as payroll, or in positions that support administrative functions, such as computer technicians. Therefore, § 1.613(a) of this rule applies to interests between the officers, employees, and other agents of the accreditation body that are involved in accreditation activities and the officers, employees, and other agents of the third-party certification body involved in auditing and certification activities. We are making corresponding changes in the subsequent provisions for recognized accreditation bodies under § 1.624(a).

(Comment 30) Some comments take issue with our decision not to include the requirements of clause 4.3.2 of ISO/IEC 17011:2004 (Ref. 5), which requires the accreditation body to have documented and implemented a structure relating to conflicts of interest that provides for effective involvement by interested parties with balanced representation ensured.

(Response 30) We decline to require that recognized accreditation bodies establish and implement a structure for involving interested parties in matters relating to the conflict of interest requirements for recognized accreditation bodies. It would be administratively burdensome for FDA to establish a mechanism for monitoring the activities of interested parties that the accreditation body elects to involve to comply with such requirements. In our third-party certification program, impartiality will be protected by the conflict of interest provisions for accreditation bodies in § 1.624, the appeals provisions in § 1.620(d), and FDA's oversight activities.

E. What quality assurance procedures must an accreditation body have to qualify for recognition? (§ 1.614)

Proposed § 1.614 requires accreditation bodies to implement a written quality assurance program and

have the capability to meet the rule's other quality assurance requirements.

(Comment 31) Some comments encourage FDA to more closely align § 1.614 with established international standards on quality assurance programs. Some ask us to rely on the relevant provisions in ISO/IEC 17011:2004 (Ref. 5) in particular.

(Response 31) We agree with the comments and as described in section I.D., we are revising § 1.610 to allow accreditation bodies to use their demonstrated conformance to ISO/IEC 17011:2004 (Ref. 5), supplemented as necessary, in meeting the requirements for recognition.

(Comment 32) Some comments ask us to clarify the language in § 1.614(a)(1) and (2) regarding food safety problems and corrective actions.

(Response 32) We agree and have revised § 1.614(a)(1) and (2) to clarify that an accreditation body must demonstrate that it has procedures to identify deficiencies and procedures to execute corrective actions for such deficiencies, using language that better aligns with international standards (see, e.g., clause 5.5 in ISO/IEC 17011:2004 (Ref. 5)).

F. What records procedures must an accreditation body have to qualify for recognition? (§ 1.615)

Proposed § 1.615 would require accreditation bodies seeking recognition to demonstrate that they have developed and implemented adequate written procedures for establishing, controlling, and retaining records and to demonstrate the capability to meet the program's records, reporting, and notification requirements, if recognized.

(Comment 33) Some comments voice general concerns about confidentiality. Others state their concern with how confidentiality of third-party certification body records would be preserved when third-party certification bodies must share information with recognized accreditation bodies and FDA. Noting that such information can be sensitive in nature and sometimes includes confidential business information, these comments urge us to place certain limits—*i.e.*, only information related to food safety would be collected during audits of third-party certification bodies and such information would be shared only with the recognized accreditation body and FDA. Some comments suggest FDA require strict protective measures for information handled by third-party certification bodies and accreditation bodies, because the release of an eligible entity's confidential business information could have detrimental

effects on U.S. businesses and their foreign suppliers. These comments suggest the use of confidentiality protections such as “confidential disclosure agreements” so that the audit climate remains conducive to robust scrutiny and open dialogue.

Some comments also express concern with the proposed use of electronic records, because of the opportunity for sensitive electronic information to be compromised. Such comments recommend that the final rule include requirements for both third-party certification bodies and accreditation bodies to ensure that electronic records remain secure in transit and during storage.

(Response 33) We decline the suggestions to require confidentiality disclosure agreements between recognized accreditation bodies and third-party certification bodies under our program and to establish data protection requirements for electronic records and communications of recognized accreditation bodies and accredited third-party certification bodies. We understand that many accreditation bodies and third-party certification bodies have contractual agreements regarding confidentiality and disclosure by those parties. We expect accreditation bodies that become recognized under our program may elect to establish contracts that incorporate language on information sharing with FDA for third-party certification bodies seeking accreditation under this program. For such accreditation bodies, how they choose to accomplish this—*e.g.*, whether by establishing a separate confidentiality agreement or through revision of current contract language or creation of a new contract addendum—is a decision best made by the parties to those contracts. Accreditation bodies and third-party certification bodies will have common interests in safeguarding the electronic records they store and transmit to each other; therefore, we have no reason to believe that any separate agreements will lack adequate protections for confidentiality of information, including information stored and shared among the parties electronically.

This rule focuses on confidentiality and disclosure with respect to information shared with FDA. As explained in section XIII.F., FDA will protect the confidentiality of information accessed by or submitted to the Agency in accordance with § 1.695 of this subpart. With respect to the storage of electronic records and electronic transmission of information by FDA, we note that we are working the FDA IT security professionals in

establishing the electronic portal for the third-party certification program to apply adequate and appropriate controls to ensure the confidentiality and integrity of data submitted to FDA through the portal.

(Comment 34) In the proposed rule preamble discussion of this section we stated that, “[a]ccreditation bodies applying for recognition must demonstrate their capacity, if recognized, to grant us access to confidential information, including information contained in records, without prior written consent of the third-party certification body involved. Having access to records relating to accreditation activities (including confidential information) under this subpart is necessary to ensure the rigor, credibility, and independence of the program.” Some comments take issue with this point, arguing that accreditation bodies would not be able to grant such access—they would only be able to grant access to confidential information *with* prior written consent. That is, the accreditation body would first need to make arrangements for FDA access to confidential records with the third-party certification bodies it accredits and the eligible entities certified by those third-party certification bodies. Comments that express doubt about private sector foreign accreditation bodies actually granting FDA access to confidential records contend that such access is particularly unlikely without the prior written consent of the third-party certification body whose records are sought.

(Response 34) We agree with the comments that the contracts accreditation bodies currently use with their third-party certification body clients do not contemplate the program we are establishing. As comments suggest, we would expect that confidentiality provisions in standard contracts would need to be revised such that, in signing a contract for accreditation under the FDA program, the third-party certification body would be giving the accreditation body its prior consent to perform any reporting or notification necessary for the recognized accreditation body to fulfill its obligations under the rule. Indeed, we expect that accreditation bodies seeking recognition will demonstrate their ability to comply with the reporting and notification provisions of this rule by providing us examples of standard contract language that has been suitably revised as comments describe.

VI. Comments on Requirements for Recognized Accreditation Bodies Under This Subpart

A. How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation? (§ 1.620)

Proposed § 1.620 would establish the criteria and procedures that a recognized accreditation body must use in assessing third-party certification bodies for accreditation. Paragraph (a) broadly addresses the different requirements for foreign governments and foreign cooperatives or other third parties. Paragraph (b) requires the accreditation body to require third-party certification bodies to satisfy the rule’s reporting and notification requirements. Paragraph (c) requires the accreditation body to maintain certain records, such as those related to withdrawal or suspension of a third-party certification body. Paragraph (d) requires an accreditation body to have written procedures for handling appeals from third-party certification bodies, and requires certain minimal appeal procedures.

On our own initiative, we are revising § 1.620(a)(2) and (3) to apply to accredited third-party certification bodies that are comprised of a single individual, as applicable. We are also removing, “and any requirements specified in FDA model accreditation standards regarding qualifications for accreditation, including legal authority, competency, capacity, conflicts of interest, quality assurance, and records” to follow good guidance practice. We are making corresponding changes to §§ 1.620(a)(1), 1.640(b), and 1.640(c). We are also revising § 1.620(c) to specify that recognized accreditation bodies must also include the date of the action in their records relating to any denial of accreditation or the withdrawal, suspension, or reduction in scope of accreditation of a third-party certification body. In addition, we are revising § 1.620(d) to clarify that the recognized accreditation body must notify any third-party certification body of an adverse decision associated with its accreditation under the subpart, including denial of accreditation or the withdrawal, suspension, or reduction in the scope of its accreditation.

(Comment 35) In paragraph (a)(3) of this proposed section we stated that a recognized accreditation body must observe “a statistically significant number of onsite audits” conducted by the third-party certification body seeking accreditation. Some comments request clarification of what we meant by “statistically significant,” so that accreditation bodies would know what

would be an adequate number of audits to observe to provide adequate confidence in the results of an analysis of such observations. The comments suggest that we should explain the criteria for determining the number of witness audits to be conducted under proposed § 1.620 and ask whether site-specific issues such as geographic factors should be considered. Other comments encourage us to abandon the phrase “statistically significant” in favor of the language of ISO/IEC 17011:2004 (Ref. 5), which requires an accreditation body to witness the performance of a representative number of third-party certification body staff.

(Response 35) We have removed the phrase “statistically significant” in § 1.620(a)(3) and inserted the phrase “representative sample.” We explain in Response 28 that comments presented compelling arguments that a significant body of knowledge and experience has developed around the meaning of a “representative” number of observations under ISO/IEC 17011:2004 (Ref. 5) to achieve an adequate level of confidence in the results. We have revised § 1.620(a)(3) accordingly. Site-specific issues may be relevant in determining the representative number of witness assessments to conduct, for example, where audit agents are located in remote offices or where food safety audits are managed by remote offices. The accrediting body, either a recognized accreditation body or FDA in the case of direct accreditation, will be best positioned to determine whether geographic issues are relevant for purposes of § 1.620(a)(3).

(Comment 36) Some comments ask us to revise § 1.620(d)(2) to clarify that the individuals used to hear appeals of adverse decisions by a recognized accreditation body could be individuals external to the accreditation body.

(Response 36) We agree with the comments and have revised this provision to clarify that individuals used to hear appeals may be external to the accreditation body, as well as a similar provision applying to appeals by eligible entities of adverse decisions by an accredited third-party certification body. We have also revised this provision to use language similar to language that is used in § 16.42(b), which describes the characteristics of a presiding officer that may be used for FDA regulatory hearings.

(Comment 37) In the preamble to the proposed rule we stated that we were not proposing to review the decisions of recognized accreditation bodies nor were we proposing to hear appeals from third-party certification bodies aggrieved by an accreditation body’s

decision(s). We sought comment on these matters. In response, some comments state their understanding that FDA would retain the authority to challenge a recognized accreditation body’s decisions, because we have authority over the entire program.

(Response 37) We agree with comments that our oversight extends to any accreditation body or third-party certification body participating in the program, including the authority to withdraw accreditation from a third-party certification body even if the accreditation was granted by a recognized accreditation body. However, FDA does not intend to serve as an appellate body for aggrieved third-party certification bodies, as this would be unworkable and unnecessary. Withdrawing the accreditation of a third-party certification body to remove it from our program is quite different than, for example, overturning an accreditation body’s decision to deny accreditation to a third-party certification body in the first place. Our program is designed to ensure the competency and independence of accreditation bodies. As part of this program, FDA will be recognizing accreditation bodies to make accreditation decisions based on a determination that the accreditation body is qualified to do so. FDA involvement in accreditation decisions would defeat the purpose of the program. Additionally, FDA retains the authority to revoke the recognition of accreditation bodies for good cause under § 1.634(a)(4) for failure to comply with this rule. For all of these reasons, FDA declines to codify a process to review appeals challenging recognized accreditation body decisions under this program.

(Comment 38) Several comments encourage us to expand on the requirement to use “independent” person(s) to hear an appeal of an adverse accreditation body decision. Some comments suggest that we clarify that an independent person is one who was not involved in the decision that is the subject of the appeal. A few comments suggest we further require the accreditation body to use person(s) who are external to the organization.

(Response 38) We agree with the suggestions to clarify § 1.620(d)(2) and are revising it to align with the impartiality provisions in 21 CFR part 16, which contains the regulations for regulatory hearings that we will generally apply under § 1.693 to an appeal of a revocation or withdrawal. Under the part 16 regulations, the person presiding over the hearing must be free from bias or prejudice and must

not have participated in the action that is the subject of the hearing or be subordinate to a person who participated in the action. We believe that the credibility of the third-party certification program will be enhanced by requiring recognized accreditation bodies to afford similar protections when considering appeals by certification bodies under this rule. While we decline the suggestion to require the use of external parties in deciding appeals, we note that a recognized accreditation body has flexibility to use an external party under § 1.620(d)(2).

B. How must a recognized accreditation body monitor the performance of third-party certification bodies it accredited? (§ 1.621)

We proposed to require a recognized accreditation body to conduct an annual evaluation of each of its accredited certification bodies that includes a review of the certification body’s self-assessments, its regulatory audit reports, notifications to FDA, and any other information reasonably available. We requested comment on whether the information we proposed to require would provide a solid basis for an evaluation. We asked stakeholders whether we should include a requirement in § 1.621 for onsite monitoring of accredited certification bodies and, if so, whether we should require the accreditation body to observe or visit the certification body’s headquarters.

(Comment 39) We received several comments on the annual assessment requirements of proposed § 1.621. Some comments agree with the requirement for an annual assessment. Some comments mention a Government Accountability Office (GAO) report entitled, “FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries’ Oversight Resources” (GAO 12–933) and dated September 2012, which notes ongoing challenges with ensuring the competency of third parties to consistently apply standards and argues that annual assessments would improve certification body reliability and competency. Some of these comments state they would even support more frequent certification body evaluations.

In contrast, some comments argue that annual assessments would be burdensome. Comments variously focus on the burden on accreditation bodies, certification bodies, and eligible entities. Some comments disapprove of the cumulative burden of all the assessments (e.g., self-assessments and monitoring assessments) required

throughout the rule. Some comments suggest biennial assessments, and note that such a requirement would be consistent with ISO/IEC 17011:2004 (Ref. 5). Still others argue that when the accreditation body or certification body is a government entity we should allow for flexibility around the timing of assessments.

(Response 39) We agree with comments that express the view that annual assessments of certification bodies will help build confidence in the third-party certification program. Annual assessments will help accreditation bodies ensure certification bodies' continued compliance with the program requirements and quickly identify and address any deficiencies with a certification body before a situation escalates.

We also acknowledge the concerns about the efforts needed to comply with the monitoring and self-assessment requirements of the rule. Section 1.621 is part of a set of proposed monitoring and self-assessment requirements intended to work together in helping to ensure that the recognized accreditation bodies and accredited third-party certification bodies maintain compliance with the rule's requirements. The certification body self-assessment in § 1.655 is intended to serve, in part, as information for use in the accreditation body monitoring in § 1.621, the results of which we intend the accreditation body to use in its self-assessment under § 1.622. We do not intend for the assessments to require duplicative efforts, with each section requiring a discrete set of activities with no opportunity to use the results of one set of activities when performing another. As explained in the preamble to the proposed rule, the accreditation body assessments of certification bodies will not only help ensure that the certification bodies continue to comply with our requirements, but also can help the accreditation body identify trends and any deficiencies in its own performance. The proposed monitoring and self-assessment activities are an essential part of the program's safety net.

With respect to § 1.621, in particular, we believe this section will be far less burdensome in practice than some of the comments anticipate, because of the convergence between the ISO/IEC standards and this rule. The activities required by § 1.621 are similar in substance to surveillance activities under ISO/IEC 17011:2004 (Ref. 5), which includes review of audit reports, results of internal quality control, and management review records identified in clause 3.18 NOTE, and thus are likely

to be activities many accreditation bodies already perform. In light of the foregoing, we have concluded that requiring accreditation bodies to perform annual evaluations of each certification body they accredit under the program is not unduly burdensome. We disagree with comments suggesting that monitoring should be more frequent than once a year, because requiring assessments to be performed and reported twice each year, for example, would result in a nearly continuous cycle of assessments and reports. Semiannual assessments are likely to produce limited data sets that would be less helpful for evaluation purposes than would larger data sets, such as compilations of 12 months of data, which allow for tracking and trending performance over time. Requiring assessments to be performed more frequently than once a year also risks creating significant disruption of the operations of accredited third-party certification bodies and eligible entities and might have the unintended effect of serving as a disincentive to participation in the program. For these reasons, we have determined that an annual monitoring requirement is appropriate to verify the overall effectiveness of the accredited third-party certification body's operations and performance in activities relevant to the third-party certification program and the validity of its certification decisions. Accordingly, we are not revising the annual certification body monitoring requirements we proposed in § 1.621.

(Comment 40) We received some comments on proposed § 1.621(b) specifically, which would require an accreditation body to consider any other "reasonably available" information relevant to a determination of whether a certification body is in compliance with this rule. Comments encourage us to set limits around assessments conducted in the wake of an incident, noting that a problem involving one certification/type of product should not involve review of all certifications/products. These comments did not want an incident in one sector (*e.g.*, human food) to unnecessarily jeopardize an accreditation in a separate sector (*e.g.*, animal food). Some comments express concern that proposed § 1.621(b) would require an accreditation body to review every certificate issued by a certification body if one of the eligible entities it certified was placed on FDA import alert.

(Response 40) We decline the suggestions to narrow the scope of proposed § 1.621(b) or to direct how recognized accreditation bodies should consider other "reasonably available"

relevant information, because it will depend on the facts of a particular situation. In the wake of incidents, we expect the accreditation body to take appropriate steps to determine whether the certification body is in compliance with this subpart. Such steps may include a review of certifications for product areas other than the subject of the incident if the accreditation body deems it needed to assess the certification body's compliance. We reiterate, as we explained in the preamble to the proposed rule, we do not expect a recognized accreditation body launch investigations of each certification body it accredited absent cause, but we do expect the accreditation body to actively monitor public information about their certification bodies and not ignore public information about problems that might be associated with a certification body it accredited.

(Comment 41) In response to our preamble questions about whether to require observations and certification body headquarters visits in § 1.621, some comments state that observations are a useful tool and should be required. Similarly, some comments support a requirement for visiting the key location of the certification body. Some comments state that the accreditation body should visit any location of the accredited third-party certification body where the certification body manages its staff or agents conducting audits under this program, which the comments note may not be the certification body's headquarters. Other comments agree that onsite visits can be a useful tool, but encourage the use of remote assessments in certain circumstances (*e.g.*, after the certification body has successfully completed a set number of accreditation cycles).

Some comments suggest that we follow the requirements of relevant ISO/IEC standards in establishing requirements for observations and site visits under § 1.621. Some comments express concern about the cumulative burden of the monitoring and self-assessments we proposed to require of accreditation bodies and certification bodies. A few comments express concern we might impose duplicative requirements for observations under §§ 1.621 and 1.622(b). Some comments request guidance on how an eligible entity would be selected as a site for an observation.

(Response 41) We agree with the comments that state that observations are useful and should be required as part of accredited third-party certification body monitoring. Likewise, we agree with the comments that state

a recognized accreditation body should visit any location of the certification body where the certification body manages its staff or agents conducting audits under this program, if different than the certification body's headquarters, to get a better understanding of how different locations operate. While we acknowledge that some accreditation bodies may be successfully using remote assessments in certain circumstances (e.g., after the certification body has successfully completed a set number of accreditation cycles), we decline the suggestion to allow for remote assessments in this rulemaking.

In establishing requirements in § 1.621 for observations and accredited third-party certification body visits, we considered comments' concerns that such requirements might be duplicative of the observation requirements in § 1.622(b), might pose practical difficulties in arranging to observe audits, and might pose difficulties if a certification body had several "key" locations. We also considered comments' concerns about the cumulative burden of the monitoring and self-assessment requirements of the rule and the comments that urge us to align the requirements of § 1.621 with the relevant international standards.

Accordingly, in the final rule we are combining all of the paragraphs in proposed § 1.621 into new § 1.621(a), and we are adding a new paragraph (b) that requires the accreditation body to perform a representative sample of onsite observations of regulatory audits conducted by each accredited third-party certification body, as explained in Response 28, and visit the certification body's headquarters (or other certification body location if its audit agents are managed by the certification body at a location other than its headquarters). The observed audits and site visits must be performed by no later than 12 months after the certification body's initial accreditation and again every 2 years thereafter for the duration of its accreditation, including renewals. The requirements for the frequency of observed audits and site visits under § 1.621(b) are similar to the intervals for surveillance onsite assessments in one of the options under clause 7.11.3 of ISO/IEC 17011:2004 (Ref. 5). We are also requiring the accreditation body to consider information from activities conducted under paragraph (b) in the annual performance report of the accredited third-party certification body.

We also are making a corresponding revision to § 1.622(b) to clarify that the accreditation body should consider the

results of onsite observations and site visits conducted under § 1.621(b) as part of its self-assessment under § 1.622.

C. How must a recognized accreditation body monitor its own performance? (§ 1.622)

Proposed § 1.622 would require recognized accreditation bodies to conduct self-assessments on an annual basis, and as required under proposed § 1.664(g) (following FDA withdrawal of accreditation of a certification body it accredited). Under the proposed rule, the accreditation body's self-assessment would include evaluating the performance of its officers, employees, or other agents; observing regulatory audits by a statistically significant number of certification bodies it accredited under this program, and creating a written report of results.

(Comment 42) Some comments encourage a broader self-assessment. They contend that, in addition to requiring that accreditation bodies assess the consistency of their performance and their compliance with conflict of interest provisions, we should also require accreditation bodies to compare their performance against competitors, compare the certification bodies they accredit to other certification bodies, and look at industry best practices and benchmarks to set improvement objectives.

(Response 42) The self-assessments are intended to help the accreditation body determine whether it is in compliance with the requirements of this rule. While the report elements suggested by comments might be useful for an accreditation body to consider, we do not believe those elements are necessary to a determination of compliance with the rule. Therefore, we decline to revise the rule in response to these comments.

(Comment 43) Some comments question whether the requirements for accreditation body self-assessment would fit the government-to-government model. Other comments suggest that the different nature of private operators and public administration warrant different requirements for each. The comments further contend that the workload associated with the program would be significant for any government agency; therefore, the time limits and frequencies of reporting should be more flexible in the case of government agencies.

(Response 43) FDA uses self-assessment tools in various government-to-government programs. As one comment notes, we require State governments to conduct annual self-assessments for their work under the

Manufactured Food Regulatory Program Standards (MFRPS) and the Animal Feed Regulatory Program Standards. We also require a foreign government seeking a systems-recognition agreement with FDA to begin the process by completing the International Comparability Assessment Tool, which is a self-assessment tool that we developed based on the approach of the MFRPS self-assessment. Our experience in using self-assessment tools with foreign and State governments suggests to us that self-assessments would be feasible and appropriate in the context of this program as well.

We decline the suggestion to afford more flexibility in deadlines for government agencies serving as recognized accreditation bodies than we afford to other recognized accreditation bodies. Section 808 of the FD&C Act makes no distinction between public and private accreditation bodies, and the proposed rule would place the same workload burden on private accreditation bodies as it would on public accreditation bodies. The comments fail to explain why the differences in nature of public and private accreditation bodies justify flexible deadlines for governmental accreditation bodies but not private accreditation bodies.

(Comment 44) Some comments suggest that accreditation body self-assessments under proposed § 1.622 should be done in concert with its monitoring of certification bodies under proposed § 1.621, because it would be more efficient and would reduce the burden on eligible entities that were observed during regulatory audits. Other comments question the need for accreditation body self-assessments to include requirements for observations, because they read our preamble discussion of proposed § 1.621 as a signal that we would be requiring accreditation bodies to conduct annual onsite observations of each certification body under that provision.

(Response 44) We agree that self-assessments under § 1.622 can be done in concert with monitoring under § 1.621. As described in Response 39, we do not intend the self-assessment and monitoring requirements of the rule to be duplicative. Having added requirements for observations and certification body site visits to certification body monitoring requirements in the final rule, we are revising § 1.622(b) to clarify that accreditation bodies may consider the results of any observations or visits conducted under § 1.621(b) in its self-assessments.

(Comment 45) Comments also suggest that international standards could provide guidance on improving the efficiency and effectiveness of an accreditation body's self-assessment. Some comments specifically suggest that FDA could rely on the internal audits and management reviews that are required under ISO/IEC 17011:2004 (Ref. 5) instead of requiring its own self-assessments.

(Response 45) We agree that documentation of internal audits and management reviews required under ISO/IEC 17011:2004 (Ref. 5) could be useful to help demonstrate compliance with the requirement for self-assessments under this program. We have revised § 1.622(d) and made a conforming change to § 1.623(b) to specifically allow a recognized accreditation body to use reports of internal audits and management reviews prepared for conformance with ISO/IEC 17011:2004 (Ref. 5), supplemented as necessary, to demonstrate compliance with the accreditation body self-assessment requirements of § 1.622.

D. What reports and notifications must a recognized accreditation body submit to FDA? (§ 1.623)

Proposed § 1.623 would require recognized accreditation bodies to submit to FDA reports of its self-assessments and annual re-assessments of certification bodies within 45 days of completing the assessment. The proposed rule also would require notification to FDA of matters affecting recognition and accreditation status; notice of denials of accreditation and any significant change that would affect how the accreditation body complies with this rule would be required within 30 days, while immediate notification would be required for other matters (*e.g.*, grant or withdrawing accreditation). Under the proposed rule the reports and notifications would have to be submitted electronically and in English.

On our own initiative, we are revising § 1.623(c)(1)(i) and (d)(1)(i) to require the recognized accreditation body to provide FDA the email address of any third-party certification body that was granted or denied accreditation (respectively) under our program. Having the email address will facilitate FDA's communications with such third-party certification bodies. We also are revising § 1.623(c)(1)(iv) on our own initiative to specify that a recognized accreditation body must also notify FDA of the expiration date of accreditation upon granting accreditation to a third-party certification body under this subpart.

(Comment 46) Some comments ask whether FDA intends to provide feedback in response to self-assessment reports.

(Response 46) While FDA will not be providing formal responses to the self-assessment reports, we will use the information in the reports in our oversight of the third-party certification program and will address any specific items of concern we identify in an accreditation body-self-assessment report directly with the accreditation body.

(Comment 47) We received several comments related to our proposal to require all reports and notifications to be submitted in English. Some comments agree that both the notifications and the reports should be submitted in English. Some comments agree that notifications should be in English, but suggested that reports of self-assessments and re-assessments of certification bodies could remain in their native language, and if FDA had any questions about such reports the accreditation body could furnish English translations.

Some comments note the difficulty and others the expense for recognized accreditation bodies in countries that do not officially or routinely conduct business in English. Some comments request a longer period of time (*e.g.*, up to 4 months) to submit documents that must be translated into English. Other comments note that if we require documents to be in English, and the translations are not done well, the documents may be difficult to understand.

Some comments propose alternative solutions, including comments that suggest that FDA explore technical translation and recognition software, which in combination with standardized report/notification templates, might facilitate submission in languages other than English. Other comments suggest that if reports and notifications are submitted in languages other than English, the recognized accreditation body should be responsible for all translation costs.

Some comments ask whether supporting documents that accompany reports also would have to be in English. Other comments inquire whether there is any flexibility in the language requirement for governmental accreditation bodies that do not maintain their records in English.

(Response 47) We decline the suggestion to remove the requirement to submit reports and notifications in English. While allowing submissions in multiple languages might be helpful to some interested parties, the

accreditation body reports and notifications required by § 1.623 are essential to our oversight and management of the third-party certification program and the programs that rely on certifications issued by accredited third-party certification bodies, and thus, must be in English in order for FDA to properly review and evaluate. Some comments ask to have up to 4 months to prepare an English translation of a submission under proposed § 1.623. Such delays would be unworkable. For example, we cannot afford delays in translating an accreditation body's notification of withdrawal of accreditation, or an accreditation body's notification that a certification body has issued a food or facility certification without meeting the requirements of this rule. We are requiring immediate notification of these and other matters under § 1.623(c) because of the implications for the program and possibly for our acceptance of certifications issued by the certification body. Unless the notification is submitted in English, our actions will be delayed until the information is translated. Although the annual certification body monitoring reports and the accreditation body self-assessments reports are not required to be submitted until 45 days after completion under § 1.623(a) and (b)(i) (and 60 days following certification body withdrawal for self-assessment reports submitted under § 1.623(b)(ii)), we will use these reports to identify areas where FDA may need to promptly engage with an accreditation body or a certification body to address apparent misunderstandings or confusion about our program requirements. We plan to use these reports to identify emerging issues that need intervention. Therefore any additional time allotted for translation purposes would delay and possibly hinder our ability to use these reports for program evaluation and management.

(Comment 48) Some comments address the proposed timeframes for submitting reports and notifications, and suggest that instead of requiring reports within 45 days of completing the assessment/re-assessment, we should require submission every 6 months or annually.

(Response 48) We disagree with comments suggesting that we modify the timeframe for submission of reports of annual self-assessments and annual certification body monitoring reports from 45 days after completion to every 6 months or every year. We are concerned that the information could be outdated and our ability to use the

reports for early intervention would be significantly diminished.

(Comment 49) Some comments contend that the volume of reports and notifications we proposed to require would be burdensome to FDA to review and maintain. They suggest that instead we require recognized accreditation bodies and their certification bodies to maintain reports of self-assessment/re-assessment, and provide prompt access to FDA upon request.

(Response 49) We disagree. We are establishing an electronic portal for submission of applications, reports, notifications, and other information under this rule and an electronic repository of this information, which will allow us to access and use the information as needed. Therefore, we decline to revise § 1.623 in response to these comments.

(Comment 50) Some comments ask if all reports and notifications submitted to FDA will be subject to the Freedom of Information Act (FOIA) or if these submissions will be considered confidential information with reasonable protections from disclosure. Other comments suggest the importance of striking the appropriate balance between disclosure and confidentiality and note the following statements in ISO/IEC 17021:2011 (Ref. 6), clause 4.1.3 and NOTE: "Principles for inspiring confidence include: Impartiality, competence, responsibility, openness, confidentiality, and responsiveness to complaints. . . . An appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints, is necessary in order to demonstrate integrity and credibility to all users of certification."

(Response 51) We agree with comments suggesting the importance of striking the appropriate balance between providing transparency to the public and maintaining the confidentiality of any trade secrets and confidential commercial information included in the applications, reports, notifications, and other information submitted to FDA. We are guided in this effort by FOIA as well as laws that protect trade secrets and confidential commercial information from disclosure. In response to comments, we are adding new § 1.695 on public disclosure, which is discussed in section XIII.F.

(Comment 51) Some comments urge us to eliminate or reduce the proposed reporting requirements in proposed § 1.623(a) and (b), for various reasons. Some of these comments suggest that we should only require regular submission

of a report or other document that shows the third-party certification bodies are maintaining their accreditation. Other comments recommend that when a certification body is first accredited, it should submit translated accreditation documents within 3 to 4 months of the accreditation body's decision. Then, as long as the accreditation is unchanged, it should not be necessary for the accreditation body to submit its—assessment reports under § 1.623(a).

Some comments suggest it should not be necessary for accreditation bodies to submit their self-assessment reports under § 1.623(b) if there is no significant change in their recognition. Other comments assert that signatories to IAF MLAs should not have to submit self-assessment reports to FDA, because IAF monitors accreditation bodies for continued compliance with ISO/IEC 17011:2004 (Ref. 5).

(Response 51) We disagree. As described in Response 47, the reports of annual certification body monitoring and accreditation body self-assessments are essential to our oversight and management of the third-party certification program and the programs that rely on certifications issued by accredited third-party certification bodies. We are not requiring accredited third-party certification bodies to submit their self-assessments to FDA (except for directly accredited third-party certification bodies); therefore, the reports that we receive of the recognized accreditation bodies' assessments of accredited third-party certification bodies are a fundamental piece of the monitoring system we are establishing, as are the self-assessment reports submitted by accreditation bodies we have recognized. Reducing or eliminating either of these reporting requirements would hinder our ability to properly oversee the program.

(Comment 52) We received some requests for clarification regarding required content of the accreditation self-assessment reports and reports of certification body annual monitoring. Some comments request that FDA either suggest a format for the reports, provide an opportunity for accreditation bodies to propose a format, or at least indicate the minimum required elements.

(Response 52) We believe we provided minimum requirements on the content of these reports in this rule and plan to provide additional information on the format and submission of these reports on our Web site.

(Comment 53) Comments suggest that to be consistent with ISO/IEC 17011:2004 (Ref. 5), a recognized accreditation body only would need to

notify FDA of the approval, suspension, or withdrawal of accreditation of a third-party certification body, as well as any changes in its scope of the accreditation scope or reduction of authorization. The comments assert that the notification should not need to include such details as the address and name of third-party certification body employees under § 1.624(c)(1).

(Response 53) We agree that submission of the information described in the comment and required by clause 8 of ISO/IEC 17011:2004 (Ref. 5) is necessary for our program management and oversight. For example, it will help us verify the identity of any certification body before taking an action to affect its status in the program based on a notification submitted under § 1.623. However, the notifications required under § 1.623(c)(3) and (d) are also necessary for our program management and oversight. Under § 1.623(c)(3), a recognized accreditation body would have to notify FDA if one of its accredited third-party certification bodies issued a food or facility certification without complying with the requirements of this rule. This notification will allow FDA to refuse to accept those improperly issued certifications and to coordinate with the accreditation body in determining appropriate next steps. Having information on a denial of accreditation under § 1.623(d) will allow FDA to monitor accreditation activities across the program, including any repeat denials of a third-party certification body.

With respect to providing the names of the audit agents of the accredited third-party certification body, we note that section 808(b)(1)(B) of the FD&C Act requires a recognized accreditation body to submit to FDA a list of all third-party certification bodies it accredited under the program and the audit agents of such accredited certification bodies. The list of audit agents we proposed to require a recognized accreditation body to submit under § 1.623(c)(1)(iii) is necessary for verification of compliance with the conflict of interest requirements by audit agents under section 808(c)(5)(A)(iii) and (B) of the FD&C Act and by proposed § 1.657, among other things. With respect to the proposed requirement to provide the address and name of one or more of the officers of the accredited third-party certification body, this information will be helpful in communicating with the accredited third-party certification body.

For the foregoing reasons, we decline the suggestion to eliminate the requirements for the recognized

accreditation body to provide FDA the name of one or more officers of the accredited third-party certification body under § 1.623(c)(1)(ii) and a list of audit agents of the accredited third-party certification body under § 1.623(c)(1)(iii).

E. How must a recognized accreditation body protect against conflicts of interest? (§ 1.624)

Proposed § 1.624 would require a recognized accreditation body to take certain steps to safeguard against conflicts of interest, including the requirement to implement a written conflict of interest program. The accreditation body would be prohibited from owning, having a financial interest in, or managing/controlling a certification body. Under the proposed rule, accreditation body employees would be unable to accept money, gifts or other items of value from the certification body, though we did exempt meals of de minimis value onsite where the assessment occurs. We also proposed to require that a recognized accreditation body maintain on its Web site a list of certification bodies it accredited under this program, the duration and scope of accreditation, and the date on which the certification bodies paid their fee or reimbursement associated accreditation. We sought comment on alternative approaches for public disclosure of payments.

On our own initiative, we are adding new provision § 1.624(b) to clarify when a recognized accreditation body can accept the payment of fees for its services so that the payment is not considered a conflict of interest for purposes of § 1.624(a).

(Comment 54) Some comments agree that a recognized accreditation body should be required to have a written program to protect against conflict of interest. Comments suggest that the written plans should include assurances of independence and safeguards to address any possibility of conflicts. Some comments state FDA should require accreditation bodies to make their conflict of interest policies public.

(Response 54) We agree with comments about the importance of a recognized accreditation body having a written program to safeguard against conflicts of interest that meets the requirements of this rule. While a recognized accreditation body may choose to make its conflicts of interest program publicly available, we are not imposing that as a program requirement because we do not believe it is necessary to ensure that accreditation bodies safeguard against conflicts of interest.

(Comment 55) We received several comments related to allowing certification bodies to provide onsite meals of de minimis value to accreditation body representatives conducting an audit. Several comments agree with the general concept of allowing meals of de minimis value. Some supporting comments state that allowing such meals would expedite the assessment, and could be necessary if the certification body is distant from meal service providers. With respect to the question of what constitutes “de minimis” value for these purposes, some comments endorse the idea of defining de minimis value in accordance with U.S. Government employee limits on accepting gifts or gratuities. Others simply encourage us to define it in some way that ensures consistency and clarity. Some comments state that we should not set a fixed amount for the de minimis value, because costs vary in different locations.

Some comments disagree with the proposal to allow meals of de minimis value, and contend that the financial relationship between the accreditation body and the certification body should be strictly limited to the fee paid for the accreditation audit/services.

(Response 55) We agree with the comments that suggest that allowing the certification body to provide meals of a de minimis value during an assessment and at the site where the assessment is being conducted might help facilitate the assessment, particularly for remote sites. We also agree with comments that state we should not set a fixed amount for the de minimis value because costs vary in different locations.

We disagree with comments suggesting that by providing meals of a de minimis value, a certification body might influence the outcome of an accreditation body assessment, particularly if the only allowable meals are ones of minimal value that are provided during the course of an activity and with the purpose of facilitating timeliness and efficiency. FDA follows a similar approach for investigators conducting foreign inspections—that is, FDA investigators performing foreign inspections are allowed to accept lunches (of little cost) provided by the firm during the course of a foreign inspection. We also note that the U.S. government allows its employees to accept meals, within per diem limits, when on official business in a foreign country, as an exception to the prohibition on the acceptance of gifts or gratuities from outside sources (5 CFR 2635.204(i)(1)), though we believe the FDA’s practices for foreign

inspections serve as a better model because foreign inspections are more analogous to foreign assessments than are the range of activities that covered by the general requirements applicable to all U.S. government employees on official business in foreign countries. Accordingly, in light of the comments received and analogous FDA guidelines, we have concluded that it is reasonable and appropriate to limit the meal exception in § 1.624(a)(3)(ii) to only lunches of de minimis value provided during the course of an assessment, on site at the premises where the assessment is being conducted, and only if necessary to facilitate the efficient conduct of the assessment. We believe these revisions help to address concerns regarding the threats to impartiality, while accommodating the practical considerations that apply to foreign assessments.

We offer the following additional input to recognized accreditation bodies seeking guidance on the application of § 1.624(a)(3)(ii). In considering whether a meal is allowable under this provision, we recommend that the assessor first consider whether accepting the lunch is necessary to facilitate the efficient conduct of the assessment. We recommend the assessor consider: (1) Whether the circumstances surrounding the travel would allow the assessor to pack a lunch to bring on site; (2) Whether the meal is being provided during the midday or early afternoon. A lunch provided in the midst of an assessment is different than a lunch or other meal provided at the completion of the audit; (3) Whether the site of the assessment is in close proximity to a retail food establishment, or is at a remote location far from a retail food establishment; (4) What is the estimated value (or cost) of the lunch in light of the costs associated with the area where the assessment is being conducted; and (5) other similar considerations.

For assessors seeking additional guidance on determining what constitutes a “de minimis” amount for purposes of complying with § 1.624(a)(3)(ii), we offer the following guidance that is based on the requirements applicable to U.S. government employees who accept certain meals while on official travel in foreign countries. Such employees must deduct from the per diem the value of that meal, calculated using a two-step process.

First, the individual must determine the per diem applicable to the foreign area where the lunch was provided, as specified in the U.S. Department of State’s Maximum Per Diem Allowances for Foreign Areas, Per Diem Supplement

Section 925 to the Standardized Regulations (GC,FA) available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, and available on the Department of State Web site at https://aoprals.state.gov/Web920/per_diem.asp. (Foreign per diem rates are established monthly by the Department of State's Office of Allowances as maximum U.S. dollar rates for reimbursement of U.S. Government civilians traveling on official business in foreign areas.)

Second, the individual must determine the appropriate allocation for the meal within the daily per diem rate which is broken down into Lodging and M&IE (Meals & Incidental Expenses) that are reported separately in Appendix B of the Federal Travel Regulation and available on the Department of State's Web site at https://aoprals.state.gov/content.asp?content_id=114&menu_id=78.

(Comment 56) Our proposal to require accreditation bodies to maintain a Web site listing of certification bodies, and information about each, drew several comments. Most comments agree with the Web site listing in principle. Some comments encourage us to require additional information in the Web site listing, such as requiring accreditation bodies to include in their Web site listing those certification bodies whose accreditations have been suspended or revoked. Some comments advise that the "scope" information required on the Web site should be specific (*e.g.*, whether the accreditation is for human food, animal food, or for specific rules).

Additionally, many comments address the proposed requirement to include fee information in the Web site listing. Some comments suggest that we require recognized accreditation bodies to specify what is included in the fee payment and what costs are reimbursable. We also received comments arguing that requiring payment schedules to be posted online is not sufficient to ensure that potential conflicts of interest will be identified; they suggested we require accreditation bodies to submit payment schedule information directly to FDA.

Some comments disagree with the proposed requirement to require the Web site posting of payment schedules contending, among other things, that such information is proprietary. Some suggest that, instead, FDA should require accreditation bodies to keep records of payments which would be available to FDA if we have reason to examine them. Others suggest it would be sufficient for the financial payment information to be maintained such that

FDA could review it during the recognition/renewal process. Still other comments seek clarification as to whether we would be requiring, in addition to the date of payment, the dollar value of payment. These comments are not in favor of such a requirement; they state such payment details constitute sensitive information and argue that FDA should instead require the amount of payment to be in the records required under § 1.625.

(Response 56) We agree with comments that state that an accreditation body's Web site posting under § 1.624(c), finalized as § 1.624(d), must include specific information about the scope(s) of accreditation, for example by relevant part of 21 CFR or by a designation, such as "part 123" or "Seafood HACCP" (Hazard Analysis Critical Control Point). We also are revising final § 1.624(d) to state that an accreditation body's Web site must identify a certification body whose accreditation was suspended, withdrawn, or reduced in scope, because we believe that this information would be important to eligible entities seeking information on accredited certification bodies. The suspension or withdrawal information must be maintained on the Web site for 4 years (the maximum duration of an accreditation under the rule) or until the suspension is lifted or the certification body is reaccredited by that accreditation body, whichever occurs first.

In the interest of transparency, we are maintaining the requirement for accreditation bodies to post information on the timing of fee payments and direct reimbursements by certification bodies. This posting requirement is similar to the posting requirements that apply to certification bodies under § 1.657(d) and will help build confidence in the impartiality of accreditation body accreditation decisions. We are not requiring posting of the amount of fees or reimbursement paid, because we do not think it is necessary to help build confidence in the impartiality of accreditation body accreditation decisions. We agree with the suggestion to specifically require fee payment records to be maintained and are revising § 1.625 accordingly.

(Comment 57) Some comments contend that § 1.624 is seriously flawed because it is inconsistent with "the latest science on the issue" and a 2009 Institute of Medicine (IOM) Report, "Conflicts of Interest in Medical Research, Education, and Practice." They encourage FDA to evaluate the most recent scientific research on conflicts of interest and consult with

leading academicians involved in such work. They contend that the fact of payment by the certification body to the accreditation body creates a conflict of interest that cannot be avoided so we should aim our regulation to minimize it. They recommend that we prohibit any financial relationship between the accreditation body and a certification body it audits for at least 1 year before accreditation was sought and 1 year after the last accreditation expires or was denied.

(Response 57) While we agree with the comments' suggestion to remain vigilant in ensuring that our conflict of interest protections represent current best practices, we disagree with the assertion that § 1.624 is seriously flawed and have concluded that the suggested revision would be infeasible and impractical. Third-party certification bodies currently accredited for food safety auditing by accreditation bodies that become recognized by FDA would have to apply to another recognized accreditation body to join our program if the comments' suggestion were adopted. This would create a disincentive to participation by experienced third-party certification bodies and would pose difficulties when the availability of recognized accreditation bodies is limited.

In response to comments citing the 2009 IOM report on financial conflicts of interest between medical researchers and medical products companies, we note that it identified some conflict of interest issues that also are relevant to our third-party certification program, such as the need to disclose payments from industry and to place limits on meals and gifts. However, the differences between the context of medical research and practice and the context of our third-party certification program pose difficulties in identifying practical implications of the analysis for our purposes—*i.e.*, the analysis of data suggesting that the acceptance of meals and gifts and other relationships may influence physicians to prescribe a company's medicines. Nor are the IOM recommendations readily adaptable to conflicts of interest in the third-party certification program. The "best practices" we employ must be suitable for the third-party certification program and may differ from the state of the art best practices for conflict of interests in medical research. For example, the recommendations to place limits on the use of drug samples for patients who lack financial access to medications and to prohibit the claiming of authorship for ghost-written publications are not applicable to this program. For the foregoing reasons, we decline the

suggestion to prohibit any financial relationship, such as the payment of fees, between a recognized accreditation body and a certification body for at least 1 year before seeking accreditation and 1 year after the last accreditation expires or is denied.

(Comment 58) Some comments reject the notion that there could be effective protections against conflict of interest. Such comments consider third-party food safety audits to possess inherent shortcomings and believe that FDA itself should conduct any food safety inspections required by FSMA.

(Response 58) We disagree with the notion that it is not possible to effectively protect against conflicts of interest. Currently, accreditation bodies and certification bodies operate under a number of private schemes successfully, with reasonably effective protections against conflicts of interest. We note that the primary regulatory functions of the third-party certification program are to facilitate participation in VQIP and to provide certifications for the purposes of section 801(q) of the FD&C Act. At this time, we do not intend for private third-parties to conduct food safety inspections required by FSMA.

F. What records requirements must an accreditation body that has been recognized meet? (§ 1.625)

Proposed § 1.625 identifies specific types of documents a recognized accreditation body would be required to establish, control, and maintain to document compliance with applicable requirements (including applications for accreditation and for renewal; regulatory audit reports and supporting information from its accredited auditors/certification bodies; reports and notifications required under proposed § 1.623, along with any supporting information). The recognized accreditation body would be required to provide FDA access to such records. The rule also proposed to require records to be maintained electronically and in English for 5 years.

In the proposed rule we acknowledged that the contracts between accreditation bodies and certification bodies frequently include confidentiality provisions that might otherwise prevent disclosure of certain records to FDA without prior approval of the certification body. We noted that any such contract provisions would need to be changed to allow the accreditation body to furnish FDA with the records identified in this section.

On our own initiative, we are including fee payment records as another type of record that an accreditation body that has been

recognized must maintain under § 1.625(a)(8).

(Comment 59) Several comments disagree with the proposed requirement for records to be maintained in English. Some comments, while noting their support for submission of reports and notifications in English under proposed § 1.623, disagree with our proposal to require that records maintained by the accreditation body be kept in English as well. Some comments, noting the cost of translating all records, request that we allow records to be maintained in the language of the country. They propose we could require the accreditation body to provide the records in English upon our request within a reasonable time; some suggest a reasonable time might be a week, depending on the volume of records requested. Other comments argue that the food industry is global and in recognition of that fact FDA should accept records in other languages. Some comments suggest that we allow three or four additional widely-used languages.

(Response 59) We agree with the recommendation to allow records held by the accreditation body to be maintained in a language other than English, coupled with a requirement that, upon FDA request, the accreditation body must provide an English translation of the records within a reasonable time.

The records required by § 1.625 are necessary to document the accreditation body's accreditation activities, and we expect to request access to the accreditation body's records as necessary to verify the accreditation body's continuing compliance with the requirements of this rule, such as when we are considering whether to renew its recognition. The accreditation body records also will be useful in helping to verify the compliance of certification bodies it accredited under the program. However, the records required by § 1.625 are generally distinguishable from the reports and notifications that must be directly submitted to us under § 1.623, which we are requiring to be submitted to FDA in English because the reports and notifications submitted directly to us are time sensitive in nature and essential to our management and oversight of the third-party certification program. For example, under § 1.623(c) we are requiring immediate notification, in English, of an accreditation body's withdrawal of accreditation from a certification body. We cannot afford delays in translating this information, because of its implications for the program and possibly for our acceptance of certifications issued by the certification

body. Unless the notification is submitted in English, our actions will be delayed until the information is translated.

By contrast, the records required under § 1.625 typically contain information that is less time sensitive; therefore, reasonable delays for translation purposes will not compromise our ability to manage or oversee the program. Accordingly, we are revising § 1.625 to allow other accreditation body records to be maintained and submitted to FDA in languages other than English, provided that an English language translation of such records is provided within a reasonable time thereafter. The circumstances surrounding each request will differ; therefore, we decline to set a specific (numerical) deadline for submission of the translation.

(Comment 60) We received several comments expressing confidentiality concerns. Some comments note that documents that are part of an audit process may contain critical business information that warrants some level of proprietary protection.

(Response 60) We acknowledge comments' concerns and note that we are including § 1.695 on public disclosure in section XIII.F. The new section explains that records obtained by FDA under this subpart are subject to the disclosure requirements under 21 CFR part 20.

(Comment 61) With regard to the proposed requirement that records must be maintained electronically, some comments discourage us from requiring compliance with 21 CFR part 11, which are regulations setting certain electronic records criteria. Comments contend that imposing part 11 requirements would be disproportionate to the need under this rule without an appreciable improvement in food safety and would create a tremendous and costly burden. They encourage FDA to explicitly exclude records under this rule from part 11. Comments propose that instead of imposing part 11 requirements, we require documentation of the chain of custody by requiring records to be signed and dated when created or modified.

(Response 61) We acknowledge comments' concerns and note that we are establishing § 1.694 on electronic records in section XIII.E. This new section will generally exempt records that are established or maintained to satisfy the requirements of this subpart from the requirements of part 11.

(Comment 61) Some comments express concern that our proposed record keeping requirement was too broad; and others express concern about

how we might use our authority to request records. Some comments request clarification of our proposed requirement that accreditation bodies' records include any supporting information for the reports and notifications required under § 1.623. Other comments suggest that our records requests should be narrower when the recognized accreditation body is a foreign government than a records request to a recognized, nonprofit accreditation body. Still other comments encourage us to clarify the circumstances under which FDA staff could request records and to include a method for an accreditation body to object to an FDA records request.

(Response 62) The records we are requiring an accreditation body to maintain under § 1.625 are necessary to document the accreditation body's accreditation activities and its compliance with the requirements of this rule. We expect to request access to the accreditation body's records in verifying an accreditation body's continuing compliance with the requirements of this rule. While the details of each records request will vary depending on its circumstances, we will tailor our records requests under § 1.625 as narrowly as possible to reach program-related records and exclude records that are irrelevant or insignificant to this program. For example, the information an accreditation body reports under § 1.623 may prompt us to request the underlying record to supplement the report as needed. Or, when an accreditation body is requesting renewal of its recognition, we may request records to supplement information provided in the application.

Therefore, we believe it is unnecessary to develop administrative procedures for accreditation body challenges to FDA records requests. We recommend accreditation bodies to fully consider the program requirements before deciding to pursue recognition under the voluntary third-party certification program.

(Comment 63) We proposed that if FDA requests records electronically, the recognized accreditation body provide the requested records within 10 days. Some comments contend that 10 days is insufficient time, and instead request a period of 3 months.

(Response 63) We believe that 10 days is ample time for accreditation bodies to electronically submit any requested records they are already required to maintain under this subpart. We note that we are revising the final rule to allow accreditation bodies to maintain and submit records in languages other

than English, provided that they electronically submit an English translation within a reasonable time thereafter. By allowing records to be submitted in a language other than English, accreditation bodies should be able to provide requested records electronically within 10 days.

VII. Comments on Procedures for Recognition of Accreditation Bodies Under This Subpart

A. How do I apply to FDA for recognition or renewal of recognition? (§ 1.630)

We proposed to establish procedures for accreditation bodies to follow when applying to FDA for recognition or for renewal of recognition. We proposed that the accreditation body must submit a signed application, accompanied by any supporting documents, electronically and in English, demonstrating that it meets the eligibility requirements in proposed § 1.610. We also proposed to require an applicant to provide any translation or interpretation services we need to process the application.

(Comment 64) Some comments assert that the proposed rule does not differentiate adequately between foreign governments and private entities that are serving as accreditation bodies and suggest that we provide a separate path for recognition of foreign government accreditation bodies that prioritizes their applications over those submitted by private accreditation bodies. The comments recommend that we draft additional rules to specifically cover recognition of foreign government accreditation bodies and/or direct accreditation of foreign government certification bodies.

(Response 64) We disagree with the recommendation to create a bifurcated system for recognition, because the line between governmental and private accreditation bodies is not always clear. Private accreditation bodies comprise approximately one third of the 72 accreditation bodies that accredit food safety certification bodies around the world, according to a report prepared by the Research Triangle Institute (RTI) (Ref. 16). In the report, RTI found that the distribution of accreditation bodies by private versus government agency is as follows: 24 private accreditation bodies, 38 governmental accreditation bodies, and 10 accreditation bodies with unknown private or government agency status. RTI found that the vast majority of the private accreditation bodies were non-profit entities. Many of the private accreditation bodies identified by RTI operate under government sanction or

in quasi-governmental roles. For example, the American National Standards Institute (ANSI) is a private, non-profit accreditation body that serves as the official U.S. representative to ISO (Ref. 17); the United Kingdom Accreditation Services is appointed as the national accreditation body for the United Kingdom, though it is independent of the government (Ref. 18); and the Danish Accreditation and Metrology Fund is a self-described "business fund" that is appointed by the Danish Safety Technology Authority as the national accreditation body for Denmark (Ref. 19). Additionally, we note that section 808 of the FD&C Act makes no distinction in the requirements or process for recognizing public or private accreditation bodies. Furthermore, we do not believe it practical to engage in additional rulemaking for foreign government accreditation bodies and certification applications, as the comments suggest.

(Comment 65) Some comments ask us to accept applications in other languages common to the major production areas exporting product to the United States. These comments assert that due to the global nature of produce supply chains allowing applications in other languages would encourage supply chain participation in third-party auditing programs as a tool to improve food safety. These comments suggest that we could develop a phased process where we only accept English applications initially, but increase flexibility to accept applications/renewal documents in other languages as the program builds up.

(Response 65) We acknowledge that accepting applications for recognition in languages other than English might be beneficial to some interested parties. However, requiring applications for recognition to be submitted in English will help us make well-informed and timely decisions. Further, FDA does not have the resources to translate or review documentation in other languages and generally requires documents submitted in other languages to be translated to English. Therefore, we decline the suggestion to develop long-term plans for accepting applications for recognition in languages other than English.

(Comment 66) Some comments ask what costs are associated with getting recognized as an accreditation body.

(Response 66) Pursuant to section 808(c)(8) of the FD&C Act, we issued proposed regulations to establish a reimbursement (user fee) program to assess fees and require reimbursement for the work performed to establish and administer the third-party certification

program. The proposed rule provides details on how user fees would be computed (80 FR 43987, July 24, 2015).

B. How will FDA review my application for recognition or for renewal of recognition and what happens once FDA decides on my application? (§ 1.631)

We proposed to establish procedures for reviewing and deciding on applications for recognition and for renewal of recognition. We proposed to order the application queue on a first in, first out basis and to only place complete applications in the queue.

On our own initiative, we are revising paragraph (a) to clarify that FDA will review submitted applications for completeness and will notify applicants of any identified deficiencies. We also are revising paragraph (b) to clarify that FDA's evaluation of any completed recognition or renewal application may include an onsite assessment of the accreditation body. In addition, we are redesignating proposed paragraph (e) as part of paragraph (b) for clarity.

On our own initiative we are adding new paragraphs (e) through (h) to § 1.631 to explain what happens when an accreditation body's renewal application is denied. We are adding provisions to clarify what the applicant must do, the manner in which FDA will notify accredited third-party certification bodies and the public of the denial, the effect of denial of an application for renewal of recognition on accredited third-party certification bodies, and the effect of denial of an application for renewal of recognition on food or facility certifications issued to eligible entities.

(Comment 67) Some comments ask us to clarify how we will recognize an accreditation body. Some comments ask that we clearly and comprehensively lay out the conditions and requirements governing the application for recognition, to ensure transparency, certainty, and predictability of the procedures and criteria governing recognition. Some comments specifically recommend that we use the IAF/ILAC/International Laboratory Accreditation Cooperation (ILAC) (A-series) documents as the foundation upon which to base our process for recognition of accreditation bodies.

(Response 67) This rule establishes the framework for the third-party certification program and generally describes procedures involved in the submission and processing of applications for recognition and will be supplemented by additional instructions. For example, we are developing an electronic portal that

accreditation bodies will use in submitting their applications for recognition, and we will be issuing directions for using the portal. We also are developing internal operational procedures for recognition of accreditation bodies and will consult the IAF/ILAC (A-series) documents in considering the types of materials that may be useful to accreditation bodies and other stakeholders interested in learning more about our program.

(Comment 68) Some comments express concern that we are limiting ourselves to a "first in, first out" review process that gives us no discretion to recognize foreign governments before we consider other applications from private accreditation bodies that apply. These comments recommend that we use guidance to industry or internal management documents, rather than this rule, to describe how we will establish the queue of applications for review.

(Response 68) For the reasons described in Response 64, we decline the suggestion to prioritize applications submitted by government accreditation bodies over applications submitted by private accreditation bodies. However, we are modifying the first in, first out approach to application review in proposed § 1.631(a) to allow FDA to prioritize an application for review based on program needs. We will consider the suggestion to use an internal management document to establish our procedures for reviewing applications for recognition as part of our operational planning.

(Comment 69) We received several comments on the timeliness of application review and decisionmaking. Some comments assert that our application review process must be comprehensive but also expedient. Some comments ask that our communications with applicants be timely. Other comments ask us to establish review timeframes by which accreditation bodies and other interested parties may expect a response to applications, asserting this will foster enhanced confidence and transparency with the review process. Some comments suggest that we review and act upon an accurately completed recognition application within 90 days and a completed recognition renewal application within 45 days.

(Response 69) We agree with the comments suggesting that our application review must be comprehensive and as expedient as possible. We decline the suggestion to establish review timelines in this rule because we lack the experience and data that would allow us to reasonably

estimate review timeframes. We also recognize that each review will differ depending on the circumstances, and we expect to become more efficient in application review as we gain experience in the program.

(Comment 70) Some comments express concern about the length of time it will take us to recognize and notify an applicant of any deficiencies in the application. These comments also assert that requiring applicants with deficiencies to resubmit their applications and sending them to the bottom of the review list would make for significant delays in the recognition and renewal processes.

(Response 70) FDA agrees that an application for recognition should be checked for completeness promptly after submission. The Agency intends to notify the submitter in a timely manner if the submission is not complete. FDA anticipates that this completeness determination could generally be made within 15 business days, because this is not a decision on the merits of the application. However, given the competing demands on Agency resources, including staff available to conduct review, the Agency declines to add a time restriction in the final rule for notifying an applicant of deficiencies that cause its application to be considered incomplete and thus not ready for processing.

(Comment 71) Some comments assert that we should include a mechanism for stakeholders to provide feedback to the Agency concerning the capacity and functioning of accreditation bodies and auditors/certification bodies because stakeholders have firsthand experience with such entities. These comments suggest that we modify § 1.631(b) to specify that FDA will also "solicit and consider information provided by stakeholders, including importers and foreign suppliers subject to the accreditation body's jurisdiction, to assist in the recognition or renewal application review process."

(Response 71) To the extent the comments suggest that the Agency's review and decisionmaking process on recognition applications should include a solicitation of comments from the public we disagree, as this would create unnecessary delay in the recognition process. FDA believes that the information it gains through the application process will be sufficient to make a recognition determination, and that this process and subsequent monitoring by FDA ensures robust oversight of the program. Nevertheless, stakeholders are always free to share with FDA any information relevant to the Agency's food safety programs. We

note that information shared with FDA is subject to the information disclosure regulations in part 20, as stated in § 1.695.

(Comment 72) Some comments note that there are no circumstances or conditions in the proposed rule that allow for an accreditation body to question or object to an FDA action or request if they believe it is not reasonable or relevant to the recognition and performance of the accreditation body.

(Response 72) We do not expect to make requests or actions of an accreditation body that are not relevant to the requirements of the third-party certification program. FDA's evaluation of accreditation bodies, as expressed in §§ 1.631(b), 1.633(a), and 1.634(a), is premised on the accreditation body's compliance with the applicable requirements of this rule.

We note that in this rulemaking, FDA has established a number of mechanisms to address challenges to FDA's decisions, including § 1.691 (for requests for reconsideration of the denial of an application for recognition, renewal, or reinstatement of recognition); § 1.692 (for internal Agency review of the denial of an accreditation body application upon reconsideration); and § 1.693 (for regulatory hearings on revocation of recognition).

We recommend accreditation bodies to fully consider the program requirements before deciding to pursue recognition under the voluntary third-party certification program.

(Comment 73) Some comments ask that we provide training and education documents regarding the application process as quickly as possible to ensure that accreditation bodies are clear on the process and its requirements. These comments assert that training and education would minimize the need for second reviews due to inaccurate or incomplete applications.

(Response 73) As indicated in Response 67, we are developing additional instructions for applications for recognition that will be useful to accreditation bodies interested in pursuing recognition.

C. What is the duration of recognition? (§ 1.632)

We proposed to grant recognition to an accreditation body for up to 5 years, though we will determine the length of recognition on a case-by-case basis.

(Comment 74) Some comments support our proposal to recognize accreditation bodies for a duration of up to 5 years, with shorter durations awarded early in the program for

accreditation bodies with little experience in accrediting third-party certification bodies.

(Response 74) We agree with comments suggesting that the duration of recognition may vary depending on a number of factors, including the accreditation body's history (or lack of history) in accrediting certification bodies. We believe the proposal allows FDA to consider such factors.

(Comment 75) Some comments express concern that we are not proposing a fixed duration of recognition and ask us to establish a specific time limit of 5 years. These comments assert that having a standardized duration of recognition for all accreditation bodies is administratively more viable for FDA to plan its resource needs and would provide consistency across the industry. Additionally, these comments assert that 5 years is a reasonable duration given the other reporting and monitoring requirements built into the system.

(Response 75) We acknowledge the advantages that certainty provides and, where appropriate, the Agency will grant recognition for the maximum duration of 5 years. However, as noted in our previous response, we also recognize it may be appropriate for the duration of recognition to vary depending on a number of factors. Where, for example, an accreditation body has little or no experience in accrediting food safety certification bodies, we may decide the initial grant of recognition should be less than 5 years.

(Comment 76) Some comments suggest that the duration of recognition for an accreditation body should be 4 years to be consistent with the duration proposed for accreditation of certification bodies in § 1.661. Other comments request clarification about the difference in durations proposed for recognition of accreditation bodies and accreditation of certification bodies.

(Response 76) We decline the suggestion to shorten the maximum duration of accreditation body recognition to 4 years and note that the comments suggesting it should be the same maximum duration as third-party certification body accreditation offered no information that would provide an adequate basis for shortening recognition such that an accreditation body could be recognized for no longer than a certification body's accreditation. Further, as stated in the proposed rule, we noted that other government programs such as the Substance Abuse and Mental Health Services Administration program for accredited

programs that use opioid agonist treatment medications approves accreditation bodies for up to 5 years (42 CFR 8.3). Under the FDA mammography program, we may approve accreditation bodies for terms up to 7 years (21 CFR 900.3(g)). As stated previously, FDA may establish a period of recognition of less than 5 years if appropriate for a particular applicant.

(Comment 77) Some comments assert that accreditation bodies that maintain their IAF signatory status should not be limited to a 5-year duration.

(Response 77) We decline the suggestion, noting that the comment lacks information demonstrating that a longer term of recognition is warranted for an accreditation body that is an IAF signatory.

D. How will FDA monitor recognized accreditation bodies? (§ 1.633)

We proposed to establish the frequency and manner for formal evaluations of recognized accreditation bodies. Specifically, we proposed to evaluate each recognized accreditation body by at least 4 years after the date of recognition of an accreditation body granted a 5-year term of recognition and by no later than the mid-term point for an accreditation body granted a term of recognition of less than 5 years. Proposed § 1.633 also notes that FDA may conduct additional assessments of recognized accreditation bodies at any time.

(Comment 78) While the comments generally support FDA performance assessments of recognized accreditation bodies, the comments express a wide range of views on how frequently such assessments should occur. Some comments support the proposed reevaluation frequency for recognized accreditation bodies. Some comments assert that we need to have a more suitable monitoring mechanism. Other comments suggest we incorporate a random, unannounced performance review for recognized accreditation bodies as a supplement to the proposed frequency. Some comments take a contrary view, asking us to clarify in the final rule the circumstances under which we may perform additional performance assessments of recognized accreditation bodies. These comments assert that FDA's ability to conduct additional audits, assessments, and investigations without the requirement to justify such actions creates the potential for a confrontational relationship and lack of trust. The comments question whether, without such clarification, any refusal by an accreditation body to grant FDA access or information would trigger revocation

of their recognition. Still other comments request clarification on the frequency of audits that will be conducted on accreditation bodies.

(Response 78) Monitoring assessments of accreditation bodies are one of several tools we will use for program oversight. Section 1.633(a) implements section 808(f) of the FD&C Act, which states that FDA must reevaluate a recognized accreditation body periodically, or at least once every 4 years, and take any other measures FDA deems necessary to ensure compliance. We anticipate that information gleaned from other monitoring tools, such as an accreditation body's self-assessment, may prompt additional performance assessments in certain instances. Although we decline to specifically codify random, unannounced performance reviews as a supplement to the proposed frequency as suggested by the comment, we note that under § 1.633(a) FDA may conduct additional assessments of recognized accreditation bodies, including unannounced assessments, at any time as it deems appropriate. We need to retain flexibility to conduct additional audits, assessments and investigations to support the credibility of the program.

With respect to the request to clarify whether any refusal to grant FDA access or information for a performance assessment would trigger revocation, under section § 1.634(a), refusal to allow FDA to conduct an assessment to ensure the accreditation body's continued compliance with the requirements of this subpart is grounds for revocation.

(Comment 79) Some comments assert that we should provide additional detail on our monitoring procedures under § 1.633(b). Some comments express concern about the ambiguity of the term "statistically significant" as well as the scope of onsite assessments and onsite audits for performance evaluation purposes. These comments assert that we must provide clear guidance to industry as to what we expect would be involved in such onsite assessments and make this guidance available for public comment. Other comments specifically request that we outline the procedures under which we will conduct audits on accreditation bodies and third-party certification bodies and specify a timeframe for when we will issue the results of the audits. Still other comments assert that we must provide guidance on how an eligible entity might be selected for an audit/inspection that relates to an accreditation body's reassessment of a certification body.

(Response 79) The objective of an assessment under § 1.633 will be to

determine an accreditation body's compliance with the requirements of this rule. When planning an assessment, we will establish the time period of activities covered by the assessment and may request records of an accreditation body under § 1.625. We also will develop plans for any locations to be visited, which may include the accreditation body's headquarters and any other locations where employees and other agents who conduct activities under this program are managed.

In conducting the assessment, we may review records, such as records relating to conflicts of interest and may interview officers, employees, and other agents of the accreditation body. We also may observe regulatory audits by certification bodies the accreditation body has accredited. For the reasons explained in Response 28, we have removed the phrase, "statistically significant" and revised the sentence to explain that we may observe a "representative sample" of certification body regulatory audits when conducting an assessment of its accreditation body. We will decide what constitutes a "representative sample" for purposes of § 1.633 on a case-by-case basis, based on factors such as how many certification bodies the accreditation body has accredited under the program, the scope of accreditation of the certification bodies accredited by the accreditation body, how many years the accreditation body has been in the program, how many prior assessments of the accreditation body we have performed, and the length of time since any prior assessments.

(Comment 80) Some comments ask that we inform recognized accreditation bodies prior to doing onsite assessments of accredited certification bodies and eligible entities as part of our performance evaluations.

(Response 80) In planning an assessment with onsite observations of certification bodies or an audit of certified eligible entities, we will consider whether to provide notice to the accreditation body and/or invite the accreditation body to be present. In some circumstances we may determine that it would be necessary or appropriate to conduct the assessment or audit without notice to the accreditation body.

(Comment 81) Some comments assert that to carry out performance evaluations for the purpose of monitoring recognized accreditation bodies, we must have an agreement directly with the certification bodies or request that recognized accreditation bodies include these requirements in

their agreements with certification bodies they have accredited.

(Response 81) We disagree that we must have an agreement directly in place with each accredited certification body for us to carry out performance evaluations, as § 1.633(b) states that FDA may include onsite assessments of a representative sample of third-party certification bodies the recognized accreditation body accredited and onsite audits of a representative sample of eligible entities certified by such third-party certification bodies under this subpart. We recommend that third-party certification bodies fully consider the program requirements before deciding to pursue accreditation under this voluntary third-party certification program. We also encourage recognized accreditation bodies to include language in their standard contracts with third-party certification bodies they accredit under this program that acknowledges FDA's ability to conduct such evaluations.

(Comment 82) Some comments ask who will cover the costs of audits on recognized accreditation bodies.

(Response 82) As discussed in Response 66, we are proposing in a separate rulemaking (80 FR 43987) the costs of FDA monitoring of recognized accreditation bodies will be covered by user fees that we will establish by regulation.

E. When will FDA revoke recognition? (§ 1.634)

Proposed § 1.634 establishes the criteria and procedures for revocation of recognition of an accreditation body, including requests for records and notifications. It describes several circumstances that warrant revocation of recognition and describes the effects (if any) of revocation on accreditations and certifications occurring prior to the revocation.

On our own initiative, we are revising § 1.634(c)(2) to require the accreditation body to notify FDA of the name and contact information of the custodian who will maintain the records required by § 1.625 instead of just providing us with a location to increase flexibility. We are making corresponding changes to §§ 1.635(a), 1.664(e)(2), and 1.665(a). We also are revising paragraphs (d) through (f) to clarify the manner of FDA's notice to affected third-party certification bodies and the public of the revocation, as well as the effect of such revocation on the accredited third-party certification bodies and certifications they issued prior to issuance of the revocation of recognition.

(Comment 83) Some comments recommend that when an accreditation

body's recognition is revoked, the information on the Web site includes the cause or causes of the revocation.

(Response 83) We agree and will include on the FDA Web site a brief description of the grounds whenever revoking the recognition of an accreditation body.

(Comment 84) Some comments agree that providing the certification body 1 year to transition and become accredited with another accreditation body is a reasonable concept, but express concerns that in many countries a limited number of accreditation bodies may make meeting that timeframe difficult. They also note that although audited entities' certifications may remain in effect until its expiration, it may be difficult for them to maintain their certifications beyond that date due to lack of accreditation bodies, or there may be instances in which their certification is set to expire in weeks or months following the revocation. These comments note a similar concern about the impact of a lack of capacity on scheduling certification audits should the certification body have to be reaccredited within 1 year. Comments recommend that FDA address this issue by performing an assessment of accreditation capacity in key production regions around the world and using that information as a baseline to inform timeframes on re-accreditation of third-party certification bodies. Other comments suggest that either FDA be required to renew the recognition of the recently revoked accreditation body or recognize a new accreditation body in time for any affected accredited certification body to comply, or FDA would be required to solicit applications for a new accreditation body after an accreditation body's recognition is revoked. Comments also recommend that certifications issued by a certification body accredited by the accreditation body whose recognition was revoked remain in effect for 1 year from the date of the revocation of the accreditation body in order to reduce the likelihood of a lapse in certification of eligible facilities.

(Response 84) We acknowledge that revocation of the recognition of an accreditation body may present difficulties for the certification bodies accredited by the accreditation body (and for the eligible entities those certification bodies certified), particularly in countries that have a single national accrediting authority. In such circumstances, we intend to work with recognized accreditation bodies and the certification bodies to identify opportunities and challenges. We believe 1 year is sufficient time for a

certification body to be reaccredited in such circumstances. The requirement for an eligible entity to become recertified after a certificate terminates by expiration is based on section 808(d) of the FD&C Act, which requires an eligible entity to apply for annual recertification. In light of the foregoing, we are declining the requests to extend the deadlines for reaccreditation and for recertification in the case of revocation of recognition of an accreditation body.

(Comment 85) Some comments request FDA provide specific provisions to address potential questions that may arise if recognition of an accreditation body is revoked, with particular emphasis on the validity of certificates or other documentation already issued when revocation occurs.

(Response 85) Section 1.634(d) specifically describes the impact of revocation of recognition of an accreditation body on the certification bodies that it accredited under this program, including that a certification body's accreditation will remain in effect if it provides a self-assessment to FDA within 60 days of issuance of the revocation and it is accredited by another recognized accreditation body or FDA no later than 1 year after the revocation or the original date of expiration of the accreditation, whichever comes first. Section 1.634(e) explains that in the case of revocation of an accreditation body's recognition, a food or facility certification issued by a certification body accredited by the accreditation body prior to the revocation of its recognition will remain in effect until the certification terminates by expiration.

(Comment 86) Some comments request that FDA clarify how individual holders of certifications would be made aware of the revocation of recognition. For example, they ask if FDA would contact certification holders directly or if the certification holder would be required to monitor the recognition status of the accreditation and certification bodies.

(Response 86) We will provide notice on the FDA Web site when we revoke the recognition of an accreditation body. We also will notify certification bodies that have been accredited by the accreditation body that has had its recognition revoked through the electronic portal we are establishing. Because revocation of recognition will not affect the duration of previously issued certificates, we will not directly contact eligible entities to inform them of the revocation. If the revocation of recognition results in the withdrawal of accreditation of a certification body, FDA will provide notice of such

withdrawal on our Web site as provided in § 1.664(h).

(Comment 87) Some comments recommend that FDA refer to the provisions in ISO/IEC 17011:2004 and ISO/IEC 17021:2011 to inform the provisions revocation of recognition in § 1.634 and withdrawal of accreditation in § 1.664 and to distinguish those actions from reduction in scope of recognition and accreditation and to establish the specific grounds and effects for those actions.

(Response 87) Neither of the ISO/IEC standards cited in the comments relate to revocation of recognition of an accreditation body; however, we reviewed ISO/IEC 17011:2004 (Ref. 5) for terminology, procedures, and grounds that might have relevance for revocation of recognition in § 1.634. We decline the suggestion to consider ISO/IEC 17021:2012 (Ref. 6), which applies to certification bodies, for purposes of this analysis as it is inapplicable.

Having reviewed ISO/IEC 17011:2004, we note that ISO/IEC 17011:2004 (Ref. 5) gives an accreditation body the flexibility to establish its own procedures for suspension, withdrawal, or reduction of the scope of an accreditation as explained in clause 7.13.1 and NOTE. FDA's procedures for revocation of recognition are thus not inconsistent with the ISO standards in this respect. Regarding the grounds for withdrawal of accreditation, ISO/IEC 17011:2004 (Ref. 5), clause 7.13, provides that an accreditation body must make decisions to suspend and/or withdraw accreditation when an accredited conformity assessment body (*i.e.*, third-party certification body) has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation. The standard for revocation of recognition under this program is established by section 808(b)(1)(C) of the FD&C Act, which requires FDA to "promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section," which is the standard that is used in proposed § 1.634. Therefore, we cannot incorporate this standard for withdrawal for purposes of this program.

(Comment 88) Some comments suggest FDA revise § 1.634(a)(3) and (4) to provide that FDA can make a decision to revoke recognition or withdraw accreditation only when it has objective evidence to demonstrate that the recognized accreditation body committed fraud or submitted material with significant false statements, demonstrated a significant bias or significant lack of objectivity when

conducting activities, or significantly failed to adequately support one or more decisions to grant accreditation.

(Response 88) We disagree. Section 808(b)(1)(C) requires FDA to promptly revoke the recognition of any recognized accreditation body found not to be in compliance with section 808 of the FD&C Act, which establishes the third-party program. This program is a system of assurances that begins with the recognition of qualified accreditation bodies, which in turn accredit certification bodies to make judgments about the compliance of eligible entities and the food they produce with the applicable food safety requirements of the FD&C Act and FDA regulations. FDA's ability to have swift recourse when a recognized accreditation fails to comply with the requirements of the third-party program is essential. Limiting FDA's ability to revoke the recognition of accreditation bodies to instances of "significant" fraud, bias, or lack of competence as the comment suggests would render the program unreliable to provide the assurance of food safety intended by this section.

F. What if I want to voluntarily relinquish recognition or do not want to renew recognition? (§ 1.635)

Proposed § 1.635 describes the procedures that an accreditation body must follow when it intends to relinquish its recognition.

FDA received comments in support of the proposed procedures for voluntary relinquishment of recognition. FDA received no adverse comments on this section. On our own initiative, we are revising the voluntary relinquishment provisions in § 1.635 to also address situations where a recognized accreditation body decides it does not want to renew its recognition once it expires. In addition we are including procedures for the certification bodies to follow after their accreditation bodies' recognitions are relinquished or not renewed.

G. How do I request reinstatement of recognition? (§ 1.636)

Proposed § 1.636 describes the procedures that an accreditation body would have to follow when seeking reinstatement of its recognition.

FDA received comments in support of the proposed procedures for reinstatement of recognition. FDA received no adverse comments on this section and is not making any substantive changes to this section in this final rule.

VIII. Comments on Accreditation of Third-Party Certification Bodies Under This Subpart

A. Who is eligible to seek accreditation? (§ 1.640)

Proposed § 1.640 states that a foreign government, agency of a foreign government, foreign cooperative, or other third-party would be eligible for accreditation from a recognized accreditation body (or, where direct accreditation is appropriate, FDA) to conduct food safety audits and issue food and facility certifications under the program. Proposed § 1.640(b) is based on section 808(c)(1)(A) of the FD&C Act and would require a foreign government/agency seeking accreditation to demonstrate that its food safety programs, systems, and standards would meet the requirements of proposed §§ 1.641 to 1.645, as specified in FDA's model standards on qualifications for accreditation, including legal authority, competency, capacity, conflicts of interest, quality assurance, and records. Proposed § 1.640(c) is based on section 808(c)(1)(B) of the FD&C Act and would require a foreign cooperative or other third-party certification body seeking accreditation to demonstrate that the training and qualifications of its audit agents and the internal systems used by the certification body would meet the requirements of proposed §§ 1.641 to 1.645, as specified in FDA's model standards on qualifications for accreditation, including legal authority, competency, capacity, conflicts of interest, quality assurance, and records.

At our own initiative, we revised § 1.640(c) to apply to accredited third-party certification bodies that are comprised of a single individual, as applicable.

(Comment 89) Some comments suggest that FDA should require third-party certification bodies conducting regulatory audits to be accredited to either: (1) ISO 17021:2011 (Ref. 6), with the complementary requirements of ISO/TS 22003:2007, Food safety management systems—Requirements for bodies providing audit and certification of food safety management systems (Ref. 20) or (2) ISO 17065:2012 (Ref. 7), with conformance to ISO 17021:2011 (Ref. 6) and ISO 22000:2005, Food safety management systems—Requirements for any organization in the food chain (Ref. 21).

Other comments suggest that ISO/IEC 17000:2004 (Ref. 4) and ISO/IEC 17021:2011 (Ref. 6) provide a common framework for managing the effectiveness of third-party certification activities and recommend incorporating

the standards by reference into the final rule. The comments assert that FDA's proposed rule, by failing to incorporate by reference the ISO standards, appears to unnecessarily establish a unique standard in contravention of the NTTAA and OMB Circular A-119 (63 FR 8546) without adequate justification. The comments include recommended revisions to § 1.640. Other comments note that ISO/IEC Guide 65:1996 (Ref. 9) will be phased out by September 2015; therefore, the wording in the final rule should be changed to reflect the successor standard, ISO/IEC 17065:2012 (Ref. 7). Some comments express concern about the additional costs to exporters from third-party audits and private interests over and above official systems.

(Response 89) As explained in section I.D., we have revised the rule to allow a third-party certification body to offer documentation of conformance to ISO/IEC 17021:2011 (Ref. 6) or ISO/IEC 17065:2013 (Ref. 7) in support of its application for accreditation, supplemented as necessary. However, we decline the suggestion to incorporate the standards by reference into this rule.

ISO/IEC ISO 17021:2011 (Ref. 6) and ISO/IEC 17065:2012 (Ref. 7), the successor to ISO Guide 65:1996 (Ref. 9), contain requirements that are inconsistent with section 808 of the FD&C Act and impractical for our program. For example, ISO/IEC 17021:2011 (Ref. 6), clause 5.2.6, prohibits a certification body, including a governmental certification body, from providing internal audits to its certified clients. Under this same clause, a certification body that has provided internal auditing services to a client must wait for 2 years before conducting an audit for certification purposes. Clause 5.2.5 of the standard also prohibits the certification body from offering or providing any management systems consultancy (defined as participation in designing, implementing, or maintaining a management system). We note that ISO/IEC 17065:2012 (Ref. 7), clause 4 contains similar requirements, e.g., in clauses 4.2.6 and 4.2.10 NOTE 1, as the requirements of clauses 5.2.5 and 5.2.6 of ISO/IEC 17011:2004 (Ref. 5).

The requirements of our third-party program are markedly different, because section 808 of the FD&C Act expressly allows an accredited third-party certification body to conduct both regulatory audits for certification purposes and consultative audits for internal purposes. Further, section 808(c)(4)(C) of the FD&C Act allows an accredited certification body to use the same audit agent in auditing the same

eligible entity, subject only to a limitation (that FDA may waive) on using the agent for a regulatory audit when the agent had conducted a consultative audit of the eligible entity in the preceding 13 months.

As another example, we note that ISO/IEC 17021:2011, clauses 6.2.1 to 6.2.3 (Ref. 6), require a certification body to establish an external committee for safeguarding impartiality that includes representation of key interests, such as audited firms. Clause 5.3.2 of the standard requires the certification body to demonstrate to the external committee that commercial, financial, or other pressures do not compromise its impartiality. Under clause 6.2.2(c), the committee has the right to take “independent action” if the top management of the certification body “does not respect the advice of this committee.” ISO/IEC 17065:2012 (Ref. 7), clause 5, contains similar requirements—*e.g.*, clause 5.2.1 NOTE 1 (committee) and 5.2.3 (right to take independent action).

It would be inappropriate and impractical for FDA to require an accredited third-party certification body to assemble a committee representing interests outside those of this program, and would be impractical for FDA to properly manage the program under such circumstances. We also are concerned about the disincentive these requirements of ISO/IEC 17011:2004 (Ref. 5) and ISO/IEC 17065:2012 (Ref. 7) might create, for example, for foreign competent authorities who have their own processes for stakeholder engagement.

Based on our review of the standard and explained in the examples provided above, we have determined that ISO/IEC 17011:2004 (Ref. 5) and ISO/IEC 17065:2012 (Ref. 7) are inconsistent with section 808 of the FD&C Act and impractical for purposes of this program and therefore deny the suggestion to incorporate by reference into this rule.

With respect to the suggestion to incorporate ISO/IEC 17000:2004 (Ref. 4) into this rule, we note that this standard uses terminology that is inconsistent with section 808 of the FD&C Act. We are concerned that incorporating the terms used in ISO/IEC 17000:2004 (Ref. 4) in this rule would create unnecessary confusion as to how the rule relates to the statute. For example, clause 7.5 of the standard uses the term “recognition” for the “acknowledgement of the validity of a conformity assessment result provided by another person or body,” while recognition is used in section 808 of the FD&C Act when describing FDA’s determination that an accreditation

body meets the requirements of this rule.

Based on our review of the standard and explained in the example provided above, we have determined that ISO/IEC 17000:2004 (Ref. 4) is inappropriate for incorporation by reference into this rule.

Although we decline to incorporate the standards mentioned in the comments, we are revising § 1.640 to allow a third-party certification body to offer documentation of its conformance to ISO/IEC 17021:2011 (Ref. 6) or ISO/IEC 17065:2013 (Ref. 7), supplemented as necessary, in support of its application for accreditation under the final rule. We conclude that this will serve to promote international consistency and allow third-party certification bodies to use a framework that is familiar to them when it can be used to meet the requirements of this rule.

(Comment 90) Some comments suggest the rule should impose different requirements on foreign government certification bodies and on other third-party certification bodies (*i.e.*, foreign cooperatives and other third-party certification bodies), because of the different nature of private operators and public administration.

(Response 90) Under section 808(a)(3) of the FD&C Act third-party certification bodies include Foreign government certification bodies, foreign cooperatives, and other third-party certification bodies. Section 808 of the FD&C Act for the most part does not distinguish between public and private certification bodies and states that both are subject to the same model accreditation standards discussed in 808(b)(2). The only difference in treatment of public and private certification bodies is set forth in section 808(c)(1) of the FD&C Act, describing what elements of oversight be assessed for accreditation. This difference is reflected in the eligibility criteria set forth in § 1.640(b) and (c). In all other areas, we decline the suggestion to impose different requirements on foreign government certification bodies and other third-party certification bodies.

(Comment 91) Some comments express skepticism about private auditing companies. Some comments note that foreign cooperatives have rarely if ever been engaged in true accredited third-party auditing/certification activities and are thus unproven in that role.

(Response 91) As stated above, section 808 of the FD&C Act expressly provides for both public and private accredited third-party certification bodies. FDA believes the system of oversight

established under this rulemaking will be sufficient to ensure the reliability of private certification bodies that are able to participate in the program. Foreign cooperatives are specifically listed in section 808 of the FD&C Act as a third party that could be a certification body, and must meet the same rigorous criteria to qualify for accreditation.

B. What legal authority must a third-party certification body have to qualify for accreditation? (§ 1.641)

Proposed § 1.641 would require third-party certification bodies to demonstrate that they have adequate legal authority, which may include authority established by contract or as a government entity to evaluate eligible entities for compliance with the applicable requirements of the FD&C Act and FDA regulations.

FDA received no adverse comments specific to this section. However, as discussed in Response 27, we have revised § 1.641 to specify that a third-party certification body has to be a legal entity.

C. What competency and capacity must a third-party certification body have to qualify for accreditation? (§ 1.642)

Proposed § 1.642 would require a third-party certification body to demonstrate it has adequate resources to fully implement its auditing and certification program and the capacity to implement the requirements of this program, if accredited.

(Comment 92) Some comments suggest that we require certification bodies to be bonded, to cover any Agency costs should the firm go bankrupt.

(Response 92) We decline the suggestion to require certification bodies to be bonded to cover any Agency costs if a certification body goes bankrupt. This requirement is unnecessary because the program is designed to operate using user fees. Additionally, § 1.642 of the final rule requires a third-party certification body to demonstrate that it has adequate resources to fully implement its auditing and certification program.

(Comment 93) Some comments recommend that we clearly define the necessary competencies of certification body staff and auditors. Some comments suggest that we require auditors to have at least 1 year of work experience in testing and assessing the conditions for food safety of certain food manufacturer(s) and to have attended at least 20 audits for management systems using hazards analysis and critical control point requirements.

(Response 93) Section 1.640 of this rule establishes the eligibility requirements for third-party certification bodies seeking to participate in the third-party certification program. Specific recommendations on qualifications such as the years and types of work experience in food safety and in conducting audits will be contained in FDA's Model Accreditation Standards final guidance, as explained in section I.D.

(Comment 94) Some comments emphasize the importance of having certification bodies accredited to the specific areas in which they will be conducting audits and issuing certifications. The comment explains that accredited auditors/certification bodies auditing pet food facilities must be adequately qualified and knowledgeable in pet food requirements. The comments express concern that human food standards might be misapplied to a facility producing raw materials, ingredients or finished food for pet food (e.g., cross-contact for allergens, ingredients destined for further processing).

(Response 94) A recognized accreditation body assessing a certification body for accreditation (or FDA under direct accreditation) must ensure that the certification body is qualified to conduct audits under the food safety requirements of the FD&C Act and FDA regulations that apply to the scope of accreditation sought. Therefore, a third-party certification body that is accredited to conduct audits under part 117 would not be accredited to perform audits under 21 CFR part 507, unless the accrediting body has assessed the certification body's qualifications and accredited it to perform audits under part 507 as well.

D. What protections against conflict of interest must a third-party certification body have to qualify for accreditation? (§ 1.643)

Proposed § 1.643 would require third-party certification bodies to have established programs to safeguard against conflicts of interest that might compromise their objectivity and independence.

On our own initiative, we are clarifying in § 1.643(a) that the conflict of interest provisions of this section apply to officers, employees, and other agents that are involved in auditing and certification activities, as relevant. We are making corresponding changes in the subsequent provisions for accredited third-party certification bodies under § 1.657(a) and (c).

(Comment 95) Some comments recommend that FDA ensure that auditors are competent and accountable and that there are adequate protections against conflicts of interest, with maximum transparency related to auditors' activities. The comments support requirements for documented safeguards against conflicts of interest to help ensure that decisions are accurate and unbiased and that auditors are independent.

(Response 95) We agree and are requiring third-party certification bodies seeking accreditation to demonstrate they have written conflict of interest measures and that they have the capacity to meet the requirements of the final rule, if accredited.

E. What quality assurance procedures must a third-party certification body have to qualify for accreditation? (§ 1.644)

Proposed § 1.644 would require a third-party certification body to have a written program for monitoring and assessing its performance, identifying deficiencies in its program or performance and quickly executing corrective actions.

FDA received no adverse comments specific to this section. However, as discussed in Response 32, we revised § 1.644(a) to clarify that a certification body must demonstrate that it has procedures to identify deficiencies and procedures to execute corrective actions for such deficiencies, which would better align with international standards (see, e.g., clause 5.5 in ISO/IEC 17011:2004 (Ref. 5)).

F. What records procedures must a third-party certification body have to qualify for accreditation? (§ 1.645)

Proposed § 1.645 would require a third-party certification body to have developed and implemented written procedures to establish, control, and retain the records. Such records are necessary to provide the recognized accreditation body (or FDA under direct accreditation) an adequate basis for assessing the certification body for accreditation under this program.

We received no adverse comments specific to § 1.645 and are making no substantive revisions to this section.

IX. Comments on Requirements for Third-Party Certification Bodies That Have Been Accredited Under This Subpart

A. How must an accredited third-party certification body ensure its audit agents are competent and objective? (§ 1.650)

Proposed § 1.650 would require an accredited third-party certification body that uses audit agents to ensure that each audit agent meets certain requirements for competency and objectivity under the final rule. Under paragraph (a), the audit agent would need to have knowledge and experience relevant to determining an eligible entity's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, conformance with industry standards and practices. The accredited certification body would have to determine the audit agent's competency to conduct food safety audits in part by observing a representative number of audits performed by the audit agent. The audit agent would have to complete annual food safety training under the accredited third-party certification body's training plan, comply with the conflict of interest requirements for audit agents, and agree to notify its certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health.

Under proposed § 1.650(b), the accredited third-party certification body would have to assign an audit agent qualified to conduct the food safety audit, based on the scope and purpose of the audit and the type of facility, its processes, and food. Proposed § 1.650(c) would prevent an accredited third-party certification body from using an audit agent to conduct a regulatory audit of an eligible entity if the agent had conducted a regulatory or consultative audit of the same eligible entity during the preceding 13 months, except FDA could waive the 13-month limitation for an accredited certification body that could demonstrate insufficient access to accredited third-party certification bodies in the country or region where the eligible entity is located.

Of our own initiative, we are revising § 1.650(a) to apply to accredited third-party certification bodies that are comprised of a single individual, as applicable. Section 808(a)(3) of the FD&C Act specifically allows an accredited third-party certification body to be an individual, which would not fall within the definition of "audit agent" in the statute or this rule.

Therefore, as part of establishing eligibility under § 1.640, an individual seeking accreditation must fulfill the requirements of § 1.650(a)(1) to become accredited under this rule and, once accredited, must comply with the annual food safety training requirements of § 1.650(a)(3). Pursuant to § 1.650(a)(4), an accredited third-party certification body also must comply with the conflict of interest provisions applicable to audit agents under § 1.657(a)(3).

We note that a recognized accreditation body that is assessing an individual seeking accreditation under this program also must assess the individual's knowledge and experience under § 1.650(a)(1) for the scope of accreditation requested and must consider the results of such assessment in determining the individual's eligibility for accreditation under § 1.640. The onsite observations of an individual seeking accreditation that are performed under § 1.620(a)(3) must be sufficient to determine competency consistent with § 1.650(a)(2).

(Comment 96) Some comments strongly support the proposed requirements of § 1.650, which would require an accredited certification body to ensure that the audit agents it uses have the knowledge and experience, within the scope of its accreditation, to examine facilities, processes, and foods for compliance with the FD&C Act and FDA regulations. The comments assert that audits are only as good as the education, training, and experience of the auditor. Other comments recommend that food safety audits under this rule should be performed by individuals that have training equivalent to FDA investigator training standards.

(Response 96) We agree with comments emphasizing the importance of ensuring that audit agents an accredited third-party certification body uses to conduct audits under the program are appropriately qualified within the scope of the third-party certification body's accreditation. Proposed § 1.650 would comprise the elements of a comprehensive assessment that an accredited third-party certification body would need to perform for each audit agent it would use to conduct a food safety audit under this rule. We further agree with comments suggesting that an auditor determined by a third-party certification body to be competent to conduct audits under private food safety schemes must nonetheless be assessed by the accredited third-party certification body for competency to conduct audits using the applicable food safety requirements

of the FD&C Act and FDA regulations as the audit criteria. Therefore, under § 1.650(a), an audit agent would need to demonstrate substantive knowledge of the applicable food safety requirements of the FD&C Act and FDA regulations relevant to the scope and purpose of the food safety audits the agent would conduct under the program. We do not agree to go so far as to require that all audit agents or individuals accredited as third-party certification bodies must have training equivalent to FDA investigator training standards, as we acknowledge that some investigator training would not be necessary to conduct audits under this program (e.g., evidence collection for enforcement purposes). Such a requirement would impose unnecessary costs and might serve as a disincentive to participation in the program.

(Comment 97) Some comments specifically endorse proposed § 1.650(a)(2), which would require each audit agent to be observed conducting audits to examine compliance with the FD&C Act in a representative number of facilities and foods. Other comments recommend that an accredited third-party certification body should observe an audit agent before the agent begins to conduct food safety audits of a different type of food, followed by random, periodic spot audits to confirm that the audit agent is applying the audit criteria consistently. The comments interpret proposed § 1.650(a)(2) to mean that the accredited third-party certification bodies would be required to "continually witness" each audit agent they use.

(Response 97) We agree that observations of audit agents under proposed § 1.650(a)(2) are essential in determining the competency of audit agents. We are revising proposed § 1.650(a)(2) to require the observation of a representative "sample" of audits, instead of a representative "number" of audits, because the focus of this provision was not intended to be on the number of audits the audit agents would be expected to conduct. Rather, we intend for the accredited third-party certification body to observe a sample of audits that are representative of the range of audits the audit agent might be assigned.

In determining what would constitute a "representative sample" for purposes of final § 1.650(a)(2), the accredited third-party certification body should consider the various types of food facilities that might be audited and the range of FDA regulations that would apply to such facilities. An accredited third-party certification body would need to observe the audit agent

conducting a number of audits across the range of facilities identified by the certification body, and the range of FDA regulations that would apply to those facilities, such that, taken together, the observed audits would be adequately representative of the facilities, processes, and foods the audit agent may be assigned to conduct. Generally, the more complex the regulations or the more complex the processes used by the facility, the greater the sample size should be, to help ensure the audit agent can apply the audit criteria consistently and reliably in various situations. The accredited third-party certification also should gather sufficient information to provide confidence in its determination of the audit agent's competency to conduct audits under this rule.

Contrary to the interpretation suggested by some comments, proposed § 1.650(a)(2) would not require an accredited third-party certification body to "continually witness" each of its audit agents. Such an approach is not practical, efficient, or necessary. However, we are clarifying in § 1.650(a)(2) that before an audit agent is used to conduct food safety audits under this rule the audit agent must be observed by the accredited third-party certification body and found to be competent to conduct food safety audits relevant to the audits they will be assigned to perform under this program. Such observations also must be performed whenever an audit agent will be assigned to perform food safety audits to determine compliance with additional food safety requirements under the FD&C Act and FDA regulations beyond what the certification body has previously observed.

Under this approach, once an accredited third-party certification body has determined an audit agent's competency and objectivity under § 1.650, the audit agent can be assigned to conduct audits for which they are qualified under § 1.650(a)(1) and (2), subject to requirements such as the annual training requirements in § 1.650(a)(3) and the accredited third-party certification body's self-assessment under § 1.655. Although we decline to require periodic observations of audit agents, once the accredited certification body has determined the competency of its audit agents under § 1.650(a)(2), we acknowledge the value of such observations in verifying audit agent competency and the rigor of the certification body's program for evaluating its audit agents.

(Comment 98) Some comments recommend that we include

requirements focusing on the performance of individual audit agents because, the comments assert, many audit complaints arise from individual auditor conduct and focusing on individual performance may help create more consistency in the process.

(Response 98) We agree, and have received similar input from other stakeholders during our public meetings. The comments and other stakeholder input underscore the importance of the requirements for an accredited third-party certification body to observe a representative sample of audits conducted by each audit agent under § 1.650(a)(2), to ensure that any audit agent it assigns to an audit is appropriately qualified under § 1.650(b), and to assess the performance of its audit agents and the consistency of performance across all its audit agents as part of the certification body's self-assessment under § 1.655.

(Comment 99) Some comments support the proposed requirement for annual food safety training under proposed § 1.650(a)(3), noting the importance of ensuring that audit agents have up-to-date training in areas relevant to their audit activities. The comments also suggest that FDA should communicate to training institutions any general audit agent training needs FDA identifies through its program management and oversight. Other comments recommend that the annual training requirement should relate to relevant food safety provisions of the FD&C Act and FDA regulations.

(Response 99) We agree and are revising § 1.650(a)(3) to clarify that an audit agent, or an individual accredited as a third-party certification body, must have annual food safety training that is relevant to activities conducted under this program. FDA works with a number of Alliances and other organizations to ensure training needs for regulatory requirements are met. For instance, having identified the need to train regulators and industry in the new FSMA preventive controls rules, FDA is working in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) to develop training materials and establish training and technical assistance programs for the preventive controls rules. The Alliance includes members from FDA, state food protection agencies, the food industry, and academia and is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health. For more information about the FSPCA, see *e.g.*, <http://www.iit.edu/ifsh/alliance/>, <http://www.iit.edu/ifsh/alliance/>.

(Comment 100) Some comments suggest that in addition to the

requirements of the proposed rule, we should require conformance to ISO/IEC 19011:2011 (Ref. 8) on auditor competency.

(Response 100) FDA's recommendations on auditor competency, among other things, will be contained in FDA's Model Accreditation Standards. As noted in section I.D., comments that address matters covered by FDA's Model Accreditation Standards are outside the scope of this rulemaking.

The issuance of the Model Accreditation Standards draft guidance was announced through publication of a notice of availability in the **Federal Register** of July 24, 2015. We plan to finalize the Model Accreditation Standards after receiving public comments on the draft guidance.

(Comment 101) Some comments note that the audit agent's education, training, and experience must be specific to the industry or industries being audited. Some comments, for example, recommend that audit agents who examine eligible entities for compliance with food additive requirements should have industry experience with food additives and relevant knowledge, experience or training in auditing these types of facilities and processes.

(Response 101) We agree that a certification body must consider an audit agent's competency whenever assigning the audit agent to a specific audit. Therefore, § 1.650(b) requires the accredited third-party certification body to ensure that an audit agent it assigns to a specific audit is appropriately qualified, based on the audit scope and purpose, the specific type of facility, processes, and foods the audit agent would be required to examine, and the food safety requirements of the FD&C Act and FDA regulations that would apply.

We note that an accredited third-party certification body that is an individual would be determined during the accreditation process to be appropriately qualified to conduct audits within the scope of its accreditation.

(Comment 102) Some comments agree with proposed § 1.650(c) and assert that it is needed to protect against conflicts of interest. Some comments assert that, under current practices, auditors in many countries frequently conduct consecutive audits at the same premises. Other comments suggest that the 13-month limit is unnecessary because adequate mechanisms already exist to manage conflicts of interest and objectivity in ISO/IEC standards. Still other comments express concern that

the proposed limit of 13 months would be too short to avoid a conflict of interest. These comments contend a short interval between consultative audits and regulatory audits that are conducted by the same audit agent could create the appearance that the audit agent is auditing the results of the prior consultation. Other comments assert we should impose a 2-year limit, rather than a 13-month limit on audit agents conducting regulatory audits of the same eligible entity.

(Response 102) We disagree with comments opposed to proposed § 1.650(c). Proposed § 1.650(c) would implement the requirements of section 808(c)(4)(C) of the FD&C Act, which limits an accredited third-party certification body's ability to use an audit agent to conduct a regulatory audit of an eligible entity if the agent conducted a consultative or regulatory audit for the same eligible entity in the preceding 13 months, unless FDA waives the limitation under criteria described in the statute. While we recognize this requirement may differ from some international standards, it balances the concern of an audit agent auditing their own prior results if the subsequent audit happens too soon with auditor capacity concerns through a waiver provision. Under proposed § 1.663, FDA would issue waivers where we determine there is insufficient access to in the country or region where the eligible entity is located.

We note that the proposed rule was unclear with respect to whether the showing of insufficient access to support a waiver was based on a lack of certification bodies or individual audit agents in a country or region, and have therefore clarified in the final rule that the showing of insufficient access necessary for FDA to grant a waiver request is based on lack of audit agents (or in cases where individuals are accredited as third-party certification bodies, those individuals). Although we are finalizing additional conflict of interest requirements in § 1.657 of this rule, these provisions do not implement the 13-month limit in section 808(c)(4) of the FD&C Act. Section § 1.650(c) complements the requirements in § 1.657 to provide additional conflict of interest protections. Note that though this response uses the term "audit agent" this provision also applies to accredited third-party certification bodies that are individuals.

(Comment 103) Several comments assert that proposed § 1.650(c) and the waiver process FDA proposes to establish would be impractical. The comments note that there is currently a significant shortage of experienced food

safety auditors around the world. Describing it as a “capacity” issue, the comments suggest that implementation of the FSMA rules will further exacerbate the problem. Some comments suggest that proposed § 1.650(c) would be impractical for small countries due to auditor capacity issues.

(Response 103) We acknowledge the concerns about the possible shortage of skilled food safety auditors to meet current global demand and are aware of efforts by GFSI, the food industry, scheme owners, and third-party food safety certification bodies to address auditor capacity, as described in section I.D. We also understand that FSMA implementation is likely to create further demand for auditors. Nonetheless, as explained in Response 102, we are required by section 808(c)(4)(C) of the FD&C Act to limit an accredited third-party certification body’s ability to use an audit agent; we have clarified in the final rule that the showing of insufficient access necessary for FDA to grant a waiver request is based on lack of audit agents (or in cases where individuals are accredited as third-party certification bodies, those individuals).

We disagree with comments suggesting that the waiver process we propose would be impractical. We are developing an IT portal that includes the capability for accepting electronic submissions of requests and electronic issuance of waivers, which will help facilitate the submission of waiver requests by accredited third-party certification bodies and FDA’s processing of such requests.

(Comment 104) Some comments contend that the proposal to require accredited third-party certification bodies to show insufficient accredited third-party certification body resources to obtain an FDA waiver of proposed § 1.650(c) would be unnecessarily burdensome because the proposed conflict of interest requirements adequately protect against concerns about “industry capture.” Some comments recommend that FDA research global food safety auditor capacity and proactively issue waivers of proposed § 1.650(c), absent waiver request(s). Still other comments suggest that eligible entities should be able to seek waivers of the 13-month limit on behalf of an accredited third-party certification body.

(Response 104) Under section 808(c)(4)(C) of the FD&C Act, the 13-month limit on audit agents conducting regulatory audits may be waived if FDA determines there is insufficient access to audit agents in a country or region.

While acknowledging capacity concerns raised in comments, we decline the suggestion that FDA should gather information to support waivers absent a request for a waiver under section 808(c)(4)(C)(ii) of the FD&C Act. We believe gathering such information would not be the best use of our limited resources, and that third-party certification bodies would be better positioned to inform FDA of audit agent capacity issues in their country or region of operation. Moreover, the final rule clarifies that accredited third-party certification bodies must demonstrate that there is insufficient access to audit agents in the country or region where the eligible entity is located in order to obtain a waiver. Because the 13-month limit is on individual audit agents, and not third-party certification bodies, this limitation is likely to be less burdensome than anticipated by the comments.

We decline the suggestion to allow eligible entities to request a waiver of proposed § 1.650(c) on behalf of an accredited third-party certification body, because we believe the accredited third-party certification body will be better suited to assess auditor capacity on a national or regional basis. Periodic rotation of audit agents is intended to help ensure that audits remain objective and do not become compromised by familiarity. The requirement to ensure an audit agent’s objectivity is placed on the accredited third-party certification body, not an eligible entity, under proposed § 1.650(a). Further, given that the accredited third-party certification body would ultimately need to agree to conduct an audit for an eligible entity, requiring the accredited third-party certification body to request the waiver would ensure that they are willing to accept the request for a food safety audit in the first place. In light of the foregoing, we have concluded that it is the accredited third-party certification body, not the eligible entity, who should seek a waiver of the 13-month limit in proposed § 1.650(c).

We disagree with comments suggesting waiver requests will be unduly burdensome or time-consuming for accredited third-party certification bodies. The IT portal we are developing for the third-party certification program includes the capability for accepting electronic submissions of requests and electronic issuance of waivers, which we believe will help minimize the administrative burden on certification bodies and FDA.

B. How must an accredited third-party certification body conduct a food safety audit of an eligible entity? (§ 1.651)

Proposed § 1.651 would establish requirements for planning and conducting consultative and regulatory audits in a manner that fulfills the purposes of section 808 of the FD&C Act. Under paragraph (a) on audit planning, the accredited third-party certification body would require the eligible entity to identify whether it was seeking a consultative or regulatory audit subject to the requirements of this subpart under the third-party certification program. The eligible entity would indicate the scope and purpose of the requested audit and, in the case of a regulatory audit, would indicate the type of certification sought. The accredited third-party certification body would also require the eligible entity to provide a 30-day operating schedule for the facility that would provide information relevant to scope and purpose of the audit. The accredited third-party certification body would then consider whether the requested audit is within the scope of its accreditation.

Proposed § 1.651(b) would require the accredited third-party certification body to ensure it would have adequate authority to conduct the requested audit, including authority to: (1) Conduct an unannounced audit; (2) access any area of the facility or any of its records relevant to the scope of the audit; (3) use an accredited laboratory in accordance with section 422 of the FD&C Act, (21 U.S.C. 350k), where FDA requires sampling and analysis; (4) notify FDA immediately upon discovering, during a consultative or regulatory audit, a condition that could cause or contribute to a serious risk to the public health; (5) prepare audit reports that would contain certain elements and, for regulatory audits, that would be submitted to FDA; and (6) allow FDA and its recognized accreditation body to observe any food safety audit under the program.

Proposed § 1.651(c) would require an unannounced audit to be conducted in a manner consistent with its scope and purpose and would include records review as well as an onsite examination of the facility, process(es), and food to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and for consultative audits, conformance with include industry standards and practices. Proposed § 1.651(c) would require the audit agent to document observations and corrective actions and, where appropriate, would include

environmental or product sampling and analysis using validated methodologies and a laboratory accredited in accordance with the requirements of section 422 of the FD&C Act.

At our own initiative, we are removing the requirement to use a laboratory consistent with section 422 of the FD&C Act and inserting a requirement in § 1.651(b)(3) to use a laboratory accredited under ISO/IEC 17025:2005 or another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results.

On our own initiative, we are also revising § 1.651(c)(1) to clarify that the audit must be focused on determining whether the facility, its process(es), and food are in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and for consultative audits, also includes conformance with applicable industry standards and practices. Based on comments received on § 1.653 and for the reasons described in Comment/Response 112 in section IX.C., we are revising § 1.651(c)(3) to clarify that an accredited third-party certification body (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

(Comment 105) Some comments suggest that we should incorporate ISO/IEC 19011:2011 (Ref. 8), which contains guidelines on auditing management systems, by reference into the rule.

(Response 105) We disagree, because ISO/IEC 19011:2011 (Ref. 8) is inconsistent with the requirements of section 808 of the FD&C Act and this rule. For example, ISO/IEC 19011:2011 (Ref. 8) is premised on announced audits that are scheduled with the client, as described in clauses 6.2.2, and 6.2.3 of the standard; however, section 808(c)(5)(C)(i) of the FD&C Act requires audits conducted under this rule to be unannounced. As another example, clause 6.4.9 of ISO/IEC 19011:2011 (Ref. 8) suggests that an audit team should attempt to resolve any “diverging opinions” between the team and the audited entity regarding the audit conclusions, such as the extent of conformity with audit criteria (clause 6.4.8), during the closing meeting. We acknowledge that differences of opinions regarding audit conclusions are likely to occur between eligible

entities and accredited third-party certification bodies or audit agents. However, the credibility of our program rests in large part on the independence and objectivity of accredited third-party certification bodies and audit agents. This rule is intended to help ensure they are free from the influence of the eligible entities and any appearance that their judgment is compromised by eligible entities. Audit conclusions regarding an eligible entity’s compliance with the applicable food safety requirements of the FD&C Act and FDA regulations are the purview of the accredited third-party certification body and any audit agents it uses. The appropriate mechanism for an eligible entity seeking to challenge adverse decisions would be the accredited third-party certification body’s appeals process.

For the foregoing reasons, we decline to incorporate ISO/IEC 19011:2011 (Ref. 8) by reference into this rule.

(Comment 106) Some comments assert the guidelines for management systems auditing in ISO/IEC 19011:2011 (Ref. 8) would provide a useful guide for audits conducted under the program. Other comments suggest the audit agents should be conducting food safety audits using a quality systems approach. Citing the production of food additives as an example, these comments note that while it would be preferable to conduct an audit while a food additive is being produced it is not always feasible. The comments suggest that as long as the audit focuses on quality systems it should not be necessary for production of the food additive to occur during the audit.

(Response 106) As explained in Response 105, some elements of ISO/IEC 19011:2011 (Ref. 8) are inconsistent with the requirements of section 808 of the FD&C Act and this rule, thereby limiting its applicability for food safety audits conducted under this rule. We agree, however, with the general principle that a “systems” approach to food safety audits with a correctly identified scope and purpose, using appropriate audit criteria, and properly executed by a competent audit agent (or individual accredited as third-party certification body), should be sufficient to cover the food within the audited system(s) of the facility, without requiring direct observation of each type of food produced. We note that it is essential that the scope of the audit covers the appropriate physical locations, activities, and processes that are part of the management system to be audited, and information collected during the audit must be relevant to the audit scope, purpose, and criteria,

including information relating to interfaces between functions, activities, and processes of the food safety system.

We use the term “systems audits” generally, acknowledging that “management systems” audits, “product certification” audits, and “quality systems” audits have specific meanings in some contexts, such as ISO/IEC standards, but may have different meanings in different contexts. To the extent that the comments referencing a “quality systems” approach are suggesting that food safety audits should be conducted using a “systems auditing” approach, we agree. Accordingly, we are revising § 1.651(c)(1) to better align with the language of section 808 of the FD&C Act and this rule, as well as “systems” auditing principles.

Our goal is to ensure the rigor of the food safety audits conducted under our program, which will be accomplished through compliance with the requirements of this rule. It is intended to help ensure that food safety audits are conducted by competent audit agents (or individuals accredited as a third-party certification bodies), in accordance with a properly defined audit scope and purpose, using the applicable audit criteria required by this rule. As such, any food safety audit conducted under the rule should provide the information necessary for the accredited third-party certification body to make a determination on compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. Whether or not a particular audit does, in fact, provide such information, with an appropriate level of confidence, is dependent on a number of factors, among them:

1. At the time that the food safety audit is procured, the eligible entity must declare the scope and purpose of the audit consistent with the requirements of this rule (and any additional criteria established in VQIP guidance for facility certifications for use in that program or, for certifications to be used for purposes of section 801(q) of the FD&C Act any additional criteria that may be established by FDA relating to the safety determination).

2. The accredited third-party certification body must assign an audit agent that is competent to perform the audit (or, for an accredited third-party certification body that is an individual, such audit must be within the scope of accreditation).

3. The audit agent (or individual accredited as a third-party certification body) must:

- a. Develop and successfully execute an audit plan that includes a records

review, which may be scheduled, and a subsequent onsite facility examination performed on an unannounced basis within a 30-day window of time according to the facility's operating schedule for the requested audit purpose and scope and using the appropriate audit criteria; and

b. during the audit collect and verify information that is relevant to the audit purpose, scope, and criteria and that will form the basis for the audit findings and conclusions.

We note that this rule establishes the requirements for the third-party certification program but does not establish requirements relating to the use of these certifications for purposes of sections 801(q) and 806 of the FD&C Act. To that end, we urge an eligible entity seeking a regulatory audit for certification to be used for VQIP purposes or for purposes of satisfying a requirement for certification under section 801(q) to ensure that the scope of the regulatory audit it procures, and any food and facility certifications that are issued as a result, will be sufficient to meet FDA requirements under sections 801(q) and 806 of the FD&C Act.

Under section 806 of the FD&C Act, FDA will require facility certifications issued by accredited third-party certification bodies under section 808 as a condition of an importer's eligibility for VQIP. We encourage eligible entities, importers, and accredited third-party certification bodies to consult the VQIP guidance, when finalized, to ensure the proper scope has been established for any regulatory audit conducted to obtain facility certification for VQIP purposes.

Any requirement for certification to satisfy a condition of admissibility under section 801(q) of the FD&C Act would be based on an FDA safety determination relating to specific circumstances, as described in section 801(q)(2). An eligible entity seeking certification from an accredited third-party certification body to meet the admissibility requirements under section 801(q) of the FD&C Act must ensure the proper scope has been established for the regulatory audit it procures to address the circumstances behind the 801(q) determination.

(Comment 107) Some comments assert that the audit requirements in proposed § 1.651 are overly detailed and inflexible, contending that accreditation bodies have their own requirements for good auditing practices. The comments also suggest that proposed § 1.651, would be problematic to implement and cite as an example the proposed requirement for unannounced audits,

which the comments say would be inconsistent with the requirements associated with planned audits that apply in other programs.

(Response 107) We understand that some of the requirements in proposed § 1.651 differ from the audit protocols currently used in conducting many third-party audits of food facilities. The comments do not identify the good auditing practices they assert accreditation bodies already require certification bodies to use; however, we are not incorporating ISO/IEC 17021:2011, ISO/IEC 17065:2012, or ISO/IEC 19011:2011 by reference into this rule for the reasons explained in section I.D. We are unable to identify a voluntary consensus standard that would encompass the audit practices required by section 808 of the FD&C Act (*e.g.*, unannounced audits and notification of conditions that could cause or contribute to a serious risk to public health) as well as other practices the statute allows (*e.g.*, audit agents conducting both consultative and regulatory audits). In the absence of existing standards that would adequately address the food safety audit requirements of section 808 of the FD&C Act, § 1.651 offers accredited third-party certification bodies and audit agents the requirements needed to conduct food safety audits in the manner the statute contemplates and requires.

The comment asserting that proposed § 1.651, would be problematic to implement cited as an example the proposed requirement for unannounced audits in § 1.651(c)(1). We acknowledge that most audits are scheduled, and a program involving unannounced audits will require changes in the current usual practices of accredited third-party certification bodies and eligible entities. However, section 808(c)(5)(C)(i) of the FD&C Act specifically requires audits performed under this rule to be unannounced. As described in Response 106, proposed § 1.651(c)(1) was designed to provide flexibility to accredited third-party certification bodies and eligible entities, while fulfilling this statutory requirement. Without additional examples or other details in the comments to explain why the other audit protocols in proposed § 1.651(a) would be problematic to implement, we decline to revise § 1.651(a)(2) to (4) in response to the comments.

(Comment 108) In addition to comments described in section III.E. regarding the impracticality of unannounced audits, some comments contend that unannounced audits would be impractical and inefficient for any food safety audit (*e.g.*, regulatory

audits) conducted under this rule. Other comments express concern about implementing unannounced audits at farms that may be geographically isolated, while offering support for unannounced audits in principle.

Other comments note that unannounced audits are conducted for operations participating in the Leafy Greens Marketing Agreements (LGMAs) in California and Arizona and in the California Cantaloupe Marketing Order (CCMO), asserting it is feasible to conduct audits of seasonal operations during harvest activities, observing practices and programs in the field and facility. Some comments suggest that unannounced audits provide a more realistic view of the entity's compliance status than planned audits do.

Some comments endorse the approach of a planned records review prior to an unscheduled site audit occurring at any point during a 30-day operating window. Other comments ask us to clarify in the final rule which parts of a food safety audit may be performed on a scheduled basis and which parts must be performed on an unannounced basis within a 30-day window.

(Response 108) We decline to revise our approach to unannounced audits under § 1.651, as section 808(c)(5)(C)(i) of the FD&C Act explicitly requires that audits be unannounced. We are, however, adding language to § 1.651(c)(1) to clarify that the records review portion of a food safety audit may be scheduled with an eligible entity and, through revisions to § 1.651(c)(2), are requiring the records review to occur before the onsite facility examination portion of the audit, consistent with the description in the preamble to the proposed rule (78 FR 45782 at 45811 to 45812). We are retaining the requirement in § 1.651(c)(1) to conduct an unannounced audit through an unscheduled onsite facility examination at any time during the 30-day timeframe identified pursuant to § 1.651(a)(1)(ii).

As discussed in the preamble to the proposed rule (78 FR 45782 at 45811), when developing the audit protocols to implement the statutory requirement for unannounced audits, we considered the British Retail Consortium (BRC) Global Standard for Food Safety (Ref. 22) unannounced audit option to help us ensure that our approach to unannounced audits would be practical and feasible to implement. The BRC unannounced audit option provides for a "Good Manufacturing Practices-type audit" to be unannounced, while a separate records review could occur during a planned visit. We have concluded that it is reasonable and appropriate to interpret the statutory

requirement for unannounced audits to allow a record review to be conducted during a planned visit to the eligible entity, provided that the onsite audit is conducted on an unannounced basis. In addition, as discussed previously, we have revised § 1.651(c)(2) to require that the records review must precede the onsite examination to facilitate the facility visit.

We agree with comments suggesting that unannounced audits are feasible and note, for example, that another GFSI-benchmarked scheme, the Safe Quality Food Code in July 2014 began implementing an unannounced audit component, wherein unannounced audits are mandatory for every third audit (Ref. 23). Additionally, while we appreciate the concern expressed by comments regarding the implementation of unannounced audits at farms that may be geographically isolated, we believe the examples cited by comments of unannounced audits of participants that are performed at least once each year under the LGMA and the CCMO are persuasive in demonstrating the feasibility of unannounced audits for primary production. Moreover, the requirements for audits specified in the statute and our experiences planning foreign inspections lead us to believe that the requirement for a 30-day operating window will assist in preventing logistic problems associated with unannounced audits in geographically isolated areas. For the foregoing reasons, we have concluded that the unannounced audit protocol in § 1.651(a)(1) is practical and efficient to implement, while meeting the requirements of section 808(c)(5)(C)(i) of the FD&C Act.

(Comment 109) Some comments suggest that FDA increase the window of time between the records review, which informs the audit planning, and the unannounced site audit, which examines the facility, its process(es), and food for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. To maximize the element of surprise while ensuring the relevance of the records review to the conduct of the site audit, the comments suggest we should expand the timeframe to allow the audit agent to conduct the site audit any time during a 90-day period.

(Response 109) Food safety audits conducted under this program, particularly regulatory audits for certification purposes, often are time sensitive in nature, because they are necessary for issuance of certifications that are used facilitate trade. Establishing a lengthy window of time during which an unannounced audit

could occur could have significant implications, for example, where certification is used in satisfying a condition of admissibility for a food subject an FDA safety determination under section 801(q) of the FD&C Act. A lengthy window of time for an unannounced audit to be conducted also could hinder participation in the VQIP program under section 806 of the FD&C Act, which requires an importer to provide facility certification as a condition of participation. In light of the foregoing, we do not believe it would be reasonable to extend the length of time between records review and the site audit from 30 to 90 days.

C. What must an accredited third-party certification body include in food safety audit reports? (§ 1.652)

Proposed § 1.652 would implement section 808(c)(3)(A) of the FD&C Act, which authorizes FDA to establish the requirements for audit reports that an accredited third-party certification body would need to prepare as a condition of its accreditation. The statute specifies that such report of an audit must include: (1) The identity of the persons at the eligible entity responsible for compliance with food safety requirements; (2) the dates and scope of the audit; and (3) any other information FDA requires that relates to or may influence an assessment of compliance.

Proposed § 1.652(a) would specify the form of consultative audit reports, which would include: The name, address, and unique facility identifier (UFI) of the facility subject to audit; the name, address, and UFI of the eligible entity (if it differs from the facility); the contact information for the person(s) responsible for food safety compliance at the facility; the dates and scope of the consultative audit; and any deficiency(ies) observed during the audit that require corrective action(s) and the date on which such corrective action(s) were completed. Proposed § 1.652(a) would require that a consultative audit report be prepared by no later than 45 days after completing the audit and would require preparing the report in English and maintaining it as a record under proposed § 1.658.

Proposed § 1.652(b) would specify the form of regulatory audit reports, which would include: (1) The name, address, and UFI of the facility subject to audit; (2) the FDA food facility registration number (where applicable); (3) the name, address, and UFI of the eligible entity (if it differs from the facility); (4) the contact information for the person(s) responsible for food safety compliance at the facility; (5) the dates and scope of the regulatory audit; (6) the process(es)

and food(s) observed during the audit; (7) whether sampling and laboratory analysis is used in the facility; (8) recent food recalls; (9) recent significant changes at the facility; and (10) any food or facility certifications recently issued to the entity. With respect to deficiencies and corrective actions, proposed § 1.652(b) would require the accredited third-party certification body to include in the regulatory audit report any deficiency(ies) observed during the audit that meet FDA's Class I and Class II recall standards—*i.e.*, the deficiency(ies) present(s) a reasonable probability that the use of or exposure to the violative product will cause serious adverse health consequences or death; or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, and the corrective action plan for any identified deficiency unless the corrective action was implemented immediately and verified onsite by the accredited third-party certification body. Proposed § 1.652(b) also would require that a regulatory audit report be submitted to FDA electronically, in English, by no later than 45 days after completing the audit.

Under proposed § 1.652(c), an accredited third-party certification body would have to submit to FDA an audit report for any regulatory audit it conducts, regardless of whether the certification body issued a certification based on the results of the regulatory audit. Proposed § 1.652(d) would require an accredited third-party certification body to implement written procedures for receiving and addressing challenges from eligible entities contesting adverse regulatory audit results and would require them to maintain records of such challenges under proposed § 1.658.

On our initiative, we revised paragraphs (a) and (b) of § 1.652 to clarify that an accredited third-party certification body must provide a copy of a consultative audit report or regulatory audit report (respectively) to the eligible entity. We also on our own initiative added a requirement for the accredited third-party certification body to include in the audit report the FDA Establishment Identifier (FEI) of the facility audited and the FEI of the eligible entity, if different than the FEI for the audited facility to help verify the identity of the facility and eligible entity based on information contained in FDA's database of FEIs. Further, we aligned the elements of the consultative audit report and regulatory audit report; for example, we redesignated proposed paragraph (a)(5) as (a)(6) and added a

new paragraph (a)(5) to require that the consultative audit report include the processes and foods observed during the consultative audit. Additionally, on our own initiative we revised § 1.652(d) to clarify that an accredited third-party certification body must notify an eligible entity of a denial of certification.

(Comment 110) Several comments raise concerns regarding the requirements that would apply to consultative audit reports under proposed § 1.652(a). The comments assert that because consultative audits are specifically intended to be for internal purposes, FDA should delete proposed § 1.652(a) and should not propose any requirements for consultative audit reports. Other comments suggest that we remove the proposed requirement to prepare a consultative audit report no later than 45 days after conducting the audit, asserting the deadline is infeasible. Still other comments suggested we should allow consultative audit reports to be prepared and maintained in languages other than English.

Some comments interpret proposed § 1.652(a) to require consultative audit reports to be submitted to FDA. Other comments urge us to emphasize to industry that proposed § 1.652(a) would only require accredited third-party certification bodies to maintain consultative audit reports in their records and not submit them to FDA, and that FDA could only access consultative audit reports in circumstances meeting the serious adverse health conditions or death to humans or animals (SAHCODHA) standard for records access under section 414 of the FD&C Act. Other comments note that the proposed rule was silent on the protection of proprietary information in audit reports.

(Response 110) We disagree with comments suggesting that because consultative audits are for internal purposes only, FDA is precluded from imposing any requirements for consultative audit reports prepared by accredited third-party certification bodies under this rule. Section 808(c)(3)(A) of the FD&C Act requires certain elements to be included in reports for all food safety audits. This includes both consultative audits and regulatory audits, which are the two types of audits described in section 808(c)(4)(B) of the FD&C Act. Section 808(c)(3)(A) sets a 45-day deadline for the preparation of all audit reports, including consultative audit reports, and sets a separate requirement that the audit reports for regulatory audits be submitted. Section 808(c)(3)(A) of the

FD&C Act also gives FDA discretion to designate the form and manner of audit reports and to require accredited third-party certification bodies to include in audit reports other information that relates to or may influence an assessment of compliance with the FD&C Act. In light of these statutory provisions, we decline the suggestions to delete proposed § 1.652(a) or to remove the proposed 45-day deadline for preparation of a consultative audit report.

We are, however, removing the proposed requirement in § 1.652(a) that consultative audit reports would need to be prepared and maintained in English in the accredited third-party certification body's records. As explained in Response 59, we are removing the proposed requirements for recognized accreditation bodies and accredited third-party certification bodies to create and maintain records that do not need to be submitted to FDA, outside of a specific request, under this rule in English.

We disagree with comments suggesting that § 1.652(a) should require accredited third-party certification bodies to submit consultative audit reports to FDA. We note that section 808(c)(3)(A) only requires the submission of regulatory audit reports. Because consultative audits are for internal purposes, we consider it appropriate to require the maintenance of these reports, but not the submission of the reports. Under section 808(c)(3)(C) of the FD&C Act, we could only access consultative audit reports in circumstances meeting the standard for records access under section 414 of the FD&C Act.

With respect to protection of proprietary information in consultative audit reports submitted to or obtained by FDA, we note that the final rule includes new provision § 1.695, which addresses disclosure and the protection of trade secrets and confidential commercial information under applicable law.

(Comment 111) Some comments support our proposal to require that consultative audit reports under proposed § 1.652(a)(2) and regulatory audit reports under proposed § 1.652(b)(1)(i) and (b)(2) include UFI for audited facilities and for eligible entities (where different from audited facilities). In the preamble to the proposed rule (78 FR 45782 at 45812), we solicited comment on whether a UFI should comprise a Data Universal Numbering System (DUNS®) number and Global Positioning System (GPS) coordinates for an audited facility and

for the eligible entity (if different from the audited facility).

Some comments support using DUNS® numbers in UFIs for eligible entities and audited facilities, asserting that approximately 230 million establishments around the world have DUNS® numbers. The comments assert that DUNS® numbers are easy to obtain and free to the establishment. Comments also emphasize that the use of DUNS® numbers would be particularly helpful under the third-party certification rule, because the numbers help to determine corporate “families”—*e.g.*, related establishments.

Other comments oppose using DUNS® numbers as UFIs, contending that DUNS® numbers are not widely used outside the United States and frequently have errors. Some of these comments propose alternatives to DUNS® numbers, including: GPS coordinates, FDA's food facility registration numbers, or the U.S. Internal Revenue Service taxpayer identification numbers which comments suggest foreign companies can request from U.S. Customs and Border Protection.

(Response 111) We received valuable input in response to our solicitation of comments on UFIs for audited facilities and eligible entities. Having a UFI for eligible entities (and audited facilities if different) would be useful to FDA in identifying an eligible entity that does not already have a numerical identifier in one of FDA's databases. For example, farms generally are not required to register with FDA under section 415 of the FD&C Act, so they would not have an FDA Food Facility Registration Number, unless they conduct activities for which such registration is required, and some eligible entities may not have been assigned an FDA Facility Establishment Identifier.

We note that FDA currently is considering whether to require UFIs for regulated establishments, such as facilities as defined in 21 CFR 1.227, and the types of numbering systems that might be used for UFIs. Under this final rule, an accredited third-party certification body will be required to include a UFI for an audited facility and for an eligible entity (if different from the audited facility) in a consultative audit report under § 1.652(a)(1)(i) and (a)(2), and a regulatory audit report under § 1.652(b)(1)(i) and (b)(2), if FDA designates a UFI system.

(Comment 112) Some comments focus on proposed § 1.652(a)(5), which would require a consultative audit report to include any deficiencies observed that require corrective action, the corrective action plan, and the date corrective

actions were completed. Some comments ask us to clarify what information about deficiencies should be included in consultative audit reports. The comments distinguish between FDA investigators who collect physical evidence during inspections and third-party certification bodies who typically observe process(es), review records, and cite nonconformity to standards—*e.g.*, “Canning retort time did not meet x temperature for y time of the scheduled process.” Other comments ask FDA to clarify that the eligible entity, not the audit agent, would be responsible for corrective actions, including analyzing the cause of the nonconformity and developing corrective actions to address the nonconformity. These comments support the proposed requirement to require documentation and verification of corrective actions, whether through document review or onsite audits.

(Response 112) As the comments suggest, third-party certification bodies commonly describe their audit findings in terms of conformity or nonconformity with audit criteria, such as a GFSI-benchmarked food safety scheme or the ISO/TS 22003:2013 series of food safety standards (Ref. 24). Under section 808 of the FD&C Act, accredited third-party certification bodies examine eligible entities and their foods for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also assess conformity with applicable industry standards and practices.

Under proposed § 1.652(a)(5), a consultative audit report would identify any deficiencies observed by audit agent, which we intended would encompass any deficiency that relates to or may influence the accredited third-party certification body’s determination of whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. We were not proposing to require that consultative audit reports include information on an observation solely related to a nonconformity with industry standards or practices that FDA does not implement or enforce. An observation relating to both a nonconformity with an industry standard or practice and a deficiency that relates to or may influence a compliance determination would need to be included in the audit report as a deficiency under proposed § 1.652(a)(5). In response to comments, we are revising § 1.652(a)(5), renumbered as § 1.652(a)(6), to clarify that a consultative audit report must include any deficiency that relates to or may influence a determination of

compliance with the applicable food safety requirements of the FD&C Act and FDA regulations and information on the corrective action(s) to address such deficiency.

We agree with comments distinguishing between the roles of eligible entities (who must identify and implement effective corrective actions) and accredited third-party certification bodies and their audit agents (who identify deficiencies and verify that effective corrective actions have been implemented). After identifying deficiencies that will require corrective action, accredited third-party certification bodies and their audit agents must maintain their impartiality by allowing eligible entities to select the appropriate corrective actions to employ. To recommend or suggest corrective actions to eligible entities during consultative or regulatory audits would undermine the objectivity of the third-party certification bodies or audit agents in performing their critical task of verifying the effectiveness of the corrective actions once implemented. To address this concern, we have elected to revise § 1.651(c)(3) as described in section IX.B., because we believe this issue is better addressed as part of the protocols for audits conducted under subpart M.

(Comment 113) Some comments assert that proposed § 1.652(b) is unnecessary, because many of the elements of regulatory audit reports that we propose already are commonly included in audit reports. The comments contend that listing specific elements to be included in a regulatory audit report would be too prescriptive and would stifle creativity. Other comments suggest that proposed § 1.652(b) is overly broad, and the comments object to the elements of the audit reports. Some comments assert that reporting of recent recalls is unnecessary because this is information already in FDA’s possession. Still other comments note that documents that are routinely part of an audit process may contain critical business information. These comments suggest that FDA should consider a “tiered” approach, by requiring only summary reports on audit results to be submitted to FDA, not proprietary information.

Other comments support proposed § 1.652(b) and the data elements we proposed to require in regulatory audit reports. Some of these comments seek additional information on the form and manner of submitting this information to FDA. The comments also ask whether the regulatory audit reports will be publicly released.

(Response 113) We disagree with comments suggesting that proposed § 1.652(b) is unnecessary because the information we proposed to require in regulatory audit reports already is included in the audit reports prepared by third-party certification bodies. Although many of the elements required to be included in the reports under this rule are currently being included in audit reports prepared by third-party certification bodies, it is important that we require the elements included in this final rule because they are essential to the preparation of audit reports that are consistent with the purpose of this program.

We disagree with the comments asserting that proposed § 1.652(b) is overly broad and the comments contending that the provision is overly prescriptive. Section 808(c)(3)(A) of the FD&C Act requires that audit reports include the dates and scope of the audit and the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements. Section 808(c)(3)(A) of the FD&C Act also gives FDA discretion to require that audit reports include other information that relates to or may influence an assessment of compliance with the FD&C Act. Under proposed § 1.652(b), a regulatory audit report would include the elements required by the statute, as well as the following information: Identifying information for the eligible entity (and for the facility, if different from the eligible entity); the food(s) and process(es) observed; any deficiencies observed during the audit that relate to an FDA Class I or Class II recall situation; and the corrective action plan for such deficiencies. We also proposed to require the regulatory audit report to indicate whether any sampling and laboratory analysis is used in the facility and whether in the 2 years preceding the audit the entity: Issued a food safety-related recall; made significant changes in the facility, its process(es), or products; or was issued any food or facility certifications.

As to the elements of the regulatory audit report in proposed § 1.652, we note that paragraphs (b)(1) and (2) provide identifying information for the eligible entity (and the facility audited, if different than the eligible entity) and paragraphs (b)(3) and (5) contain the elements required by section 808(c)(3)(A) of the FD&C Act. We agree with comments asserting that it is not necessary to include information in regulatory audit reports that is already in FDA records; therefore, we are removing the proposed requirements in § 1.652(b)(9) and (11) to report information on food-safety related

recalls conducted by the eligible entity and food and facility certifications issued to the eligible entity in the 2 years preceding the audit. We are retaining the other elements of the regulatory audit report under proposed § 1.652(b)(4), (6) to (8), and (10)—*i.e.*, whether the facility uses sampling and laboratory analysis, whether the entity has made significant changes to the facility, its process(es), or products during the 2 years preceding the audit; the foods and process(es) that were observed, as well as any deficiencies related to a Class I or Class II recall situation and the corrective action plans for deficiencies—because they are related to or influential to a determination of compliance with the applicable food safety standards of the FD&C Act and FDA regulations.

As discussed in Response 67, we intend to provide additional instructions relating to the form and manner of submitting information to FDA. We also acknowledge comments' concerns about the protection of proprietary information in regulatory audit reports submitted to FDA. Information submitted to FDA is subject to public disclosure and under part 20, and we are including new § 1.695 on public disclosure in section XIII.F of this final rule.

(Comment 114) Some comments contend that the submission of regulatory audit reports under proposed § 1.652 would “empower” accredited third-party certification bodies as “*de facto*” regulatory authorities.

(Response 114) We disagree. Nothing in section 808 of the FD&C Act or in the proposed rule would empower accredited third-party certification bodies to implement or enforce the FD&C Act or FDA regulations. Further, section 808(h) of the FD&C Act clearly states that audits performed under this section shall not be considered inspections under section 704 of the FD&C Act, which governs FDA inspections.

(Comment 115) Some comments assert that regulatory audit reports should be submitted to FDA only when there are questions about product safety. Some comments suggest that proposed § 1.652(b) could be onerous because it would require regulatory audit reports to be submitted to FDA in English by no later than 45 days after the audit was completed. The comments assert that a lack of auditor capacity in countries that export food to the United States could make it difficult for accredited third-party certification bodies to meet the 45-day deadline and suggest that FDA should consider adjusting the deadline for regulatory audit report submission in

light of factors such as auditor capacity and the needs of seasonal producers. Other comments support the proposed 45-day deadline for audit report submission, noting that many audit reports currently take more than 45 days to complete, some taking nearly a year to be issued. Still other comments focus on the proposed requirement in § 1.652(b) to submit regulatory audit reports in English, urging us to accept reports in various languages, including Spanish.

(Response 115) Section 808(c)(3)(A) of the FD&C Act requires as a condition of accreditation that regulatory audit reports to be submitted to FDA within 45 days after conducting the audit. Accordingly, we decline the suggestion to limit the submission of regulatory audit reports to circumstances where there are questions about product safety. We also decline to extend the statutory 45-day deadline for submission of a regulatory audit report.

We believe that allowing regulatory audit reports to be submitted in languages other than English, as some comments suggest, would create unnecessary obstacles to our program management and oversight. For example, we may review a regulatory audit report to assist us in deciding whether to accept a certification or to reject the certification after determining that is not valid or reliable. If we were to allow regulatory audit reports to be submitted in languages other than English, we might have to wait weeks for a translation. Such a delay would postpone our decision on whether to accept or refuse the certification and might have negative effects on the flow of trade.

(Comment 116) Some comments oppose a proposal to use DUNS® numbers in UFIs for audited facilities and eligible entities that would be required to be submitted to FDA in regulatory audit reports under proposed § 1.652(b)(1)(i) and (b)(2). The comments suggest that using DUNS® numbers in UFIs would create a monopoly for Dun and Bradstreet (D&B) and give D&B an unfair competitive advantage. The comments also express concern that establishments will face increased pressure to buy other D&B products. Other comments suggest that DUNS® numbers are not used outside the United States because, for example, DUNS® numbers require data such as street names, telephone numbers and other data points that small producers located outside the United States might not have. Instead, these comments suggest, FDA should use GPS latitude and longitude coordinates as UFIs.

Some other comments express support for UFI requirements that would include the use of DUNS® numbers in UFIs for audited facilities and eligible entities. The comments assert that because DUNS® numbers are widely used, it would be reasonable for FDA to require DUNS® numbers to be used in UFIs under the third-party certification program.

(Response 116) As explained in Response 111, FDA currently is considering whether to require regulated establishments to have UFIs and, if so, whether DUNS® numbers should be included in UFIs. As explained previously, under this final rule, an accredited third-party certification body will be required to include a UFI for an audited facility and for an eligible entity (if different from the audited facility) in a regulatory audit report under § 1.652(b)(1)(i) and (b)(2), if FDA designates a UFI system.

(Comment 117) Some comments agree with proposed § 1.652(b)(4), which would require regulatory audit reports to include information on the process(es) and food(s) observed during the audit. Some comments request clarification of what process(es) and food(s) would need to be observed in a facility with several processes, and other comments ask what information FDA is seeking about the process(es) that were observed during a regulatory audit.

(Response 117) As explained in Response 106, we do not believe that direct observation of each type of food produced under a management system is necessary when an audit covers the appropriate physical locations, activities, and processes that are part of the management system to be audited, and information collected during the audit must be relevant to the audit scope, purpose, and criteria, including information relating to interfaces between functions, activities, and processes of the management system. Therefore, information on the process(es) and food(s) observed by the audit agent (or accredited third-party certification body that is an individual) is useful in light of the scope of the audit and the management system(s) audited.

(Comment 118) Some comments endorse proposed § 1.652(b)(8), which would require the regulatory audit report to include information on whether sampling and analysis is used at the facility being audited. Of the comments that support proposed § 1.652(b)(8), some would further require regulatory audit reports to include reporting of sampling and analytical results of sampling by the

eligible entity. Others suggest including analytical results relating to any deficiencies observed during an audit and the effectiveness of corrective actions taken to address the deficiency.

(Response 118) We agree that it is useful for FDA to have information on whether an eligible entity uses sampling and analysis as a tool for verifying the effectiveness of its controls. Section 1.652 does not require sampling or analysis on a routine basis; however, analytical reports must be included in regulatory audit reports if the certification body finds them to be relevant to the any elements of an audit report, such as a verification of corrective actions or in support of a decision not to certify. We note that sampling or analytical reports that are collected as part of a regulatory audit must be maintained as required under § 1.658(a)(3).

(Comment 119) Some comments support proposed § 1.652(b)(9), which would require information on recent recalls to be included in regulatory audit reports. Other comments suggest that requiring recall information to be included in a regulatory audit report might lead to questions about the validity of a certification that the accredited third-party certification body might issue based on the results of its regulatory audit of the eligible entity. Some other comments suggest that requiring an accredited third-party certification body to include information on recent recalls in a regulatory audit report would be duplicative, because FDA should already have information on any recalls of regulated product exported to the United States, and recalls of product that was not exported to the United States would not be relevant to the regulatory audit report.

(Response 119) We agree with comments suggesting that it would be duplicative to require accredited third-party certification bodies to include information on recent recalls in regulatory audit reports and are removing proposed § 1.652(b)(9) in the final rule.

(Comment 120) Some comments ask for clarification on proposed § 1.652(b)(11), which would require information on recent certifications to be included in regulatory audit reports. The comments ask whether a certification issued outside of the third-party certification program should be included in a regulatory audit report and if so, should the report identify the standards under which the certification was issued.

(Response 120) Requiring information on certifications issued under the third-

party certification program would be duplicative because certifications previously issued by the accredited third-party certification body under the program already would have been submitted to FDA. Further, we see no benefit to requiring the submission of information on certifications issued outside of this program. Accordingly, we are removing proposed § 1.652(b)(11) from the final rule.

(Comment 121) Some comments urge us to create a clear mechanism for eligible entities to appeal adverse audit results.

(Response 121) Under proposed § 1.652(d) an accredited third-party certification body would have to implement written procedures for receiving, evaluating, and deciding on eligible entity challenges to adverse regulatory audit results. We believe this section provides a clear mechanism for eligible entities to be able to appeal adverse regulatory audit results. As explained in Response 36, we are clarifying that persons presiding over such appeals may be internal or external to the accredited third-party certification body.

D. What must an accredited third-party certification body do when issuing food or facility certifications? (§ 1.653)

The proposed rule describes the activities that an accredited third-party certification body would have to perform when issuing food and facility certifications. Proposed § 1.653 would require the certification body to have conducted a regulatory audit under proposed § 1.651 and to conduct any other activities necessary to determine compliance under the applicable food safety requirements of the FD&C Act and FDA regulations.

No certificate could be issued until the eligible entity took corrective actions to address any deficiencies reported under proposed § 1.652(b)(6), and the corrective actions were verified by the accredited third-party certification body. The verification would need to occur onsite, unless the deficiency was a minor issue. A single audit could result in food and facility certifications or multiple food certifications only if the regulatory audit requirements were met as to each.

Where a certification body uses audit agents, the certification body, not the audit agent, would make the determination whether to issue certification. However, the statute allows for individuals to be accredited as certification bodies; in that circumstance, the same individual would conduct the audit and also determine whether to issue certification.

On our own initiative, we are revising § 1.653(a)(3) to replace the phrase “assessment made during” with “the data and other information” to clarify what an accredited third-party certification body must consider when determining whether an eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

On our own initiative, we are making a number of revisions § 1.653(b). We are revising paragraph (b)(1) to clarify that the accredited third-party certification body may issue a food or facility certification under this subpart for a term of up to 12 months. Throughout paragraph (b)(2) we are specifying that the food or facility certification must contain information about regulatory audits. At our own initiative, we are revising § 1.653(b)(2)(ii) and (iii) to require accredited third-party certification bodies to provide the FEI of the audited facility and the FEI of the eligible entity, if different from the audited facility, and we revised § 1.653(b)(2) (iv) to require accredited third-party certification bodies to assign numbers to certifications they issue under the program. We are revising paragraph (b)(3) to clarify that FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act if we determine that the certification is not valid or reliable. We are also adding new subparagraph (b)(3)(iii) to specify that if the certification was issued without reliable demonstration that the requirements of paragraph (a) were met, we may determine that the certification is not valid or reliable.

(Comment 122) Some comments contend that proposed § 1.653(a)(2) would require accredited third-party certification bodies to perform onsite verifications of corrective actions in situations where other methods of verification would be adequate. The comments assert that, by requiring onsite verification for any corrective action (other than an action taken to address recordkeeping deficiencies), the proposed rule would impose undue costs on eligible entities and would exacerbate issues of auditor capacity.

The comments suggest that we allow for remote verification of corrective actions through photographs, live webcam transmissions, and any other means that would provide evidence that corrective action has been taken and the eligible entity is in compliance with the FD&C Act. The comments suggest that FDA may, in its discretion, require onsite visits to confirm that corrective actions were taken in extraordinary situations where efforts short of onsite

observation would be insufficient to protect the public, such as in Class I recall situations. Some comments urge us to follow the requirements of ISO/IEC 17021:2011 (Ref. 6) for verification of corrective actions.

(Response 122) We agree that onsite verification of corrective actions would not be necessary to address every deficiency identified in a regulatory audit report under proposed § 1.652(b)(6). ISO/IEC 17021:2011 (Ref. 6) (clauses 9.1.12–9.1.13) describes a range of activities—from document review to onsite verification to additional full audits—that a third-party certification body may use verifying the effectiveness of corrective actions. Remote verification may be appropriate where it would provide an adequate basis for the accredited third-party certification body to determine that the eligible entity had implemented effective corrective action(s) to address the identified deficiency or deficiencies. Accordingly, we are revising § 1.653(a)(2) to expand the methods of verification an accredited third-party certification body may use to verify corrective actions for deficiencies identified in § 1.652(b)(6), except that corrective actions in a facility that was the subject of a notification under § 1.656(c) must be verified onsite.

(Comment 123) Some comments urge FDA to establish qualifications for the individuals accredited third-party certification bodies would use to make certification decisions. The comments suggest that an accredited third-party certification body should use a panel of experts with appropriate industry or regulatory experience to make certification decisions on behalf of the body. Other comments urge FDA to identify the criteria an accredited third-party certification body should use in determining whether to issue certification under section 808 of the FD&C Act.

(Response 123) We agree with the comments suggesting that individuals involved in compliance determinations and certification decisions under section 808 of the FD&C Act must be appropriately qualified for those responsibilities. We agree that decisions on certification should be made by individuals other than audit agents who conducted the regulatory audits that would form the basis for the decisions on certification, except individuals accredited as third-party certification bodies may perform regulatory audits and issue certifications based on the results of regulatory audits they performed. An assessment for accreditation of a third-party certification body under § 1.642 would

focus not only on its competency and capacity for auditing food facilities but also on its capacity to review audit results to determine compliance with applicable food safety requirements for purposes of certification. While an accredited third-party certification body may wish to use a panel of experts for certification decisions, it is not necessary under this rule.

(Comment 124) Some comments suggest that certifications issued under section 808 of the FD&C Act should clearly delineate the scope of products and processes covered by the certification.

(Response 124) Proposed § 1.653(b)(2)(iv) and (vi) would require the certification to include both the scope of the audit and the scope of the food or facility certification. We believe the concern about the scope of products and processes covered by the food or facility certification is adequately addressed by the proposed rule, and we are retaining these provisions in the final rule.

E. When must an accredited third-party certification body monitor an eligible entity that it has issued a food or facility certification? (§ 1.654)

Proposed § 1.654 would require an accredited third-party certification body to conduct monitoring of an eligible entity if the certification body has reason to believe that an eligible entity to which it issued a certification may no longer be in compliance with the FD&C Act.

(Comment 125) Comments endorsing proposed § 1.654 suggest that FDA establish criteria for the “reason to believe” standard—that is, the circumstances FDA believes would trigger a requirement for an accredited third-party certification body to monitor an eligible entity. The comment further suggests that FDA should make these criteria available for public comment.

(Response 125) FDA declines to codify specific criteria that would trigger the need for an accredited third-party certification body to conduct monitoring of an eligible entity to determine whether the entity is still in compliance with applicable requirements, as such criteria would be fact-specific and FDA cannot contemplate all situations that would require such monitoring. FDA envisions that the circumstances that might trigger monitoring under § 1.654 are ones that may affect the eligible entity’s capability to continue to comply with the applicable food safety requirements of the FD&C Act and FDA regulations, such as: (1) Significant changes to the audited facility, such as capital

improvements; (2) major changes to the eligible entity’s management system and processes; or (3) changes to the scope of operations, such as changes in manufacturing processes, that may affect the compliance status of an eligible entity.

(Comment 126) Other comments urge FDA to require an accredited third-party certification body to notify an eligible entity immediately upon determining that monitoring of the eligible entity prior to recertification would be necessary.

(Response 126) We decline the suggestion to require notification of an eligible entity prior to monitoring under § 1.654, as we believe it is more appropriate for the accredited third-party certification body to decide based on the circumstances whether it should alert an eligible entity it has certified that monitoring is necessary or conduct unannounced monitoring activities. An accredited third-party certification body may choose to notify an eligible entity before conducting monitoring activities that are unrelated to the eligible entity’s annual audit for recertification purposes, which must be conducted on an unannounced basis pursuant to § 1.651(c)(1).

F. How must an accredited third-party certification body monitor its own performance? (§ 1.655)

Proposed § 1.655 would require an accredited third-party certification body to conduct self-assessments annually and in the case of revocation of the recognition of its accreditation body and prepare a report of the results of each self-assessment.

On our own initiative, we are revising § 1.655(a)(1) to clarify that as part of the self-assessment, an accredited third-party certification body must evaluate the performance of its audit agents in examining facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations, which will conform with other changes being made to the final rule.

(Comment 127) Some comments support the proposal to require accredited third-party certification bodies to conduct self-assessments. Other comments recommend that FDA should be more explicit in the requirements for self-assessments.

(Response 127) We decline the suggestion to be more explicit in the requirements for self-assessments, as the requirements in § 1.655 include sufficient details for conducting self-assessments. Comments did not provide adequate justification for adding

additional elements to the self-assessment.

(Comment 128) Some comments request that accredited governmental certification bodies be allowed to conduct self-assessments at a frequency different than other accredited third-party certification bodies.

(Response 128) We decline to create different timeframes for self-assessments for governmental versus private certifications bodies. As explained in Response 39, § 1.655 is part of a set of proposed monitoring and self-assessment requirements intended to work together in helping to ensure that the recognized accreditation bodies and accredited third-party certification bodies maintain compliance with the rule's requirements. The certification body self-assessment in § 1.655 is intended to serve, in part, as information for use in the annual accreditation body monitoring in § 1.621, the results of which we intend the accreditation body to use in its annual self-assessment under § 1.622. This system of assessments takes place on an annual basis and is an essential part of the program's safety net. Allowing different timeframes for assessments by different participants would undermine the credibility of the program and create undue administrative complexity. We believe this section will be far less burdensome in practice than some of the commenters may have anticipated. We note that to address general concerns about the burden of these requirements, similar to other sections of the final rule, FDA is adding a new § 1.655(e) to allow an accredited third-party certification body to use documentation of its conformance to ISO/IEC 17021:2011 or ISO/IEC 17065:2012, supplemented as necessary, to meet the requirements of this section.

(Comment 129) Some comments assert that accredited third-party certification bodies should not be required to be prepare self-assessment reports in English under proposed § 1.655(d).

(Response 129) In response to comments and consistent with revisions made elsewhere in the final rule, we are removing the English language requirement in § 1.655(d) for self-assessment reports prepared by third-party certification bodies accredited by a recognized accreditation body. However, we are now including a requirement in § 1.656(b) of submission in English for self-assessment reports prepared by third-party certification bodies directly accredited by FDA and self-assessments submitted to FDA as a result of an FDA request for cause or

due to the termination of an accreditation body's recognition due to denial of renewal, revocation, or relinquishment/failure to renew under § 1.631(f)(1)(i), 1.634(d)(1)(i), or 1.635(c)(1)(i), respectively.

G. What reports and notifications must an accredited third-party certification body submit? (§ 1.656)

Proposed § 1.656 would establish requirements for various reports and notifications that accredited third-party certification bodies would have to submit to FDA and, as appropriate, recognized accreditation bodies. Proposed § 1.656(a) would establish the requirements for submission of regulatory audit reports, and proposed § 1.656(b) would establish the requirements for submission of reports of accredited third-party certification body self-assessments.

Proposed § 1.656(c) would require an accredited third-party certification body to immediately notify us, in English, of a condition that could cause or contribute to a serious risk to the public health (notifiable condition) that the certification body (or its audit agent) discovered while conducting a regulatory or consultative audit of an eligible entity. In the preamble discussion of proposed § 1.656(c) (78 FR 45782 at 45815), we solicited examples of conditions that might and might not meet the standard in section 808(c)(4)(A) of the FD&C Act for notifying FDA. We asked for input on whether the FDA Class I and Class II recall standards, taken together, might adequately address any condition covered by section 808(c)(4)(A) of the FD&C Act.

Proposed § 1.656(d) would require an accredited third-party certification body to immediately notify us electronically, in English, upon withdrawing or suspending the food or facility certification of an eligible entity. Proposed § 1.656(e)(1) would require an accredited third-party certification body that notified FDA under proposed § 1.656(c) also to notify the eligible entity where the condition was discovered. Proposed § 1.656(e)(2) would require the accredited third-party certification body to notify its accreditation body (or, in the case of direct accreditation, to us) electronically, in English, within 30 days after making any significant change that may affect its compliance with the requirements of §§ 1.640 through 1.658.

On our own initiative we are revising § 1.656(c)(1) and (2) to clarify if a condition that could cause or contribute to a serious public risk to the public health is discovered, that in addition to

the name of the eligible entity and/or facility, an accredited third-party certification body must also provide the physical address, unique facility identifier (if designated by FDA), and the registration number under subpart H of this part (where applicable).

(Comment 130) Some comments support proposed § 1.656(a), which would require submission of regulatory audit reports to FDA, but would not require reports of consultative audits to be submitted. Other comments interpret the proposed rule as requiring submission of consultative audit reports to FDA and the reporting of laboratory analytical results under section 422 of the FD&C Act.

(Response 130) Under section 808(c)(3)(A) of the FD&C Act, an accredited third-party certification body or an audit agent of a third-party certification body, where applicable, "shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted . . ." Based on the statutory language, it is clear that Congress only desired reports of regulatory audits to be submitted to FDA. We also note that section 808(c)(3)(C) of the FD&C Act limits the ability for FDA to access the results of consultative audits to circumstances described in the records access standard of section 414 of the FD&C Act. Some comments incorrectly interpreted the proposed rule to require the submission of the certification bodies' laboratory records and results. We are only requiring maintenance of such records and results under § 1.658.

(Comment 131) Some comments contend that we are interpreting the notification standard in section 808(c)(4)(A) of the FD&C Act too broadly, because the statute only requires accredited third-party certification bodies to notify FDA of notifiable conditions discovered during a regulatory audit. The comments assert that Congress did not intend us to require notification of conditions found during consultative audits, because those audits are for internal purposes; therefore, we should revise proposed § 1.656(c) to remove the reference to a consultative audit. Other comments assert that notifications submitted for conditions found during a consultative audit could overwhelm FDA with data that could make it difficult to identify the most serious risks to public health. Still other comments support our proposal to require notification of conditions found during consultative and regulatory audits.

Some comments describe a range of activities that generally may be referred to as consultative audits and suggest

that requiring notification to FDA of conditions found during these types of consultative audits may have unintended consequences. The comments note the important role of third-party audits (and consultative audits, in particular) in assisting the food industry identify and fix internal problems and drive continuous improvements. The comments suggest that requiring notification during consultative audits might create disincentives for firms who might otherwise use accredited third-party certification bodies to perform consultative audits and for third-party certification bodies who might otherwise be interested in participating in the program.

(Response 131) We decline the suggestion to limit § 1.656(c) to require notification only of conditions found during a regulatory audit, because section 808(c)(4)(A) and (B) of the FD&C Act require notification based on conditions found “at any time during an audit” and identifies “audits” as both consultative and regulatory audits.

Although we decline to limit § 1.656(c) as the comment suggests we believe that many of the concerns about notification during a consultative audit are mitigated by revisions that clarify the scope of the consultative audits that are, and are not, covered by the rule (see Sections III.E and III.J). Under the final rule, an accredited third-party certification body would only be required to notify FDA of a condition that could cause or contribute to a serious risk to the public health if the condition was discovered during an audit that an eligible entity has specifically declared to be a regulatory audit for certification purposes or a consultative audit in preparation for a regulatory audit under this rule.

(Comment 132) Several comments contend that “serious risk to the public health” has the same meaning as “serious adverse health conditions or death to humans or animals” (SAHCODHA) as that phrase is used throughout the FD&C Act. Specifically, the comments assert that FDA should only require accredited third-party certification bodies to notify FDA of conditions that pose a risk of SAHCODHA, as that standard is interpreted for purposes of the Reportable Food Registry (RFR) under section 417 of the FD&C Act (21 U.S.C. 350f).

The comments reject our tentative conclusion that the range of conditions that require notification under section 808(c)(4)(A) of the FD&C Act is broader than SAHCODHA, because the statute describes notifiable conditions as ones

that “could” cause or contribute to a serious risk to public health. In response to our request for input, the comments specifically reject an interpretation of “serious risk to the public health” that might include, for example, conditions that pose a risk of temporary or medically reversible adverse health consequences or where the probability of adverse health consequences is remote. Some comments suggest that accredited third-party certification bodies and audit agents would be more readily able to identify conditions that pose a SAHCODHA risk but would find it more difficult to identify other conditions that would need to be notified to FDA under proposed § 1.656(c). Other comments support our tentative conclusion that a “condition that could cause or contribute to a serious risk to the public health” is broader than a condition relating to a SAHCODHA risk.

(Response 132) We disagree with comments suggesting that the phrase “serious risk to public health” in section 808(c)(4)(A) of the FD&C Act should be interpreted as a risk of SAHCODHA. We note that Congress chose to incorporate SAHCODHA in section 808(c)(6)(A) to describe outbreak situations that would lead to withdrawal of accreditation, but did not use SAHCODHA in describing the conditions that must be notified to FDA under section 808(c)(4)(A) of the FD&C Act. Additionally, Congress chose to incorporate SAHCODHA in other sections of FSMA, such as in provisions on suspension of registration in section 102(b) amending section 415 of the FD&C Act. In light of the foregoing, we believe that Congress intended for a “serious risk to the public health” to be distinct from a risk of SAHCODHA and, therefore, reject the suggestion that accredited third-party certification bodies would only need to notify FDA of conditions that pose a risk of SAHCODHA under proposed § 1.656(c). We conclude that notifiable conditions include not only those that present a risk of SAHCODHA, but also other conditions that “could cause or contribute to a serious risk to the public health.”

Although it is difficult to predict the range of conditions or circumstances that accredited third-party certification bodies and audit agents might encounter, we offer some factors that may be useful in identifying whether a condition would need to be notified under § 1.656(c), such as whether the condition relates to incoming ingredients that will be subject to control within the facility, or an area of the facility where pre-production

materials are held; whether the condition relates to the post-processing environment or where finished product is held prior to distribution; and whether the condition relates to food, process(es), or areas of the facility associated with food that is destined for export to the United States, and not if it relates solely to food, process(es), or areas of the facility associated with food for consumption other than in the United States.

(Comment 133) Some comments urge us to revise proposed § 1.656(c) to incorporate the limitations on reporting that apply to the RFR under section 417(d)(2) of the FD&C Act, such that notification would only be submitted if food adulterated as a result of the notifiable condition had left the control of the eligible entity. The comments assert it would be reasonable for FDA to interpret section 808(c)(4)(A) of the FD&C Act such that an accredited third-party certification body would not need to alert FDA immediately upon discovering a notifiable condition if the eligible entity reworked adulterated product or destroyed it before the adulterated food was transferred to another person. Other comments suggest that proposed § 1.656(c) is redundant because such conditions are subject to RFR reporting.

(Response 133) We decline the suggestion to revise § 1.656(c) to incorporate an exception similar to section 417(d) of the FD&C Act as there is no exception to the notification requirement in section 808(c)(4) as there is in section 417(d). Further, we believe the notification requirement in section 808(c)(4) serves not only to inform FDA of potential risks to the public, but also enhances credibility of the program by giving FDA, accredited certification bodies, and recognized accreditation bodies information that may be relevant to our oversight of the food safety and third-party programs. We believe that given the statutory language and goals of the third-party certification program, it is appropriate for the notification requirement in this rule to have different requirements and exceptions than other notification provisions in the FD&C Act.

As such, we also disagree with comments suggesting the obligation of a responsible party to submit a report to FDA through the RFR makes proposed § 1.656(c) redundant. Among other things, RFR requirements only apply to facilities that are required to register with FDA under section 415 of the FD&C Act. An eligible entity that is a farm, for example, would not be subject to RFR requirements. Additionally, as discussed previously, the reporting

requirement under this rule contains no exception for circumstances when the food adulterated as a result of the notifiable condition has not left the control of the eligible entity. In light of the foregoing, we are retaining § 1.656(c) without the revisions suggested by the comments.

(Comment 134) Some comments urge us to revise proposed § 1.656(e)(1) to allow for concurrent notification of FDA and the eligible entity where the notifiable condition was discovered.

(Response 134) We agree and are adding to § 1.656(e)(1) a provision that allows, where feasible and reliable, for the accredited third-party certification body to contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA. We note that this provision does not affect the obligation for the accredited third-party certification body to notify FDA immediately of a notifiable condition under § 1.656(c).

H. How must an accredited third-party certification body protect against conflicts of interest? (§ 1.657)

Proposed § 1.657 sets out the elements of a conflict of interest program that an accredited third-party certification body would be required to have. Proposed § 1.657(a) would require the accredited third-party certification body to have a written program that covers the certification body itself and any of its officers, employees, or other agents (e.g., audit agents) conducting audits or certification activities under this program. Proposed § 1.657(b) would address the requirement, in section 808(c)(5)(C) of the FD&C Act, to issue implementing regulations that include a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party certification bodies. Proposed § 1.657(c) would impute to an accredited third-party certification body's officer, employee, or other agent the financial interests of his or her spouse and minor children, if any. Proposed § 1.657(d) would require an accredited third-party certification body to maintain on its Web site an up-to-date list of eligible entities to which it issued certifications under this subpart, the duration and scope of each such certifications, and the date on which the eligible entity paid any fee or reimbursement under proposed § 1.657(c).

On our own initiative, we are revising the accredited third-party certification body conflict of interest provisions in § 1.657(a)(1) to clarify that the certification body, its officers, employees, and other agents involved in

auditing and certification activities cannot own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified. We also are redesignating proposed paragraphs (a)(2) to (4) as (a)(3) to (5) and adding a new paragraph (a)(2) to conform to section 808(c)(5)(A)(i) of the FD&C Act. Additionally, we are revising redesignated § 1.657(a)(3) to add financial interests, management, or control to the proposed list of prohibited interests for audit agents.

(Comment 135) Some comments support proposed § 1.657, asserting that it strikes the right balance between ensuring rigorous protections against conflicts of interest and protection of trade secrets and confidential commercial information. Other comments oppose the third-party certification program that is the subject of this rulemaking because private auditors are inherently conflicted and food safety inspections should be conducted only by FDA.

Other comments suggest various additional conflict of interest restrictions that should be placed, such as requiring an individual audit agent or an individual accredited as a third-party certification body to divest of all interests in FDA-regulated food firms; prohibiting such individual from conducting a regulatory audit of an eligible entity where the individual previously conducted a consultative audit or where the individual was previously employed; and prohibiting the individual from accepting an offer of employment from an audited eligible entity for 1 year following an audit. Still other comments urge FDA to prohibit meals or beverages from being provided during an audit or to define the de minimis value of meals and beverages that may be provided onsite during an audit.

(Response 135) We believe the accredited third-party certification program that Congress directed us to establish under section 808 of the FD&C Act will provide a valuable complement to FDA inspections and will allow us to leverage rigorous, independent third-party audits in helping to ensure the safety of the U.S. food supply. We disagree with comments contending that third-party certification programs are so inherently conflicted that such a program is not worthwhile.

We believe the conflict of interest restrictions for accredited third-party certification bodies and for their audit agents that are established by section 808 of the FD&C Act for public and private third-party certification bodies, as implemented by this rule, provide the safeguards necessary for a credible

third-party certification program. Accordingly, we decline suggestions to revise § 1.657 to place additional conflict of interest limitations that would be impractical and unnecessary, such as requiring: (1) Requiring full divestment by audit agents of interests in any FDA-regulated food firm; (2) prohibiting an individual who conducted a consultative audit of an eligible entity from ever conducting a regulatory audit of the same eligible entity; (3) prohibiting an individual who audited an eligible entity from accepting an offer of employment from the eligible entity for 1 year following the audit; and (4) prohibiting an individual conducting an audit from accepting a beverage or a meal of de minimis value that is provided onsite during audit.

We disagree with comments suggesting that by providing meals of a de minimis value, an eligible entity or facility might influence the outcome of an audit by an accredited third-party certification body, particularly if the only allowable meals are ones of minimal value that are provided during the course of an activity and with the purpose of facilitating timeliness and efficiency. As explained in Response 55, FDA follows a similar approach for investigators conducting foreign inspections—that is, FDA investigators performing foreign inspections are allowed to accept lunches (of little cost) provided by firms during the course of foreign inspections. We also note that the U.S. government allows its employees to accept meals, within per diem limits, when on official business in a foreign country, as an exception to the prohibition on the acceptance of gifts or gratuities from outside sources (5 CFR 2635.204(i)(1)), though we believe the FDA's practices for foreign inspections serve as a better model because foreign inspections are more analogous to foreign audits than are the range of activities that covered by the general requirements applicable to all U.S. government employees on official business in foreign countries. Accordingly, in light of the comments received and analogous FDA guidelines, we have concluded that it is reasonable and appropriate to limit the meal exception in § 1.657(a)(4)(ii) to only lunches of de minimis value provided during the course of an audit, on site at the premises where the assessment is being conducted, and only if necessary to facilitate the efficient conduct of the audit. We believe these revisions help to address concerns regarding the threats to impartiality, while accommodating the practical considerations that apply to foreign audits.

Consistent with our guidance to recognized accreditation bodies under Response 55, we offer the following additional input to accredited third-party bodies seeking guidance on the application of § 1.657(a)(4)(ii). In considering whether a meal is allowable under this provision, we recommend first considering whether accepting the lunch is necessary to facilitate the efficient conduct of the audit. We recommend considering: (1) Whether the circumstances surrounding the travel would allow a lunch to be packed bring on site; (2) Whether the meal is being provided during the midday or early afternoon. A lunch provided in the midst of an audit is different than a lunch or other meal provided at the completion of the audit; (3) Whether the site of the audit is in close proximity to a retail food establishment, or is at a remote location far from a retail food establishment; (4) What is the estimated value (or cost) of the lunch in light of the costs associated with the area where the audit is being conducted; and (5) other similar considerations.

For accredited third-party certification bodies or audit agents seeking additional guidance on determining what constitutes a “de minimis” amount for purposes of complying with § 1.624(a)(3)(ii), we offer the following guidance that is based on the requirements applicable to U.S. government employees who accept certain meals while on official travel in foreign countries. Such employees must deduct from the per diem the value of that meal, calculated using a two-step process.

First, the individual must determine the per diem applicable to the foreign area where the meal was provided, as specified in the U.S. Department of State’s Maximum Per Diem Allowances for Foreign Areas, Per Diem Supplement Section 925 to the Standardized Regulations (GC,FA) available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, and available on the Department of State Web site at https://aoprals.state.gov/Web920/per_diem.asp. (Foreign per diem rates are established monthly by the Department of State’s Office of Allowances as maximum U.S. dollar rates for reimbursement of U.S. Government civilians traveling on official business in foreign areas.)

Second, the individual must determine the appropriate allocation for the meal within the daily per diem rate which is broken down into Lodging and M&IE that are reported separately in Appendix B of the Federal Travel Regulation and available on the

Department of State’s Web site at https://aoprals.state.gov/content.asp?content_id=114&menu_id=78.

Accordingly, under § 1.657(a)(4)(ii), an accredited third-party certification body that is an individual or an audit agent of an accredited third-party certification body who is conducting a food safety audit of an eligible entity may accept lunch provided during an audit and on the premises where the audit is conducted, if necessary to facilitate the efficient conduct of the audit.

(Comment 136) Some comments raise concerns about possible conflicts of interests. Some comments urge us to attach additional controls to the accreditation of foreign cooperatives to prevent them from auditing and certifying their members’ facilities and food. Other comments recommend we further consider the difficulties involved with foreign governments demonstrating impartiality of their processes in auditing and certifying facilities owned by the foreign government.

(Response 136) We note that under proposed § 1.657, foreign cooperatives accredited as third-party certification bodies would not be able to audit or certify their members’ facilities or foods under the program, because of their shared financial interests.

We decline the suggestion to develop special sets of controls for one or more types of third-party certification bodies eligible to be considered for accreditation under section 808 of the FD&C Act. We note that the conflict of interest requirements in section 808(c)(5) of the FD&C Act apply equally to the foreign governments, agencies of foreign governments, foreign cooperatives, and other third-parties. That is, a foreign government accreditation body that is recognized by FDA under this program may accredit government auditors (*i.e.*, the competent authority for food safety) from the same nation, provided that the conflict of interest requirements in § 1.657 are met. Consistent with the approach taken in the statute, we believe that this comprehensive, rigorous set of conflict of interest requirements make it unnecessary for us to create a different or special controls for certain types of certification bodies.

(Comment 137) Some comments support the proposal to require accredited third-party certification bodies to maintain up-to-date lists of eligible entities to which food or facility certification were issued, together with the duration and scope of each such certification. The comments suggest that having this information readily

available would be helpful to importers seeking to participate in VQIP and those seeking to import food that is subject to import certification under section 801(q) of the FD&C Act.

Other comments suggest that requiring an accredited third-party certification body to maintain a list of certified eligible entities on its Web site, together with the dates each eligible entity paid certification fees, could create an unfair competition. The comments contend that the statute does not require disclosure of the date of payment of fees and seek clarification on the basis for disclosing the timing of fee payments. Other comments suggest that information on payment of fees should remain confidential between the accredited third-party certification body and the eligible entities it audited and suggest the information could be made available to FDA on request. Still other comments contend that FDA should only have access to information on fee payments by eligible entities upon a showing of cause.

(Response 137) We agree with comments suggesting that Web site listings of eligible entities to which food or facility certification were issued would be helpful to importers. We disagree that such information would create unfair competition, and the comment did not provide an explanation as to why this would be the case. To the contrary, publicizing this information will increase transparency and accountability of the program. We are not proposing to require disclosure of the amount of fees paid by eligible entities, because we are concerned that publicizing the amounts of fee payments may lead to certification bodies using this information to gain a competitive advantage by offering audits at discount rates. However, we believe proposed § 1.657(c) meets the requirement of section 808(c)(5)(C)(ii) of the FD&C Act to provide information on the timing of fee payments and will help build confidence in the third-party certification program by providing assurances that payments are not related to the results of regulatory audits. We decline to adopt the alternative approach suggested by comments—*i.e.*, such information should be disclosed to FDA only when needed to investigate problems if they occur, and publicly released only if disclosure would improve public health—as inadequate to satisfy the requirements of section 808(c)(5)(C)(ii) of the FD&C Act. In light of the foregoing, we are retaining § 1.657(c), redesignated as § 1.657(d), as proposed.

I. What records requirements must a third-party certification body that has been accredited meet? (§ 1.658)

Proposed § 1.658 would require accredited third-party certification bodies to maintain the following documents and data electronically, in English, for 4 years, to document compliance with the rule: (1) Requests for regulatory audits; (2) audit reports and other documents resulting from a consultative or regulatory audit; (3) any notification of a condition under proposed § 1.650(a)(5) or by the accredited third-party certification body to FDA under proposed § 1.656(c); (4) any food or facility certification issued under this program; (5) any challenge to an adverse regulatory audit decision and its disposition; (6) any monitoring it conducted of a certified eligible entity; (7) the auditor's/certification body's self-assessments and corrective actions; and (8) any significant change to the auditing and certification program that might affect compliance with this rule.

On our own initiative, we are requiring under § 1.658(a)(3) the maintenance of any laboratory testing records and results and documentation demonstrating that such laboratory is accredited in accordance with § 1.651(b)(3).

(Comment 138) Some comments recommend that we allow accredited third-party certification bodies to maintain their records in languages other than English, coupled with a requirement to provide an English language translation upon FDA request. Some comments suggest that we should allow for flexibility in the timeline for submission of translated records in the regulations, rather than establishing a specific deadline, because the circumstances of each records request will dictate what would be appropriate—*e.g.*, where there is a recall involving a certified facility, then the timeframe for providing translations should be very stringent, but where records are requested for routine verification purposes, the accredited third-party certification body should have more time to comply. Other comments note that a minimum of 5 business days would be required for English language translations of records.

(Response 138) We agree that records should not be required to be maintained in English, for the same reasons as we explained in Response 64 (regarding the records of recognized accreditation bodies) and are revising § 1.658 accordingly. We further agree with comments suggesting that we should have a flexible, rather than a fixed timeline for providing English language

translations of requested records to FDA and are requiring translations to be provided within a reasonable time after an FDA request.

(Comment 139) Some comments urge us ensure that § 1.658 fully incorporates the limitation on access to reports and documents relating to consultative audits in section 808(c)(3)(C) of the FD&C Act.

(Response 139) Section 808(c)(3)(C) of the FD&C Act states that reports or other documents resulting from a consultative audit are accessible to us only under circumstances that meet the requirements for records access under section 414 of the FD&C Act. Proposed § 1.658(a)(1) utilizes the language of section 808(c)(3)(C) of the FD&C Act in describing the types of records of consultative audits that an accredited third-party certification body must maintain, and proposed § 1.658(b) states that those records must be made available to FDA in accordance with 21 CFR part 1, subpart J, which implements section 414 of the FD&C Act. Therefore, the requirements in § 1.658 do fully incorporate the limitation on access to reports and documents relating to consultative audits as specified in section 808(c)(3)(C) of the FD&C Act.

(Comment 140) Some comments urge us to ensure that trade secrets and confidential commercial information contained in any records submitted to FDA would be adequately protected. The comments note that the proposed rule does not contain language on the protection of trade secrets, such as the language in 21 CFR parts 120 and 123 indicating that HACCP plans are trade secrets exempt from disclosure. Other comments suggest that FDA should consider examining accredited third-party certification body records without taking custody of them. The comments further suggest that FDA should establish an administrative process for requesting records from accredited third-party certification bodies participating in the program.

Some comments urge us to clarify that we will not be applying the records access and submission requirements of subpart M to audits that are not conducted under the rule or to records of the audited food facilities.

(Response 140) We acknowledge concerns about protecting proprietary information and are adding § 1.695 to address disclosure issues (see Section XIII.F).

We decline the suggestion to review records of accredited third-party certification bodies without taking custody of the records, because such an approach would be inconsistent with the records provisions in section

808(c)(3)(B) of the FD&C Act and would undermine the credibility of the program. We also decline the suggestion to establish separate administrative processes for handling records requests that might include, for example, procedures for challenges to records requests and appealing adverse decisions on records requests. Establishing and administering a process for FDA records requests would hinder our program oversight and would be overly burdensome. We note that in this rulemaking, FDA has established a number of mechanisms to address challenges to FDA's decisions, including § 1.691 (for requests for reconsideration of the denial of an application of waiver request); § 1.692 (for internal agency review of the denial of an application or waiver request upon reconsideration); and § 1.693 (for regulatory hearings on withdrawal of accreditation).

We recommend third-party certification bodies to fully consider the program requirements before deciding to pursue recognition under the voluntary third-party certification program. Once accredited a certification body may voluntarily relinquish its accreditation under § 1.665.

We note that the records maintenance and access requirements of subpart M apply only to records relating to an accreditation of a third-party certification body under this rule and to the audits and certification activities conducted under this program. Records of audits or certifications issued by an accredited third-party certification body for any other purpose outside of the scope of the program under subpart M are not covered by § 1.658. We also note that the rule does not affect the records maintenance and access requirements that apply to facilities under subpart J of this part.

X. Comments on Procedures for Accreditation of Third-Party Certification Bodies Under This Subpart

A. Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body and what happens once the recognized accreditation body decides on my application? (§ 1.660)

Proposed § 1.660 states that auditors/certification bodies must apply directly to a recognized accreditation body for accreditation (except for circumstances meeting the requirements of § 1.670 for direct accreditation).

On our own initiative, we are adding new provisions (b) through (d) to § 1.660 to explain what happens when a third-party certification body's renewal

application is denied. We are adding provisions to clarify what the applicant must do, the effect of denial of an application for renewal of accreditation on food or facility certifications issued to eligible entities, and how FDA will notify the public.

(Comment 141) Some comments propose that we include a time limit for recognized accreditation bodies to issue an accreditation decision. They argue a time limit would set measurable standards for the process and would also help ensure an adequate supply of accredited auditors/certification bodies. Comments suggest the timeframe be 90 days. Some comments suggest the timeframe could be stipulated in the Model Accreditation Standards.

(Response 141) We acknowledge the interest in having timely accreditation decisions. However, the comments failed to provide an adequate basis to support a decision to impose a 90-day deadline for decisions on accreditation. No other information available to FDA provides an adequate basis for us to establish such a deadline, nor do we think it would be appropriate to do so at this time. We expect that the time required to perform various actions in the program will be longer in the early days of the program than it will when FDA, the accreditation bodies, and the third-party certification bodies gain experience with the program.

We decline to revise these regulations to impose a deadline for accreditation decisions, but may consider addressing the issue of deadlines for accreditation decisions in guidance, if we later determine it would be appropriate. We are mindful that section 808(c)(1)(C) of the FD&C Act requires revocation of recognition for failure to comply with the applicable requirements of the FD&C Act and FDA regulations. We would not want an accreditation body to take shortcuts in accreditation assessments to ensure that it could meet a regulatory deadline for its accreditation decisions out of concern for revocation for failure to comply with the deadline. The final rule reflects our view that the rigor of the accreditation assessment is essential in helping to ensure the credibility and success of the third-party certification program.

(Comment 142) Some comments ask whether the processes for accreditation are the same for governmental and private bodies.

(Response 142) Section 808(c)(1)(A) and (B) of the FD&C Act establishes different requirements for public certification bodies and for private certification bodies by specifying different criteria for the assessment of foreign governments/agencies than it

does for foreign cooperatives and other private third-party certification bodies seeking accreditation. However, the statute makes no distinction between public and private certification bodies in procedural matters for accreditation. Therefore, we are establishing a single set of accreditation procedures in this rule that apply to both public and private third-party certification bodies.

(Comment 143) Some comments ask how a third-party certification body could apply for accreditation under this program.

(Response 143) Third-party certification bodies seeking to apply for accreditation under our program may wish to review § 1.660 of this final rule, which describes the general procedures for applying for accreditation from a recognized accreditation body, as well as the eligibility requirements for certification bodies seeking accreditation in §§ 1.640 through 1.645. We will post on the FDA Web site a list of all recognized accreditation bodies and will include a description of the scope of recognition of each.

As provided in § 1.670(a)(3), FDA will announce on our Web site if we determine that the conditions for direct accreditation by FDA in section 808(b)(1)(A)(ii) of the FD&C Act have been met. We will accept applications for direct accreditation or renewal of direct accreditation only if we determine that we have not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing the program. Unless and until FDA makes such a determination, third-party certification bodies must apply for accreditation from an accreditation body that FDA has recognized.

(Comment 144) Some comments suggest that third-party certification bodies who receive an adverse decision on accreditation from a recognized accreditation body should have access to a competent, independent person outside the recognized accreditation body to whom they could appeal.

Other comments contend that we have the authority to challenge the decisions of an accreditation body.

(Response 144) As explained in Response 36, we are revising § 1.620(d)(2) to require a recognized accreditation body must use competent persons, who may be external to the accreditation body, for investigating and deciding on certification body challenges to an adverse accreditation body decision. Such competent persons must meet the following criteria: (1) Are free from bias or prejudice; (2) did not participate in the accreditation decision

being appealed; and (3) are not subordinate to a person who participated in such accreditation decision. Although we are not requiring the accreditation body to use an external party for certification body appeals, we believe the enhanced requirements of § 1.620(d)(2) will be adequate to ensure any person the accreditation body would select for investigating and deciding on appeals—whether internal or external—would be objective and independent.

With respect to comments suggesting that we should exercise our authority over recognized accreditation bodies to challenge their accreditation decisions, we note that the enhanced requirements in § 1.620(d) align with the impartiality provisions in part 16, which contains the regulations for FDA regulatory hearings that we will generally apply under § 1.693 to an appeal of a revocation or withdrawal. We also note that FDA retains the authority to revoke the recognition of accreditation bodies for good cause under § 1.634(a)(4) for failure to comply with this rule. For these reasons, we decline to establish a process appealing recognized accreditation body decisions to FDA.

B. What is the duration of accreditation by a recognized accreditation body? (§ 1.661)

Proposed § 1.661 states that the accreditation of a third-party certification body may be granted for a period up to 4 years.

(Comment 145) Most comments agree with our proposed maximum 4-year accreditation timeframe. In this regard, some comments state they are comfortable with this length of time as long as accreditation bodies annually review the accreditation. Some comments contend that instead of allowing accreditation to last “up to 4 years,” we should establish a definite duration period and it should be 5 years. These comments contend that would align the duration of accreditation with the duration of recognition. They also argue that having a definite duration period would be more viable administratively.

(Response 145) We agree with the comments supporting our proposal to allow accreditation to be issued for a term of up to 4 years. The comments suggesting accreditation should be granted for 5 years offered no information that would provide an adequate basis for extending accreditation such that a third-party certification body could be accredited for as long as a recognized accreditation body. We note that the rigor and credibility of the program rests, in part,

on the extent of oversight of accredited third-party certification bodies. Through the renewal process, recognized accreditation bodies (and FDA, for directly accredited third-party certification bodies) look closely at all aspects of a certification body's and performance and have the opportunity to decide anew whether the certification body meets the eligibility requirements.

With respect to comments suggesting that we establish a definite duration of accreditation that would apply to any third-party certification body accredited under the program, we acknowledge the advantages that certainty provides and, where appropriate, we expect that recognized accreditation bodies will issue accreditation for the maximum duration of 4 years. Where, for example, a certification body has little or no experience conducting audits assessing the safety of food, a recognized accreditation body (or FDA under direct accreditation) may decide the initial grant of accreditation should be less than 4 years. A recognized accreditation body (or FDA under direct accreditation) will make its own decision on whether to approve a third-party's application for accreditation and has the flexibility to issue accreditation for a duration it believes appropriate, up to a 4-year maximum established by this rule.

C. How will FDA monitor accredited third-party certification bodies? (§ 1.662)

We proposed in § 1.662 to monitor directly accredited certification bodies annually; we proposed to evaluate certification bodies accredited by a recognized accreditation body by not later than 3 years after the date of accreditation for a 4-year accreditation term or by no later than the mid-term point of a less-than-4-year accreditation term. We proposed to review a variety of records and information such as assessments by a recognized accreditation body, information regarding the auditor's/certification body's qualifications, and information obtained during onsite observations. We proposed to conduct our evaluation through onsite observations of performance during a food safety audit of an eligible entity or through document review.

(Comment 146) Some comments advocate for more clarity on the frequency and methods by which we'll be providing oversight of accredited third-party certification bodies. Some comments question whether we have sufficient resources to conduct onsite observation at any specific frequency. They advise that we further explain how

we are going to provide oversight and how compliance will be reported.

(Response 146) Monitoring assessments of accredited third-party certification bodies are one of several tools we will use for program oversight. Section 1.662(a) implements section 808(f) of the FD&C Act, which states that FDA must evaluate an accredited third-party certification body periodically, or at least once every 4 years, and take any other measures FDA deems necessary to ensure compliance. We anticipate that information gleaned from other monitoring tools, such as the accreditation body's annual assessment of the certification body, will also aid in program oversight and may perform additional assessments of certification bodies in certain instances.

The objective of an assessment under § 1.662 will be to determine the accredited third-party certification body's compliance with the requirements of this rule. FDA may conduct an assessment through a site visit of the third-party certification body's headquarters, onsite observation of an accredited third-party body's performance during a food safety audit, document review, or a combination of these activities. We will develop plans for assessing accredited third-party certification bodies based on risk and informed by data and other information available to FDA regarding their programs and performance in our program. The starting point for each assessment will be document review, and any additional assessment activities (e.g., site visits or onsite observations) will be conducted where circumstances may warrant or for spot-checks of randomly selected third-party certification bodies. When planning an assessment, we will establish the time period of activities covered by the assessment. We may request records of the certification body under § 1.658. We also may develop plans for any site visits or onsite observations, including locations to be visited. As part of the assessment, we may review records relating to conflicts of interest, and interview officers, employees, and audit agents, and other agents who participate in decisions on issuance of certification under this program. We are revising this section to explicitly state that FDA may visit the certification body's headquarters or other locations where audit agents are managed.

(Comment 147) Some comments propose alternative schedules for FDA monitoring of accredited third-party certification bodies. Some comments propose that if we revise the final rule to establish a fixed, 5-year duration for accreditation, we should monitor

accredited third-party certification bodies not later than 4 years after the date of accreditation. Other comments state that we should conduct our own assessments of certification bodies accredited by recognized accreditation bodies every 3 years. Still other comments ask who will cover the costs of such assessments.

(Response 147) As explained in Response 145, we decline the suggestion to lengthen the maximum duration of accreditation from 4 years to 5 years. We will use annual performance assessments by recognized accreditation bodies and information submitted to FDA as part of our ongoing monitoring of accredited third-party certification bodies. The FDA monitoring assessment under § 1.662 will occur at least once every 4 years and may occur more frequently depending on circumstances, including available resources. We are proposing that costs for FDA monitoring will be included in the user fees that are assessed under section 808(c)(8) of the FD&C Act to recover FDA's costs in administering the program (80 FR 43987).

(Comment 148) Some comments propose that FDA monitoring of accredited third-party certification bodies should periodically focus on compliance with food additive requirements.

(Response 148) Our monitoring will be tailored to the scope of accreditation under which the accredited third-party certification body may conduct food safety audits under this program. We will prioritize our monitoring activities to ensure compliance with the requirements of section 808(f)(2) based on factors such as our risk-based program priorities.

(Comment 149) Some comments suggest that, in addition to conducting onsite observations of accredited certification bodies when conducting a food safety audits, we could also do so when the recognized accreditation body assesses the auditor/certification body.

(Response 149) We agree and will do so as appropriate and as circumstances allow.

(Comment 150) Comments suggest that when FDA selects an accredited certification body for onsite observation, we should notify it 2 months in advance, to allow time to make the arrangements.

(Response 150) At this time, we have no basis for determining that we would be able to provide 2 months' notice prior to each certification body onsite observation; therefore, we decline the suggestion. We note that we may begin working with an accredited third-party

certification body well before we perform onsite observations, as feasible.

D. How do I request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits? (§ 1.663)

Proposed § 1.663 would allow accredited third-party certification bodies to seek an FDA waiver of the limit on audit agents conducting regulatory audits of an eligible entity where they conducted a regulatory or consultative audit in the preceding 13 months. Under section 808(c)(4)(C)(ii) of the FD&C Act, we may waive the limit, which appears in § 1.650(c), where there is insufficient access to accredited certification bodies in the country or region where an eligible entity is located.

Of our own initiative, we are clarifying in the final rule that the showing of insufficient access is based on lack of audit agents (or in case where accredited third-party certification bodies are comprised of an individual, that individual), consistent with changes made to § 1.650 (see Section IX.A).

(Comment 151) Some comments note that capacity issues are currently problematic, even in regions with highly developed third-party food safety auditing systems, and are likely to increase once the FSMA rules are implemented. Some comments contend that we should allow the request for the waiver to come from other affected parties in addition to accredited certification bodies. In particular, comments suggest we should allow the requests to come from a foreign supplier and/or the importer. Some comments estimate that, with the increased demand from FSMA for audit services, it will take time for capacity to expand sufficiently to satisfy the increased demand. Accordingly, they urge us to act expeditiously on waiver and waiver extension requests. Other comments express concern that FDA will be overwhelmed with waiver requests and urge FDA to develop a process for expedited issuance of waivers.

(Response 151) We acknowledge the concerns and are aware capacity is an issue the food industry and certification bodies currently face. However, we decline the suggestion to allow importers and foreign suppliers to seek waivers on behalf of an accredited certification body, because we believe the certification body is better positioned to determine its own capacity than an importer or foreign supplier would be. Further, it would ultimately be the certification body's choice regarding whether to take on

additional auditing work. If an accredited third-party certification body concluded it needed a waiver to be able to perform a particular audit, the certification body would be motivated to seek a waiver.

We agree with the comments suggesting it will take time to build adequate food safety auditing capacity around the world and will be prepared to act on waiver requests as expeditiously as possible. It is difficult to estimate the amount of the time required to process waiver requests, because the program has not launched. We anticipate that we will be able to process most waiver requests within 15 business days, as permitted by resources and other program activities. In response to comments suggesting that we should prioritize certain types of waiver requests, we have modified the first-in, first-out rule of § 1.663(d) to allow specific waiver requests to be prioritized based on program needs.

We also note that as we gain experience with the program and with information offered in support of waiver requests, we expect to be able to process waiver requests more quickly and may reevaluate whether FDA has adequate information to support issuance of a waiver for a particular country or region.

E. When would FDA withdraw accreditation? (§ 1.664)

Proposed § 1.664 would establish the conditions under which we could withdraw accreditation from a third-party certification body, regardless of whether it was directly accredited or accredited by a recognized accreditation body. This section would implement section 808(c)(6)(A) of the FD&C Act, which requires us to withdraw accreditation in certain outbreak situations, whenever we find that an accredited third-party certification body is no longer meeting the requirements for accreditation, or following a refusal to allow U.S. officials to conduct audits and investigations to ensure compliance with these requirements. The statute directs us to withdraw accreditation if a food or facility certified by an accredited third-party certification body under our program is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in human or animals. There is an exception if we conduct an investigation of the material facts of the outbreak, review the steps and actions taken by the third-party certification body, and determine that the accredited third-party certification body satisfied the

requirements for issuance of certification under this rule.

Section 808(c)(6)(B) of the FD&C Act allows us to withdraw accreditation from an accredited third-party certification body whose accrediting body had its recognition revoked, if we determine there is good cause for withdrawal. This statutory provision is reflected in proposed § 1.664(c), which also provides two examples of circumstances we believe provide good cause for withdrawal, including bias or lack of objectivity and performance calling into question the validity or reliability of its food safety audits and certifications.

In proposed § 1.664(d) we provide for records access when considering possible withdrawal of accreditation. In proposed § 1.664(e) we provide for notice of withdrawal of accreditation and describe the processes to challenge such withdrawal.

Proposed § 1.664(f) describes the effect of withdrawal on eligible entities. Proposed § 1.664(g)(1) explains that FDA will notify the recognized accreditation body that accredited the third-party certification body whose accreditation was withdrawn by FDA. Proposed § 1.664(g)(2) explains that FDA may revoke recognition of an accreditation body whenever FDA determines there is good cause for revocation under proposed § 1.634. Proposed § 1.664(h) provides for public notice of withdrawal of accreditation on FDA's Web site.

At our own initiative, we revised proposed § 1.664(c) on discretionary withdrawal of accreditation to allow for partial withdrawal of accreditation. For example, if FDA reviews a self-assessment submitted by an accredited third-party certification body following revocation of its accreditation body's recognition and determines the third-party certification body has failed to perform food safety audits consistent with this rule in some but not all areas for which it is accredited, FDA may partially withdraw the third-party certification body's accreditation as to those areas in which it has failed to comply with this rule.

(Comment 152) Some comments contend that FDA's interpretation of the statutory mandatory withdrawal provisions in section 808(c)(6)(A) of the FD&C Act is overly strict. The comments focus specifically on mandatory withdrawal when an eligible entity that was issued certification by an accredited third-party certification body is linked to a foodborne illness outbreak that meets the SAHCOHHA standard. The comments argue that one adverse event does not necessarily mean the

third-party certification body should lose its accreditation, emphasizing that a single certification body might conduct hundreds of audits in various regions of the world and in diverse product areas. The comments propose that we limit mandatory withdrawal following an SAHCODHA outbreak to the country, region, type of food product and process involved in the event.

Some comments agree that, as described in proposed § 1.664(f), certifications issued by a third-party certification body prior to withdrawal of its accreditation should remain in effect until they expire. Other comments assert that withdrawal of accreditation might result in unfairly revoking a significant number of certifications at tremendous cost, adversely affect other eligible entities that depend on the certification body and its certifications, and disrupt the marketplace. Still other comments request greater detail on the withdrawal procedures.

(Response 152) We believe the concerns about mandatory withdrawal of accreditation in the outbreak situation described above or similar situations are satisfactorily addressed in § 1.664(b), codifying section 808(c)(6)(C) of the FD&C Act, which allows FDA to waive mandatory withdrawal if FDA investigates the material facts of the outbreak, reviews the steps and actions taken by the certification body, and determines that the certification body satisfied the criteria for issuance of certification under this subpart.

Regarding the comments expressing concerns about the possible adverse effects of withdrawal of accreditation on certifications issued by the certification body to other eligible entities, we note that § 1.664(f) states that certifications issued by an accredited third-party certification body prior to withdrawal of accreditation by FDA will remain in effect until they expire, except that FDA may refuse to consider a certification under sections 801(q) or 806 of the FD&C Act if FDA has reason to believe such certification is not valid or reliable.

The comments seeking additional detail on our withdrawal procedures did not specify what areas of § 1.664 required further explanation. We believe the procedures described in § 1.664 offer sufficient detail for interested parties to understand the standards for withdrawal of accreditation by FDA and the processes involved.

(Comment 153) Some comments suggest that a recognized accreditation body, not FDA, should withdraw accreditation from a certification body it accredited, except for certification bodies directly accredited by FDA.

Other comments urge us to include a requirement, in § 1.634(a), for FDA to consult with the appropriate accreditation body before withdrawal of an accreditation it had issued. The comments argue that consultation would facilitate coordination with the recognized accreditation body and would complement § 1.664(c), which addresses discretionary withdrawal of accreditation in the event we revoke our recognition of the accrediting accreditation body. Other comments recommend that we meet with the certification body's accrediting body when considering possible withdrawal of accreditation and that we allow for a formal appeal process.

(Response 153) We disagree with the comment asserting that only accreditation bodies may withdraw accreditations of certification bodies they have accredited, as FDA is mandated under section 808(c)(6) of the FD&C Act to withdraw accreditation of a certification body under the conditions set forth in the section, subject to the waiver provision in 808(c)(6)(C). We note that a third-party certification body whose accreditation was withdrawn by FDA may appeal the action by requesting a regulatory hearing under § 1.693. We further note that a recognized accreditation body has far broader authority to suspend, withdraw, reduce, or otherwise dispose of an accreditation it issued, than FDA does under section 808(c)(6) of the FD&C Act. Even in circumstances that meet the statutory criteria for withdrawal of accreditation, FDA believes it generally would not need to initiate withdrawal unless the recognized accreditation body failed to withdraw the certification body's accreditation in a timely manner.

We agree that in some cases, consultation with a certification body's accrediting body before withdrawal could have advantages to FDA and the accreditation body, if circumstances allow. Decisions on whether to consult with the certification body's accrediting body prior to withdrawal will be made on a case-by-case basis. Consultation might not be appropriate if, for example, the facts that support withdrawal of the third-party certification body's accreditation also support revocation of the accreditation body's recognition.

(Comment 154) Some comments ask how individual holders of food or facility certificates would be made aware of the withdrawal of accreditation of the third-party certification body that issued the certificate. Other comments recommended that FDA post on its Web site not only that fact that a certification body's accreditation has been

withdrawn, but also the reason for the withdrawal.

(Response 154) If we withdraw accreditation of any third-party certification body, whether accredited by a recognized accreditation body or by FDA through direct accreditation, we will post information regarding the withdrawal, including a description of the basis for the action, on the FDA Web site pursuant to § 1.664(h). We do not intend to contact each eligible entity that was issued a certification by the third-party certification body because, as indicated in Response 152, certifications issued to eligible entities prior to withdrawal of accreditation will remain in effect until they expire, except where FDA has reason to believe the certification is not valid or reliable and on that basis may refuse to consider the certification under sections 801(q) or 806 of the FD&C Act.

(Comment 155) Some comments recommend we use ISO/IEC 17011:2004 as the reference document for the requirements of this section.

(Response 155) We decline the suggestion, because the grounds for withdrawal under section 808(c)(6) of the FD&C Act are much broader than those described in ISO/IEC 17011:2004 (Ref. 5). For example, under section 808(c)(6)(A)(i) and (C) of the FD&C Act FDA may withdraw accreditation of a certification body if a food or facility it certified under our program is linked to an outbreak of foodborne illness that has a reasonable probability of causing SAHCODHA, unless FDA determines the certification body satisfied the requirements for issuance of such certification. In such an outbreak situation, the statute contemplates that withdrawal of accreditation would occur after a single—albeit significant—failure by the certification body. By contrast ISO/IEC 17011:2004 allows for withdrawal of accreditation only when a certification body persistently fails to meet the requirements of accreditation or abide by the rules of accreditation.

We note that by declining to revise § 1.664 based on the comments, we are not suggesting that FDA will withdraw accreditation when the Agency identifies a single incident or mistake by a certification body, except where required by the statute. Any decision to withdraw accreditation will be based on the facts and circumstances of the situation and following due consideration by FDA.

(Comment 156) Some comments state that in a case where FDA withdraws an accredited certification body, the accreditation body should make an investigation and analysis and submit the analysis result to FDA within 3

months after the analysis report has been established.

(Response 156) We disagree. This rule does not require that the accreditation body make a full investigation and analysis and submit the analysis result to FDA within 3 months. Section 1.664(g) requires the accreditation body to perform a self-assessment and report the results of the self-assessment to FDA within 60 days. FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under § 1.634. These procedures will help ensure that accreditation bodies remain in compliance with the requirements of the third-party program.

F. What if I want to voluntarily relinquish accreditation or do not want to renew accreditation? (§ 1.665)

Proposed § 1.665 offers a mechanism for an accredited third-party certification body to voluntarily relinquish its accreditation before it terminates by expiration.

Although we received no adverse comments on this section, we received comments on other sections of the rule that led us to identify a gap in procedural requirements when an accredited certification body decides to allow its accreditation to expire without renewing it. At our own initiative, we are revising the voluntary relinquishment provisions in § 1.665 to also address situations where a certification body decides it does not want to renew its accreditation once it expires.

G. How do I request reaccreditation? (Proposed § 1.666)

Proposed § 1.666 describes the procedures a certification body must follow when seeking to be reaccredited after its accreditation was withdrawn by FDA or after voluntarily relinquishing its accreditation.

FDA received no adverse comments on this section. On our own initiative we are revising paragraph (a)(2)(i) to conform to the changes in § 1.634(d) to clarify that the third-party certification body has to become accredited by another accreditation body or by FDA through direct accreditation no later than 1 year after the withdrawal or accreditation, or the original date of expiration of the accreditation, whichever comes first.

XI. Comments on Additional Procedures for Direct Accreditation of Third-Party Certification Bodies Under This Subpart

A. How do I apply to FDA for direct accreditation or renewal of direct accreditation? (§ 1.670)

Section 808(b)(1)(A)(ii) of the FD&C Act allows us to directly accredit third-party auditors/certification bodies if we have not identified and recognized an accreditation body to meet the requirements of section 808 within 2 years after establishing this program. We proposed circumstances and procedures that would apply for direct accreditation and renewal of direct accreditation.

(Comment 157) Some comments assert that the statute anticipates a bifurcated system for direct accreditation of certification bodies, because the standards for review for accreditation of foreign governments are distinct from those of the private auditing entities under section 808(c)(1) of the FD&C Act. The comments ask that we draft additional rules to specifically cover direct accreditation of foreign governments, asserting that we should provide a separate path for direct accreditation of foreign governments that prioritizes their applications based on, among other things, the language in section 808(c)(1) of the FD&C Act. Some comments ask whether the same eligibility requirements and procedures are required of both governmental and private bodies applying for direct accreditation.

(Response 157) We disagree with the suggestion to create a bifurcated system. We acknowledge that section 808(c)(1) of the FD&C Act contains different requirements for foreign governments/agencies than it does for foreign cooperatives and other private third-party certification bodies seeking accreditation. However, we do not interpret this language as suggesting a preference for public certification bodies over private certification bodies.

We believe sections 808(c)(1)(A) and (B) of the FD&C Act are tailored to reflect the objectives and scope of each type of assessment, which would vary because of the differences between public and private certification bodies. While governments typically are both auditors/inspectors and owners of food safety schemes, private certification bodies usually are not scheme owners, because of concerns about possible conflicts of interest associated with serving in dual roles. Therefore, a private certification body would not be assessed for its food safety program or standards; it would be assessed for the training and qualifications of its

auditors and its internal management system. In light of the foregoing, we decline the suggestion to interpret sections 808(c)(1)(A) and (B) of the FD&C Act as supporting provisions for direct accreditation that would prioritize the applications of foreign governments/agencies over applications from private third-party certification bodies.

(Comment 158) Some comments suggest that FDA should not serve as an accreditation body for third-party certification bodies because it would open the door for other countries with less capability to do the same. The comments contend that FDA and its foreign regulatory partners need to provide the oversight of the industry, but should not be accreditation bodies.

(Response 158) We disagree. Section 808 of the FD&C Act contemplates that FDA can provide proper oversight of the program, while directly accrediting third-party certification bodies. We are unable to comment on what effects, if any, this would have on the actions of other countries. However, we emphasize that FDA will not perform direct accreditation unless the circumstances of section 808(b)(1)(A)(ii) of the FD&C Act are met—that is, if FDA has not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing this program.

(Comment 159) Some comments ask that we wait for more than 2 years after the program is established to accept applications for direct accreditation, to allow enough time for accreditation bodies applying for recognition to satisfy all the necessary requirements. Other comments assert that we should not directly accredit certification bodies in a country if we have already recognized an accreditation body in that country. Some comments ask us to clarify when, under what conditions, and how we would choose to directly accredit a certification body.

(Response 159) Under section 808(b)(1)(A)(ii) of the FD&C Act, 2 years after establishing the program is the earliest date that FDA may begin to directly accredit third-party certification bodies. Further, we may only do so if we determine that we have not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act 2 years after establishing the program. In the proposed rule, we provided examples of how we may make this determination, such as identifying a type of expertise or geographic location for which a recognized accreditation body is

lacking, and stated that we will only accept applications for direct accreditation and renewal applications that are within the scope of the determination. FDA declines to limit itself to a time period longer than 2 years before it can consider direct accreditation as any decision to directly accredit will depend on the circumstances the needs of the program, as determined by FDA under § 1.670(a).

(Comment 160) Some comments express concern that we will not have the capacity to undertake the responsibility of directly accrediting certification bodies.

(Response 160) Section 808(c)(8) of the FD&C Act requires FDA to create a user fee program to section 808 of the FD&C Act. FDA is in the process of establishing this program by rulemaking (80 FR 43987). For more information about the costs of this program, please see the regulatory analysis of this final rule.

(Comment 161) Some comments ask if we will have a contract agreement with directly accredited certification bodies. These comments assert that if we do, the contract should specify that we have the capacity to access confidential information without prior written consent of the certification body. The contract should also specify that having access to records relating to accreditation activities under this subpart is necessary to ensure the rigor, credibility, and independence of the program.

(Response 161) Under § 1.671(d), FDA will list any conditions associated with the accreditation in the issuance and may establish an agreement with the certification body at that time. With respect to access to records, a third-party certification body that is directly accredited by FDA must comply with the records maintenance and access requirements of § 1.658. Records obtained by FDA will be subject to the disclosure requirements of § 1.695.

B. How will FDA review my application for direct accreditation or renewal of direct accreditation and what happens once FDA decides on my application? (§ 1.671)

Proposed § 1.671 describes a process for reviewing and deciding on applications for direct accreditation and renewal that is consistent with the procedures for reviewing and deciding on applications under other provisions in this rule.

On our own initiative we are revising paragraph (a) to clarify that FDA will review submitted applications for completeness and notify applicants of any deficiencies. We also are adding

new paragraphs (e) through (h) to § 1.671 to explain what happens when a directly accredited certification body's renewal application is denied. We are adding provisions to clarify what the applicant must do, the effect of denial of an application for renewal of direct accreditation on food or facility certifications issued to eligible entities, and how FDA will notify the public.

(Comment 162) Some comments express concern that we are limiting ourselves to a "first in, first out" review process that gives us no discretion to accredit foreign governments before we consider other applications from private third-party entities that apply.

Some comments ask that we consider prioritizing approval of applications for direct accreditation on areas and regions where it is most needed to benefit our food safety mandates.

Some comments assert that priority for review of applications for direct accreditation should be for countries without an accreditation body or in circumstances where it is not economically feasible for a national accreditation body to expand its scope to include a certain single certification body.

(Response 162) As indicated Response 25, we intend to treat public and private certification bodies equally under this program, as both public and private certification bodies are capable of meeting the requirements of the program. Additionally, because we will only be accepting applications for direct accreditation in limited circumstances as discussed in Responses 158 and 159, all applications for direct accreditation will need to be able to demonstrate that there is a need for direct accreditation based on a determination made by FDA under § 1.670(a)(1). We note that we have revised § 1.671(a) to allow FDA to prioritize specific direct accreditation applications to meet the needs of the program.

(Comment 163) Some comments assert that our application review process must be comprehensive but also expedient. Some comments ask that our communications with applicants be timely.

Some comments express concern about the length of time it will take us to recognize and notify an applicant of any deficiencies in the application. These comments also assert that requiring applicants with deficiencies to resubmit their applications and sending it to the bottom of the review list would make for significant delays in the direct accreditation and renewal of direct accreditation application process.

(Response 163) We understand the concern expressed by comments with

regard to timeliness. Although we decline to set specific deadlines for this review, FDA anticipates that a completeness determination could generally be made within 15 business days, because this is not a decision on the merits of the application. Nonetheless, the time needed to identify deficiencies in any particular individual application will depend on a number of factors, including the quality of the submission, the availability of resources, and other competing priorities at the time the application is submitted. With respect to the concerns about requiring incomplete applications to be resubmitted and added to the bottom of the review list, we note that from our experience gained from the third-party certification pilot for aquacultured shrimp, extensive followup was needed with many of the applicants in order to gain sufficient information for a complete application. With this in mind, we are processing only complete applications so that we are not delaying others that have correctly prepared complete applications. Further, we are establishing an electronic portal for submission of applications, reports, notifications, and other information under this rule and an electronic repository of this information, which will allow us to communicate with applicants as needed.

C. What is the duration of direct accreditation? (§ 1.672)

We proposed that direct accreditation of a third-party certification body may be granted for a period up to 4 years. We tentatively concluded that 4 years is an appropriate duration for an accreditation because we believe the rigor and credibility of this program rests, in part, on the oversight of accredited certification bodies to conduct audits and to certify eligible foreign entities. We requested comment on this tentative conclusion.

(Comment 164) Some comments ask that we establish a specific fixed duration of 5 years for direct accreditation before renewal is required. These comments also ask that the duration for recognition of accreditation bodies and accreditation of third-party certifications bodies also be fixed at 5 years and assert that having a standardized accreditation term for all parties in the third-party program would be more administratively viable for us.

(Response 164) For the reasons we explained in Response 145 we decline to establish a fixed duration of accreditation and also decline to establish a standard term of 5 years for

accreditation for all parties in the third-party program.

XII. Comments on Requirements for Eligible Entities Under This Subpart

A. How and when will FDA monitor eligible entities? (§ 1.680)

Proposed § 1.680 would allow FDA to conduct onsite audits of eligible entities that have received certification from an accredited certification body at any time, with or without the accredited third-party certification body present. It also proposed that a food safety audit by an accredited certification body is not considered an inspection under section 704 of the FD&C Act. For clarification purposes at our own initiative, we are revising the second sentence of § 1.680(a) to add, “[w]here FDA determines necessary or appropriate,” before “the audit may be conducted with or without the accredited certification body or the recognized accreditation body (where applicable) present.”

(Comment 165) Some comments address the timing of FDA’s audits of eligible entities. Some comments encourage FDA to conduct audits of eligible entities regularly, particularly in the first years of the program, to ensure compliance with the program and to verify that certification is appropriate. Some comments encourage FDA to conduct random as well as targeted audits of eligible entities. For example, the comments suggest that if FDA withdraws the accreditation of a certification body, the Agency should conduct onsite audits of a sample of the eligible entities to which the withdrawn certification body issued certifications.

(Response 165) We agree that robust government oversight of the third-party program will be vital to its success and periodic audits of eligible entities will be conducted consistent with our risk-based priorities and resources.

(Comment 166) Some comments discuss the substance of FDA’s audits of eligible entities. Some of these comments encourage FDA to ensure that eligible entities implement corrective actions when deficiencies are identified. Some comments recommend that company data on tests of both products and the environment be made available to FDA auditors, and argue that without access to such data, FDA auditors would not be able to perform a thorough audit. Comments also maintain that, during an audit, FDA should be able to access results of the eligible entity’s testing of both products and the environment.

(Response 166) We currently are developing internal operational procedures for the third-party

certification program and will make these procedures public. As part of this process, we are developing protocols for FDA audits of eligible entities.

(Comment 167) Some comments argue that unannounced audits of eligible entities by FDA that have been certified by an accredited third-party certification body would likely result in incomplete audits and urge the agency to consider contacting the eligible entity to schedule such audits. Comments state that scheduled audits would be more efficient and less burdensome for both eligible entities and FDA because eligible entities would have a better understanding of what is needed during the audit and which employees should be present.

(Response 167) Section 808(c)(5)(C) of the FD&C Act directs FDA to promulgate regulations requiring that “audits performed under this section be unannounced.” Section 808(f)(3) of the FD&C Act allows FDA to, at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party certification body to ensure compliance with the requirements of section 808. Given this statutory language, we are clarifying in § 1.680 that an FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule. We note that it may not be appropriate at all times to precede audits for a 30-day operating schedule, such as in the case of a for-cause audit.

(Comment 168) Some comments state that when FDA has questions about eligible entities, it should notify the accreditation bodies and certification bodies to conduct a joint audit.

(Response 168) It is unclear what the comment means by conducting a joint audit, but § 1.680 would allow for the certification body and accreditation body to be present during the FDA audit when FDA determines it is necessary and appropriate.

(Comment 169) Some comments argue that the monitoring of eligible entities should be conducted by the competent authority of the exporting country, particularly where a systems recognition agreement is in place or where there is a robust national food control system in place.

(Response 169) We intend to coordinate as appropriate with our foreign regulatory counterparts; however, section 808(f)(3) of the FD&C Act specifically directs FDA to conduct onsite audits of eligible entities to ensure compliance with the requirements of section 808 of the FD&C Act. We believe onsite audits of certified

eligible entities are an important component of the robust oversight essential to the success of the third-party program. Without the ability to conduct onsite audits of a certified eligible entity, FDA would not be able to directly ascertain whether the certification body and/or its accreditation body are in fact making accurate determinations of compliance with FDA requirements. Such oversight is necessary to maintain confidence in the certifications issued by accredited certification bodies under this program.

(Comment 170) Some comments ask FDA to clarify why an onsite audit of an eligible entity is not considered an inspection under section 704 of the FD&C Act, particularly since the purpose of the audit is to determine if the entity is in compliance with the FD&C Act and since an FDA inspection may be used to meet the verification requirements under the proposed FSVP regulation. Other comments endorse FDA’s decision not to consider a food safety audit under this program an inspection under section 704 of the FD&C Act.

(Response 170) Section 808(h)(1) of the FD&C Act explicitly states that audits under the third-party certification program “shall not” be considered inspections under section 704. The inspections done under section 704 of the FD&C Act, unlike audits conducted under section 808(f)(3), are not conducted for the purpose of ensuring compliance with section 808 of the FD&C Act. The objective of an audit under § 1.680(a) extends beyond the eligible entity—through its audit of the eligible entity FDA is gathering information to use in its monitoring of the accredited certification body that audited the entity and the recognized accreditation body that accredited certification body that audited the eligible entity. We note that an audit under section 808(f)(3) is not a “food safety audit” under this subpart. As noted previously, the audits conducted under section 808(f)(3) are done specifically to ensure compliance with section 808 of the FD&C Act. As discussed in section III.C., we are clarifying that an audit conducted under this subpart is not an inspection under section 704 under the FD&C Act. Accordingly, we are removing § 1.680(b).

B. How frequently must eligible entities be recertified? (§ 1.681)

Proposed § 1.681 stated that an eligible entity seeking to maintain its facility certification must seek recertification prior to expiration of its certification. It also proposed that under

section 801(q)(4)(A) of the FD&C Act, FDA could require, at any time we deem appropriate, that an eligible entity renew a food certification.

We received no comments on this proposed section. However, to clarify certain matters, we are amending this section on our own initiative. We are adding to first sentence the words, "food or" before "facility certification" because the maximum duration of certifications under section 808(d) of the FD&C Act applies to both food and facility certifications. Additionally, we are revising this section to state that FDA can require an eligible entity to apply for recertification of both food and facility certifications at any time that FDA deems appropriate.

XIII. Comments on General Requirements of This Subpart

A. How will FDA make information about recognized accreditation bodies and accredited third-party certification bodies available to the public? (§ 1.690)

We proposed to post on our Web site a registry of recognized accreditation bodies and of accredited third-party certification bodies, including the name and contact information for each. The registry may provide information on certification bodies accredited by recognized accreditation bodies through links to the Web sites of such accreditation bodies. We requested comment on our proposed public registry.

(Comment 171) Some comments support our proposal to place a registry of recognized accreditation bodies and accredited certification bodies on our Web site and to provide links to the Web sites of recognized accreditation bodies. Some comments assert that such a web-based resource where members of the industry and public could access standards associated with accreditation/certification and a list of accreditation and certification bodies is a meaningful demonstration of FDA oversight. Some comments ask that this list be updated regularly so that it stays accurate. These comments also ask that we provide appropriate indexing and filtering functions so that the registry is easily searchable and stakeholders can conveniently and reliably find and use this information.

(Response 171) FDA agrees that the online registry will be a valuable tool. We intend for it to be updated regularly. We also intend for it to have indexing and filtering functions which will make searches more efficient and productive.

(Comment 172) Some comments ask that we not include the name(s) of audit agent(s) on our Web site or otherwise

publicly disclose such information could disrupt the marketplace for third-party certification services

Some comments assert that access to detailed, specific, and sensitive information is not necessary to gain credibility with consumers. These comments refer us to industry models that provide detailed information on the requirements of their program and posts a list of members in good standing along with a list of companies who have been decertified is an example of credible, balanced information that is actionable by consumers (*i.e.*, California Leafy Green Products Handler Marketing Agreement).

(Response 172) To clarify, we do not intend to disclose the names of audit agents on our Web site. We will be providing the business name and business contact information for each recognized accreditation body. The business name and business contact information for each accredited third-party certification body may be listed on our Web site or may be provided by link to Web sites of their accreditation bodies. The Web site will contain program information as well and may be similar to the industry models recommended by some comments.

(Comment 173) Some comments seek maximum transparency, asserting that we must also post on our Web site the audit reports, self-assessments, and notifications prepared by the third-party certification bodies and submitted to FDA. The comments contend that making this information public would increase program transparency and help to ensure that imported products do not receive an unfair competitive advantage over products available domestically.

Other comments suggest that we allow accreditation bodies and third-party certification bodies to submit redacted versions of these documents, where confidential information is blacked out, so that these documents can also be made publicly available without compromising confidential information. These comments assert that making public these reports, self-assessments, and notifications would improve self-assessments, reduce the Agency's burden of responding to FOIA requests, and allow independent analysis to complement the Agency's evaluation. Thus, comments ask us to specify in § 1.690 that we will also place on our Web site the reports and notifications submitted pursuant to §§ 1.623 and 1.656 and that we will allow a recognized accreditation body and accredited auditors/certification body to submit a redacted version of the report or notification that is intended to be made publicly available.

(Response 173) Generally, we do not intend to post redacted versions of reports on our Web site. Information submitted to the Agency, including reports and notifications submitted pursuant to §§ 1.623 and 1.656, becomes an Agency record. We have added a new § 1.695 to the final rule to clarify that records under this subpart are subject to part 20; part 20 provides protections for trade secrets and confidential commercial information (CCI) from public disclosure (*see, e.g.*, § 20.61).

(Comment 173) Some comments ask us to take action to ensure that third-party certification bodies act with maximum transparency and to ensure adequate protections against conflicts of interest. Some comments ask that we post on our Web site information concerning the scope of the recognized accreditation body recognition and accredited certification body accreditation, duration of accreditation, payments made to those accreditation bodies and certification bodies, and whether accreditation has been withdrawn or suspended. Some comments assert that requiring recognized accreditation bodies and accredited certification bodies to make this information available on their own Web sites does not ensure that all potential conflicts of interest will be identified, and suggest that we require that this information be submitted directly to us as well.

(Response 174) FDA agrees that it would be helpful to include on our Web site information concerning the scope of accreditation services that each recognized accreditation body is recognized for, and the scope of accreditation for each accredited certification body is accredited for. We also agree it would be useful and increase transparency to include the duration of recognition for each accreditation body, and the duration of accreditation for each certification body. Scope and duration information will make the site more practically useful and will increase transparency. Therefore, we intend to include this information on our Web site and we are revising § 1.690 to reflect this. In addition, we are revising this section to state that FDA will post on its Web site a list of accreditation bodies for which it has denied renewal of recognition, for which FDA has revoked recognition, and that have relinquished their recognition or have allowed their recognition to expire. Further, FDA will place on its Web site a list of certification bodies whose renewal of accreditation has been denied, for which FDA has withdrawn accreditation, and that have

relinquished their accreditations or have allowed their accreditations to expire. Finally, FDA will place on its Web site determinations under § 1.670(a)(1) and modifications of such determinations under § 1.670(a)(2). This additional information will help ensure maximum transparency under the program.

With regard to information on dates of payment, we have determined there is little additional value to posting such information on the FDA Web site, and it would create an additional administrative burden; we do not believe the value exceeds the burden. In our view, conflict of interest and transparency concerns are sufficiently satisfied by making information on dates of payment publicly available online via the Web sites of recognized accreditation bodies (see § 1.624(c)) and accredited certification bodies (see § 1.657(d)).

(Comment 175) Some comments request clarification concerning whether and what information we collect pursuant to this program will be made available to importers and the public. Some comments question the extent and format of the audit data that will be shared, and what might be held confidential. These comments assert that businesses have a need to protect proprietary information (e.g., sales lists, supplier lists, equipment designs and specific information about product attributes), and any sharing of such information might compromise their ability to carry out business functions or to maintain competitive advantage. Some comments inquire about the extent and formats of audit data we intend to make public, what might be held confidential, and whether we will take steps to protect information provided by certification bodies from FOIA requests.

Some comments express concern about our ability to develop and maintain a dynamic system that will be able to collect, update, and present audit data to consumers, and assert that it is important for industry to gain a better understanding of what type of audit data we will require.

Some comments suggest that we look to USDA's Food Safety and Inspection Service (FSIS) Public Health Information System for insight into how to develop a database system that seeks to define the boundary between increasing public access to data and addressing confidentiality concerns by companies. Some comments note that the FSIS program is the result of several years of effort to establish a mechanism for public access to data that can lead to research and analysis that improves

public health while protecting the proprietary rights of the establishments.

(Response 175) As discussed previously, newly added § 1.695 clarifies that records under this subpart are subject to part 20; part 20 provides protections for trade secrets and confidential commercial information from public disclosure (see, e.g., § 20.61).

FDA will provide periodic updates on program activities through our Web site, and our disclosures will be consistent with our statutory obligations to protect trade secrets and CCI from disclosure. With regard to the expressed concern about FDA's ability to develop and maintain an adequate data system to collect, update, and present audit data to consumers, we are aware of the size and importance of this undertaking and are diligently pursuing an effective system. We appreciate the suggestion to review the FSIS database system and intend to do so.

(Comment 176) Some comments encourage us to develop communication strategies to help consumers view the data in audit reports within the context of food production; specifically, to set proper program expectations and to provide proper context for consumers to understand what the data means. These comments assert that it is important to provide a frame of reference so that consumers have a basis for understanding what the audit data means and can then proceed to make informed decisions. The comments note that audits and certifications are not declarations or guarantees that products are safe, and that FDA and the industry need to feature this reality in communications strategies aimed to assist consumer groups and consumers in using any audit data that might be available for review.

(Response 176) As noted above, we do intend to share updates on program activities with the public; we will work to properly contextualize the data in our communications about and presentation of the information. As noted in Response 173, FDA does not generally intend to make audit reports public.

(Comment 177) Some comments assert that we must clearly describe how compliance with the program will be reported to the public.

(Response 177) As noted above, we intend to provide periodic updates on program activities through our Web site. Where appropriate, these updates may include aggregated program data. Additional information about program updates will be shared as we implement this program. Further, as noted in response to Comment 86, FDA will post information on its Web site regarding

accreditation bodies that have had their recognition revoked, accreditation bodies for which FDA fails to renew recognition, certification bodies that have had their accreditation withdrawn, and certification bodies whose renewal of accreditation has been denied.

B. How do I request reconsideration of a denial by FDA of an application or a waiver request? (§ 1.691)

We proposed procedures for accreditation bodies and certification bodies to seek reconsideration of a denial of an application or a waiver request. We also proposed that after completing our review and evaluation of the request for reconsideration, we will notify the requestor, in writing, of our decision to grant or deny the application or waiver request upon reconsideration.

On our own initiative, we are revising § 1.691(c) to specify that a request for reconsideration or a waiver request must be submitted electronically. We are making corresponding changes to § 1.692(b).

(Comment 178) Some comments suggest that we provide an opportunity for interested stakeholders, in addition to the accreditation body or third-party certification body seeking reconsideration, to provide information to us that will inform our decisionmaking on any reconsideration request.

(Response 178) We decline to adopt comments' suggestion to allow for others beyond the accreditation body or third-party certification body seeking reconsideration to engage in this process. Our reconsideration of a denial is not a public process nor do we wish to make it one. Applications often contain confidential information not appropriate for public comment. We note that information shared with FDA is subject to the information disclosure regulations in part 20, as stated in § 1.695.

(Comment 179) Some comments ask us to specify that we will notify the requestor of our decision within 20 business days after receiving a request for reconsideration. These comments assert that the open-ended timeframe for our review of reconsideration request may place an undue burden on the party seeking reconsideration.

(Response 179) FDA agrees that a request for reconsideration should be reviewed in a timely fashion. FDA would anticipate that this review will generally be made within 30 business days. However, given the conflicting demands on Agency resources at various times, the Agency declines to add this time restriction to § 1.691.

C. How do I request internal agency review of a denial of an application or waiver request upon reconsideration? (§ 1.692)

We proposed that the requestor who received a denial upon reconsideration under § 1.691 may seek internal Agency review of such denial under 21 CFR 10.75(c)(1).

(Comment 180) Some comments suggest that we provide an opportunity for interested stakeholders to provide information to us that will inform our decisionmaking on any such reconsideration request.

(Response 180) As with the parallel suggestion in the context of a request for reconsideration, we decline to adopt comments' suggestion. The Agency's review of a denial is not a public process nor do we wish to make it one. As noted previously, applications often contain confidential information not appropriate for public comment. We note that information shared with FDA is subject to the information disclosure regulations in part 20, as stated in § 1.695.

D. How do I request a regulatory hearing on a revocation of a recognition or withdrawal of accreditation? (§ 1.693)

We proposed procedures that would be used for challenges to revocation of recognition or withdrawal of accreditation.

On our own initiative, we revised § 1.693(f) to include the standard for denial of a request for a regulatory hearing under 21 CFR 16.26(a).

(Comment 181) Some comments suggest that we provide an opportunity for interested stakeholders, in addition to the accreditation body or third-party certification body seeking a regulatory hearing, to provide information to us that will inform our decisionmaking during a regulatory hearing.

(Response 181) Again, we decline to adopt comments' suggestion to allow for others beyond the accreditation body or third-party certification body seeking to challenge an FDA decision to engage in this process. For purposes of this final rule, we are not making the regulatory hearing a public process because issues pertaining to revocation and withdrawal generally contain confidential or sensitive information. We note that information shared with FDA is subject to the information disclosure regulations in part 20, as stated in § 1.695. We are amending proposed § 1.693(g)(3), redesignated as § 1.693(g)(2), to state that § 16.60(a) (public process) is inapplicable to hearings under this rule.

E. Are electronic records created under this subpart subject to the electronic records requirements of part 11? (§ 1.694)

We did not specify requirements for the retention of electronic records in the proposed rule. However, as discussed in relation to § 1.625, we received several comments regarding the potential application of the requirements for electronic records in part 11 to records under this subpart; several comments ask that we not apply the part 11 requirements here.

We agree that it would be unnecessarily burdensome to require that records under the third-party program comply with the requirements in part 11. Therefore, we are adding § 1.694 to the final rule which states that records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. We further specify that records that satisfy the requirements of this subpart, but those that also are required under other applicable statutory provisions or regulations, remain subject to part 11 to the extent that they are not separately exempted. Consistent with these provisions, we are making a conforming change in part 11 to specify in § 11.1(m) that part 11 does not apply to records that meet the definition of electronic records in § 11.3(b)(6) required to be established or maintained under this subpart, and that records that satisfy the requirements of this subpart, but that also are required under other statutory provisions or regulations, remain subject to part 11 to the extent that they are not separately exempted.

F. Are the records required by this subpart subject to public disclosure? (§ 1.695)

In the proposed rule, we did not specify requirements regarding the public disclosure of records created and retained under this subpart. However, as discussed previously in the preamble, several comments express concerns about whether notifications, records, and reports required by this rule would be protected from public disclosure. The comments state that notifications, records, and reports will often contain commercially sensitive information. Some comments ask that the regulations specify that such information under this program have the same level of protection from public disclosure under FOIA as juice and seafood HACCP records.

Information submitted to the Agency, including reports and notifications submitted pursuant to §§ 1.623 and 1.656, becomes an Agency record. We note we have added a new § 1.695 to the final rule to clarify that records under this subpart are subject to part 20; part 20 provides protections for trade secrets and CCI from public disclosure (see, e.g., § 20.61).

G. May importers use reports of regulatory audits by accredited certification bodies for purposes of subpart L of this part? (§ 1.698)

We proposed that an importer as defined in § 1.500 of this part may use a regulatory audit of an eligible entity, documented in a regulatory audit report, in meeting the requirements for an onsite audit of a foreign supplier under subpart L of this part.

(Comment 182) Some comments agree with FDA's proposal to allow importers to use regulatory audit reports of foreign suppliers, conducted for VQIP or import certification purposes, in meeting the verification requirements under the proposed FSVP program. These comments state that the use of regulatory audits by accredited third-party certification bodies should not be required under FSVP. The comments assert that importers should be free to choose how best to meet the verification requirements. Some comments misunderstood proposed § 1.698 to require the use of accredited third-party certification bodies for FSVP purposes.

(Response 182) To clarify that the use of an accredited third-party certification body for FSVP purposes is not required by this rule, we are removing this provision. This rule establishes the framework and procedures for participation in the accredited third-party certification program for purposes of sections 808 of the FD&C Act and does not create substantive requirements for the FSVP program. However, regulatory audits may be used to meet supplier verification requirements under FDA's final preventive controls regulations and FSVP regulations if they comport with those requirements.

XIV. Editorial and Conforming Changes

The revised regulatory text includes several changes that we have made to clarify requirements and to improve readability. The revised regulatory text also includes several conforming changes that we have made when a change to one provision affects other provisions. We summarize the principal editorial and conforming changes in table 5. We also made very minor editorial corrections, such as inserting a

missing end parenthesis symbol; those changes are not included in this chart.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES

Designation in the revised regulatory text (section)	Revision	Explanation
Throughout part 1, subpart M	Where applicable, substituted the term “assessment”, or its derivations, for the terms “audit” or “review”, or their derivations, when describing an FDA evaluation of an accreditation body and when describing an evaluation of a third-party certification body performed by a recognized accreditation body or by FDA.	Conforming change.
Throughout part 1, subpart M	Where applicable, substituted “evaluate”, or its derivations, for “assess” or “determine”, or their derivations, when describing the nature of activities involved in an “assessment” (as defined in this rule) of an accreditation body or a third-party certification body.	Conforming change.
Throughout part 1, subpart M	Where applicable, substituted “examine”, or its derivations, for “audit”, “assess”, “determine”, or “evaluate”, or their derivations, when describing the nature of activities involved in an “audit,” as defined in this rule, of an eligible entity.	Conforming change.
Throughout part 1, subpart M	Where applicable, revised to refer to “audit agent” rather than “agent” when describing individuals who conduct audits for accredited third-party certification bodies. Use “agent(s) used to conduct audits” rather than, “audit agent(s)” when referring to individuals who conduct audits for a third-party certification body prior to its accreditation under this program.	Improve clarity.
Throughout part 1, subpart M	Revised to refer to “competency” rather than “competence”	Improve clarity.
Throughout part 1, subpart M	Where appropriate, revised to refer to “recognized accreditation bodies” rather than “accreditation bodies”.	Improve clarity.
Throughout part 1, subpart M	Where appropriate, revised to refer to “accredited third-party certification bodies” rather than “third-party certification bodies”.	Improve clarity.
Throughout part 1, subpart M	Where appropriate, rephrased “[i]f FDA has reason to believe that a food certification issued for purposes of section 801(q) of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered.”	Improve clarity.
Throughout part 1, subpart M	Replaced “personnel” with “employees”	Improve clarity.
§ 1.600(c)	Deleted “, including the model accreditation standards” from the definition of “accreditation”.	Conforming change.
§ 1.600(c)	Revised the definition of “accredited third party certification body” to replace “is authorized” with “is accredited”.	Improve clarity.
§ 1.600(c)	Revised the definition of “eligible entity” to replace “subject to the registration requirements of” with “required to be registered under”.	Improve clarity.
§ 1.600(c)	Revised the definition of “facility certification” to replace “establish that a facility meets” with “establish whether a facility complies with”.	Improve clarity.
§ 1.600(c)	Revised the definition of “food certification” to replace “establish that a food meets” with “establish whether a food of an eligible entity complies with”.	Improve clarity.
§ 1.600(c)	Revised the definition of “relinquishment” to state that relinquishment occurs prior to the expiration of recognition or accreditation for accreditation bodies and certification bodies, respectively.	Improve clarity.
§ 1.601(a)	Changed “for conducting food safety audits and for issuing food and facility certifications to eligible entities” to “to conduct food safety audits and to issue food and facility certifications”.	Improve clarity.
§ 1.601(b)(2)	Changed “Issuing food and facility certifications” to “Issuing certifications”.	Improve clarity.
§ 1.601(c)	Changed “or in meeting the eligibility requirements” to “or issuing a facility certification for meeting the eligibility requirements”.	Improve clarity.
§ 1.601(d)	Replaced “except as provided in paragraph (d) of this section” with “under this subpart”.	Correction.
§ 1.601(d)	Redesignated paragraphs (1), (1)(i), (1)(ii), (2), (2)(i), and (2)(ii) as paragraphs (1)(i), (1)(i)(A), (1)(i)(B), (1)(ii), (1)(ii)(A), and (1)(ii)(B).	Editorial change.
§ 1.601(d)(1)(i)	Changed “[t]he certification of food under section 801(q)” to “[a]ny certification required under section 801(q)”.	Conforming change.
§ 1.601(d)(1)(ii)	Changed “[c]ertification of food under section 801(q)” to “Any certification required under section 801(q)”.	Conforming change.
§ 1.601(d)(1)(ii)	Changed “food other than alcoholic beverages that is from a facility” to “food that is not an alcoholic beverage that is received and distributed by a facility”.	Improve clarity.
§ 1.610	Section heading changed from “[w]ho is eligible for recognition,” to “[w]ho is eligible to seek recognition;” Text changed from “eligible for recognition” to “eligible to seek recognition.”	Improve clarity.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (section)	Revision	Explanation
§ 1.611(a)	Changed “through” to “as a legal entity with” Removed “such” from between “perform” and “assessments.”	Improve clarity.
§ 1.611(a)(2)	Changed “its capability to audit” to “its capability to conduct audits.” Replaced “personnel and other agents,” with “its agents, (or the third-party certification body in the case of a third-party certification body that is an individual, such individual)”.	Conforming change.
§§ 1.611(b), 1.612(b), 1.613(b), 1.614(b), 1.615(b), 1.623(d)(2), 1.630(b), 1.631(b), 1.641(b), 1.642(b), and 1.645(b).	In sentences referencing requirements for recognized accreditation bodies or accredited third-party certification bodies, replaced specific references to other sections of this rule with “the applicable [* * *] requirements of this subpart”.	Improve clarity.
§ 1.612(b)	Changed “capability to meet the* * *” to “capability to meet the applicable”.	Clarify that only the applicable assessment and monitoring requirements apply.
§ 1.615(a)	Added “pertaining to this subpart” between “legal obligations” and “and to provide”.	Improve clarity.
§ 1.615(b)	Replaced “[i]s capable of meeting,” with “The capability to meet”	Editorial change.
§ 1.620(a)(2)	Removed “that aggregates the products of growers or processor [sic],” after “foreign cooperative”.	Conforming change.
§ 1.620(d)	Replaced “including,” with, “and include”	Editorial change.
§ 1.621	Last word of section heading changed from “accredits” to “accredited”.	Editorial change.
§ 1.621(a)	At the end of the previously undesignated paragraph which is now paragraph (a), moved “recognized accreditation body . . . with this subpart”.	Improve clarity.
§ 1.622(a)	Added “compliance with this subpart, including” at the end of the opening phrase.	Improve clarity.
§ 1.622(a)(1)	Replaced “or other agents in activities under this subpart and the degree of consistency among such performances,” with “or other agents involved in accreditation activities and the degree of consistency in conducting accreditation activities”.	To clarify that the relevant activities under this subpart are accreditation activities.
§ 1.622(a)(2)	Added “involved in accreditation activities,” between “other agents,” and “with the conflict of interest requirements”.	Conforming change.
§ 1.622(c)(1)	Changed “area(s) needing improvement,” to “area(s) where deficiencies exist”.	Improve clarity.
§ 1.622(c)(2)	Changed “implement effective correction action(s) to address those area(s)” to “implement corrective action(s) that effectively address those deficiencies”.	Improve clarity.
§ 1.622(c)(3)	Inserted “any” between “records of,” and “such corrective action(s)”	Improve clarity.
§ 1.622(d)	Changed “includes:” to “includes the following elements.”	Conforming change.
§ 1.622(d)(2)	Added “involved in accreditation activities,” between, “other agents,” and “complied with the conflict of interest requirements”.	Conforming change.
§ 1.623(b)	Created subparagraphs by inserting, “(i)” before “a report of the results of an annual self-assessment” and “(ii)” before “for a recognized accreditation body subject to § 1.664(g)(1);” Removed “must submit” from between “§ 1.664(g)(1),” and “a report of such self-assessment;” Changed “to FDA within 2 months” to “to FDA within 60 days of the third party certification body’s withdrawal.”	Improve clarity.
§ 1.623(c)(1)	Added “(including expanding the scope of),” between “[g]ranting,” and “accreditation”.	Improve clarity.
§ 1.623(d)(1)(iv)	Added “scope and,” between “the” and “basis for such denial”	Improve clarity.
§ 1.624(a)	Changed from “other agents)” to “other agents involved in accreditation activities)”.	Conforming change.
§ 1.624(b) redesignated as § 1.624(c).	Rephrased “[t]he financial interests of the spouses and children younger than 18 years of age of officers, personnel, and other agents of a recognized accreditation body will be considered the financial interests of such officers, personnel, and other agents of the accreditation body”.	Improve clarity.
§ 1.624(d)	Changed “and date(s) on each the accredited” to “and the date(s) on which the accredited”.	Editorial change.
§ 1.625 title and paragraphs (a), (b), and (c).	Changed from “A recognized accreditation body,” to “An accreditation body that has been recognized”.	To clarify that the duties with respect to records as required under this subpart adhere to any accreditation body that has been recognized, including accreditation bodies that are no longer recognized.
§ 1.625(a)(2)	Added “expand or” after “withdraw, or”	Improve clarity.
§ 1.630(c)	Changed from “needed by FDA to process the application” to “needed by FDA during processing of the application”.	Improve clarity.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (section)	Revision	Explanation
§ 1.630(d)	Changed from “signed by the applicant or by any individual authorized” to “signed by an individual authorized”.	Improve clarity.
§ 1.631 heading	Changed heading from “How will FDA review applications for recognition and renewal of recognition?” to “How will FDA review my application for recognition or renewal of recognition and what happens once FDA decides on my application?”	Improve clarity.
§ 1.631(a)	Added “an accreditation body’s” after FDA will review, deleted “a”	Improve clarity.
§ 1.631(b)	Inserted “regarding” before “whether the application has been approved or denied.”	Editorial change.
§ 1.631(c)	Changed to state that the FDA will notify an applicant that its recognition or renewal application has been approved through issuance of recognition that will list any limitations associated with the recognition.	Improve clarity.
§ 1.631(d)	Changed to state that the FDA will notify an applicant that its recognition or renewal application has been denied through issuance of a denial of recognition that will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.	Improve clarity.
§ 1.632	Added “from the date of recognition” to the end of the sentence	Improve clarity.
§ 1.633(a)	Removed “periodically”	Improve clarity.
§ 1.633(a)	Rephrased “date of accreditation for a 5-year term of recognition, or by no later than mid-term point for recognition granted for less than 5 years.”	Improve clarity.
§ 1.633(b)	Rephrased “These may be conducted at any time, with or without the accreditation body or auditor/certification body present”.	Improve clarity.
§ 1.634(a)	Inserted “found not to be in compliance with the requirements of this subpart, including” after “of an accreditation body”.	Improve clarity.
§ 1.634(a)(2)(ii)	Changed “problem with the accreditation body” to “deficiency”	Improve clarity.
§ 1.634(a)(2)(iii)	Inserted “to do so” after “[d]irected”	Improve clarity.
§ 1.634(c)(1)	Changed “Upon revocation, FDA will notify that accreditation body, electronically, in English, stating * * *”.	Improve clarity.
§ 1.634(d)(1)	Removed “electronically and in English”	Improve clarity.
§ 1.634(d)(1)(i)	Rephrased from “[n]o later than 2 months after the revocation” to “[n]o later than 60 days after the date of issuance of the revocation”.	Improve clarity.
§ 1.634(d)(1)(ii)	Added “or the original date of the expiration of the accreditation, whichever comes first” after “revocation”.	Improve clarity.
§ 1.634(d)(2)	Changed from “a recognized” to, “another recognized”	Improve clarity.
§ 1.635 heading	Added “(c)” after “1.664”	Improve clarity.
§ 1.636(a)	Changed heading from “How do I voluntarily relinquish recognition?” to “What if I want to voluntarily relinquish recognition or do not want to renew recognition?”	Improve clarity.
§ 1.636(a)	Removed “or may be required to submit such application after a determination in a regulatory hearing under § 1.693”.	Improve clarity.
§ 1.640 heading	Changed heading from, “Who is eligible for accreditation?” to, “Who is eligible to seek accreditation?”	Improve clarity.
§ 1.641(a)	Changed “or through contractual rights” to “or as a legal entity with contractual rights” and added “and conformance with applicable” before “industry standards and practices”.	Conforming change.
§ 1.642(a)(1)	Changed “industry standards and practices and to issue” to “conformance with applicable industry standards and practices and issuance of”.	Improve clarity.
§ 1.641(a)(2)	Changed “of the eligible entity” to “of an eligible entity”	Conforming change.
§ 1.643(a)	Removed “such as witnessing the performance of a statistically significant number of personnel and other agents conducting audits of food facilities.”	Improve clarity.
§ 1.643(a)	Replaced “certification body (and its officers, personnel, and other agents) and eligible entities (and their owners and operators) seeking assessment and certification from,”	Improve clarity.
§ 1.644(a)(1)	Rephrased “[i]dentify areas in its auditing and certification program or performance that need improvement” to “[i]dentify deficiencies in its auditing and certification program or performance”.	Improve clarity.
§ 1.644(a)(2)	Rephrased from “Quickly execute corrective actions when problems are found” to “[q]uickly execute corrective actions that effectively address any identified deficiencies”.	Improve clarity.
§ 1.650 heading	Changed heading from “How must an accredited auditor/third-party certification body ensure its audit agents are competent and objective”, to “How must an accredited third-party certification body ensure competency and objectivity?”	Improve clarity.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (section)	Revision	Explanation
§ 1.650(a)(3)	Changed from “[p]articipates in annual food safety under the accredited auditor’s/certification body’s training plan,” to “[c]ompletes annual food safety training that is relevant to activities conducted under this subpart”.	Improve clarity.
Throughout §§ 1.651 and 1.652	Where appropriate, added “eligible” before “entity” and “food safety” before “audit”.	Improve clarity.
§ 1.651(a)(1)(i)	Inserted “subject to the requirements of this subpart” after “be conducted as a consultative or regulatory audit”.	Improve clarity.
§ 1.651(b)(1)	Changed from “[c]onduct an unannounced audit to verify whether the activities and results” to “[c]onduct an unannounced audit to determine whether the facility, process(es), and food”.	Conforming change.
§ 1.651(b)(2)	Removed “and, where appropriate, to issue food and facility certifications” from end of phrase.	Improve clarity.
§ 1.651(b)(5)	Inserted “audits conducted under this subpart as follows” after “[p]repare reports of”.	Improve clarity.
§ 1.651(b)(5)(i) (previously § 1.651(b)(5)).	Inserted “For” before “consultative audits,” Inserted “maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act.”	Improve clarity.
§ 1.651(b)(5)	Created (i) and (ii) to more easily distinguish between the different requirements for consultative and regulatory audits.	Improve clarity.
§ 1.651(b)(6)	Inserted “under this subpart” after “food safety audit”	Improve clarity.
§ 1.651(c)(2)	Changed “to establish compliance with the FD&C Act” to “to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices”.	Improve clarity.
§ 1.651(c)(3)	Rephrased “entity would be likely to remain in compliance with the applicable requirements of the FD&C Act for at least 12 months following the audit, provided that the facility and its process(es) are properly maintained and implemented.”	Improve clarity.
§ 1.651(c)(4)	Removed “assessment” and added “other data and information from the examination, including information on”. Removed “of the accredited auditor/certification body.”	Improve clarity.
Throughout §§ 1.652, 1.653	Where appropriate, inserted, “regulatory” before, “audit”	Improve clarity.
§ 1.652(a)	Reformatted requirements in § 1.652(a)(1) through (6) to more closely align with formatting of § 1.652(b)(1) through (6); Inserted “subject to FDA access in accordance with the requirements of section 414 of the FD&C Act.”	Editorial change.
§ 1.652(b)(1)	Replaced “audited facility” with “site or location where the regulatory audit was conducted”.	Improve clarity.
§ 1.652(b)(6)(i) and (ii)	Inserted “to humans or animals” after “serious adverse health consequences or death”.	Improve clarity.
§ 1.652(b)(8)	Rephrased from “is used in the facility” to “is performed in or used by the facility”.	Improve clarity.
§ 1.653 heading	Changed heading from “What must accredited auditor/certification body do when issuing food or facility certifications?” to “What must an accredited third-party certification body do when issuing food or facility certifications?”	Improve clarity.
§ 1.653(a)(1)	Changed “(or an audit agent” to “(or, where applicable, an audit agent”.	Improve clarity.
§ 1.653(a)(2)	Changed “to establish compliance” to “to determine compliance.”	Improve clarity.
§ 1.654 heading	Rephrased language in heading from “eligible entity with a food or facility certification” to “eligible entity that it has issued a food or facility certification”.	Improve clarity.
§ 1.654	Added “with such requirements” after “compliance” Changed “if it determines the eligible entity is no longer” to “if it withdraws or suspends a food or facility certification because it determines that the entity is no longer.”	Improve clarity.
§ 1.655(a)	Changed “must annually, and as required under § 1.631(f)(1)(i) or upon FDA request made for cause, conduct a self-assessment that includes evaluation of.”	Improve clarity.
§§ 1.655(a)(1), 1.655(a)(2), 1.655(a)(3), 1.655(d)(2), 1.657(a), 1.657(a)(1), 1.657(c).	Added “involved in auditing and certification activities,” after “other agents”.	Improve clarity.
§§ 1.655(a)(1), 1.655(a)(2)	Removed “under this subpart”	Improve clarity.
§ 1.655(a)(5)	Inserted “of” between “determination” and “whether”	Editorial change.
§ 1.655(c)(1)	Replaced “area(s) needing improvement” with, “deficiencies in complying with the requirements of this subpart”.	Improve clarity.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (section)	Revision	Explanation
§ 1.655(c)(2)	Rephrased from “effective corrective action(s) to address those area(s)” to “corrective action(s) that effectively address the identified deficiencies”.	Improve clarity.
§ 1.656(b)	Modified submission timeframe from 2 months to 60 days	Conforming change.
§ 1.656(c)	Rephrased “when any of its audit agents or the accredited auditor/ third-party certification body itself, discovers any condition found during a regulatory or consultative audit of an eligible entity, which”.	Improve clarity.
§ 1.657(a)(3) redesignated as § 1.657(a)(4).	Added “accredited third-party certification body’s” after “[p]rohibiting an”.	Improve clarity.
§ 1.657(a)(4) redesignated as § 1.657(a)(5).	Changed “other agent of the accredited auditor/certification body from accepting any money, gift, gratuity, or item of value” to “other agent involving in auditing and certification activities from accepting any money, gift, gratuity, or other item of value.”	Editorial change.
§ 1.657(a)(4)(i) redesignated as § 1.657(a)(5)(i).	Changed reference from “(a)(3)” to “(a)(4)”	Correction.
§ 1.657(c)	Changed from “accreditation” to, “auditing and certification”	Improve clarity.
§ 1.657(c)	Added “accredited third-party certification body’s” before “officers” ... Changed “other agents of an accredited auditor/certification body” to “other agents involving in auditing and certification activities.”	Improve clarity.
§ 1.658 heading	Changed heading to “What records requirements must an accredited auditor/certification body that has been accredited meet?”	Improve clarity.
§ 1.658(a)	Rephrased from “certification body must maintain electronically for 4 years records” to “certification body that has been accredited must maintain electronically for 4 years records created during its period of accreditation”.	Improve clarity.
§ 1.658(a)(1)	Removed “laboratory testing records and results (as applicable)	Conforming change.
§§ 1.658(a)(1), 1.658(a)(3)	Rephrased from “and corrective actions” to “verification of any corrective action(s) taken”.	Improve clarity.
§ 1.658(a)(4)	Replaced “under § 1.650(a)(5) or by the accredited auditor/certification body to FDA under § 1.656(e)” with “in accordance with § 1.650(a)(5)”.	Conforming change.
§ 1.658(a)(5)–(a)(9) redesignated as § 1.658(a)(5)–(a)(8).	Removed paragraph (a)(5)	Conforming change.
§ 1.658(a)(8) redesignated as § 1.658(a)(7).	Rephrased from, “taken as a result” to “taken to address any deficiencies identified during a self-assessment”.	Improve clarity.
§ 1.658(a)(9) redesignated as § 1.658(a)(8).	Changed “the auditing or certification program” to “its auditing or certification program”.	Improve clarity.
§ 1.658(b)	Changed from “FDA in accordance with the requirements of subpart J of this chapter” to “FDA in accordance with section 414 of the FD&C Act”.	Correction.
§ 1.660 heading	Changed heading to “Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body and what happens once the recognized accreditation body decides on my application?”	Improve clarity.
§ 1.661	Added “by a recognized accreditation body” at end of header	Improve clarity.
§ 1.662(a)	Rephrased “comply with the requirements of §§ 1.640 to 1.658 and whether there are deficiencies in the performance of the accredited auditor/certification body that, if not corrected, would warrant withdrawal of its accreditation under this subpart.”	Improve clarity.
§ 1.662(b)(4)	Rephrased from “regarding the accredited auditor’s/certification body’s authority, qualifications (including the expertise and training of its audit agents), conflict of interest program, internal quality assurance program, and monitoring by its accreditation body (or, in the case of direct accreditation, FDA);”	Improve clarity.
§ 1.663(d)	Rephrased from “submission was completed” to “completed submission is received”.	Improve clarity.
§ 1.663(e)	Removed “in writing” and “Such notification may be made electronically.”	Conforming change.
§ 1.663(f)	Replaced “conditions” with “limitations”	Improve clarity.
§ 1.663(f)	Replaced “notification” with “issuance of the waiver” and “issuance of a denial of a waiver request” as appropriate.	Improve clarity.
§ 1.664(a)(1)	Replaced “conditions” with “limitations.”	Correction.
§ 1.664(a)(2)	Added “or chemical or physical hazard”	Correction.
§ 1.664(a)(2)	Changed “meets the requirements” to “complies with the applicable requirements”.	Improve clarity.
§ 1.664(b)(2)	Replaced “steps” with “relevant audit records”	Improve clarity.
§ 1.664(b)(2)	Replaced “to justify the food or facility certification” with “in support of its decision to certify”.	Improve clarity.
§ 1.664(c)(2)	Deleted “food or facility”	For flexibility.

TABLE 5—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (section)	Revision	Explanation
§ 1.664(e)(1)	Added “of its accreditation through issuance of a withdrawal that will state”.	Improve clarity.
§ 1.664(e)(1)	Deleted, “electronically, in English”	Conforming change.
§ 1.664(e)(2)	Added “issuance of the” between “date of” and “withdrawal”	Improve clarity.
§ 1.664(g)(1)	Replaced “bodies” with “body it accredited”	Improve clarity.
§ 1.664(g)(1)	Added “by FDA.”	
§ 1.664(g)(1)	Changed “2 months” to “60 days.”	
§ 1.664(g)(2)	Removed “electronically and in English.”	
§ 1.664(h)	Replaced “such” with “an”	Editorial change.
§ 1.664(h)	Replaced “and the status of recognition and food and facility certifications” in the heading with “accreditation”.	Improve clarity.
§ 1.664(h)	Replaced “under this subpart” with “and provide a description of the basis for withdrawal”.	Improve clarity.
§ 1.665 heading	Changed heading from “How do I voluntarily relinquish accreditation?” to “what if I want to voluntarily relinquish accreditation or do not want to renew?”	Improve clarity.
§ 1.665(a)	Changed “2 months” to “60 days”	Improve clarity.
§ 1.665(b)	Added “The accreditation body must establish and maintain records of such notification under § 1.625(a).”	Clarification.
§ 1.666(a)(1)	Replaced “requirements for accreditation” with “applicable requirements of this subpart”.	Improve clarity.
§ 1.666(a)(2)(i)	Replaced “a” with “another” and “not” with “no”	Editorial changes.
§ 1.670(a)(3)	Added “(a)(1) of this section, as described in paragraph (a)(2)”	Correction.
§ 1.670(b)(1)	Revised to specify provision “(a)(1)”	Improve clarity.
§ 1.670(b)(2)	Added subsection title “ <i>Submission</i> ”	Improve clarity.
§ 1.670(b)(3)	Added subsection title “ <i>Signature</i> ”	Improve clarity.
§ 1.671 heading	Changed title from “How will FDA review applications for direct accreditation and for renewal of direct accreditation?” to “How will FDA review my application for direct accreditation or for renewal of direct accreditation and what happens once FDA decides on my application?”	Improve clarity.
§ 1.671(b)	Reorganized the provision: Moved original (f) under (b)	Improve clarity.
§ 1.671(c) previously (c) and (d)	Redesignated as (c) to state that FDA will notify an applicant that its direct accreditation or renewal application has been approved through issuance of direct accreditation that will list any limitations associated with the accreditation.	Improve clarity.
§ 1.671(e)	Redesignated (e) to (d)	Improve clarity.
§ 1.671(e)	Replaced “denies” with “issues a denial”	
§ 1.671(e)	Added “for direct accreditation or for renewal of direct accreditation.”	
§ 1.671(e)	Replaced “notification” with “issuance of the denial of direct accreditation.”	
§ 1.681	Deleted “address and”	
§ 1.681	Combined (a) and (b)	Improve clarity.
§ 1.681	Replaced “seek” with “apply for”	
§ 1.691(a) and (b)	Replaced “decision” with “the issuance of such denial”	Improve clarity.
§ 1.691(c)	Replaced “it describes” with “described in the notice”	Editorial change.
§ 1.691(d)	Deleted “in writing”	Improve clarity.
§ 1.691(d)	Rephrased “of its decision to grant the application or waiver request upon reconsideration, or its decision to deny the application or waiver request upon reconsideration.”	
§ 1.692(a)	Replaced “FDA issued” to “of issuance of”	Editorial change.
§ 1.692(d)	Deleted “electronically”	Improve clarity.
§ 1.692(d)	Added phrases “through issuance of an application or waiver request upon reconsideration” and “application or waiver request upon reconsideration through issuance of a denial of.”	
§ 1.692(e)	Replaced “Affirmation” with “Issuance”	Improve clarity.
§ 1.693	Replaced “FDA issued” and “written notice” with “issuance of”	For consistency and to improve clarity.
§ 1.693(a)	Rephrased “the accreditation body or an individual authorized to act on its behalf” to “an individual authorized to act on the accreditation body’s behalf”.	Improve clarity.
§ 1.693(b)	Rephrased “the auditor/certification body or an individual authorized to act on its behalf” to “an individual authorized to act on the third-party certification body’s behalf”.	Improve clarity.

XV. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of Tribal officials' concerns and how FDA has addressed them (Ref. 26). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

XVI. Analysis of Economic Impact

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the Third-Party program will be used primarily on voluntary basis where private enterprises determine that the benefits of participating in our program outweighs their associated user fee and compliance costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount. Annualized cost of the

Third-Party final rule is estimated at approximately \$2.8 to \$11.6 million, depending on the scenario.

XVII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications (Third-Party final rule)

Description: FDA is amending its regulations to provide for accreditation of third-party certification bodies (CBs) to conduct food safety audits of eligible foreign food entities, including foreign food facilities, and to issue food and facility certifications, pursuant to the FDA Food Safety Modernization Act. Use of accredited third-party CBs and food and facility certifications will help us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. We also expect that these regulations will increase efficiency by reducing the number of redundant audits to assess compliance with applicable food safety requirements of the FD&C Act and FDA regulations.

Description of respondents: The coverage of the Third-Party final rule includes eligible entities seeking audits, certification, and/or recertification by accredited CBs participating in our program, accreditation bodies (ABs) seeking to comply with the recognition requirements of the Third-Party final rule, and CBs seeking to comply with the accreditation requirements of the Third-Party final rule (including those accredited by recognized ABs and those directly-accredited by FDA). An eligible entity is a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit conducted by an accredited third-party certification body.

Based on FDA Operational and Administration System for Import Support database information, we estimate that there are 200,692 foreign food and feed exporters that offer their food and feed for import into the United

States. These foreign food and feed exporters include 129,757 food and feed production facilities and 70,935 farms. A proportion of these foreign food and feed exporters may offer food subject to mandatory certification requirements under section 801(q) of the FD&C Act. In that case, the eligible entities must either comply with the Third-Party final rule in order to obtain certification from a CB accredited under the third-party program to continue exporting their food products into the United States, or a foreign government designated by FDA, or lose their access to U.S. markets. In the economic analysis of the Third-Party final rule, we assume that in any given year 75 foreign food and feed exporters will be subject to section 801(q) of the FD&C Act.

In addition to the entities subject to § 801(q), some food exporters will seek certificates to participate in VQIP under section 806 of the FD&C Act. We consider three different scenarios for the participation rate of VQIP importers and their associated foreign suppliers in a 10-year period: (1) Constant number of VQIP importers in every year, (2) increasing participation over time, peaking at 20 percent of all importers of perishable products by the fifth year, with stagnant growth in subsequent years, (3) increasing participation over time, peaking at 40 percent of all importers of perishable products by the 10th year of the program.

The VQIP draft guidance document caps the acceptance of applications by importers for VQIP at 200 for the initial year of the program. Under Scenario 1, we consider 200 importers participating in each of first 10 years of VQIP (see table 6). Average number of foreign suppliers per importers is approximately 5.58; therefore, under Scenario 1, we expect that 200 importers and approximately 1,116 foreign suppliers (200 importers × 5.58 foreign supplier per importer) will be participating in VQIP every year for a 10-year period (see tables 6 and 7).

According to FDA's Office of Regulatory Affairs Reporting Analysis and Decision Support System database, the number of importers of perishable products is approximately 2,759. These importers would have an incentive to participate in VQIP in order to expedite entry of their perishable food products into the United States. Under Scenario 2, we consider 200 importers participating in the initial year of VQIP and increasing steadily until the fifth year of the program until 552 importers (20 percent × 2,759 importers of perishable products) are participating in the program. For years 6 through 10, we consider 3 percent increase in

participation of new importers in VQIP (see table 6). Multiplying the number of importers by the number of foreign suppliers per importers (5.58), we expect that the number of foreign suppliers participating in VQIP, under Scenario 2, would increase from 1,116 to 3,527 in a 10-year period (see table 7).

Under Scenario 3, we consider the number of importers will increase from 200 in the initial year of VQIP to 1,104 importers (40 percent × 2,759 importers of perishable products) in the 10th year of the program. Tables 6 and 7 include the number of importers and their associated foreign suppliers for scenario 3. Table 9 includes total number of eligible entities in the Third-Party final rule based on the three considered

scenarios in the 10th year of the program.

The economic analysis of the Third-Party final rule estimates compliance costs under the assumption that expected efficiency gains, and foreign food suppliers' incentive to maintain continued importation of their food to the United States would lead all foreign suppliers subject to section 801(q) of the FD&C Act, and foreign suppliers who choose to use third-party food safety audits to satisfy requirements of FDA's VQIP, to become eligible entities and seek food safety audits under the Third-Party final rule.

Considering the demand for food safety audits under the Third-Party program by foreign suppliers subject to section 801(q) of the FD&C Act and those wanting to participate in VQIP, we

expect that some of the ABs and CBs operating globally will also have an incentive to participate and comply with the Third-Party final rule. Under the three different scenarios discussed above, we have estimated that 11 to 25 ABs will accredit CBs that will conduct food safety audits of foreign eligible entities that offer food or feed for import to the United States. We also estimate that approximately 91 to 207 CBs will be accredited by the potential 11 to 25 AB applicants; these CBs will comply with the Third-Party final rule in order to participate in the program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA under the Third-Party final rule (see table 9).

TABLE 6—POTENTIAL NUMBER OF IMPORTERS PARTICIPATING IN VQIP IN ITS INITIAL 10 YEARS

Scenario	Year									
	1	2	3	4	5	6	7	8	9	10
1	200	200	200	200	200	200	200	200	200	200
2	200	288	376	464	552	562	579	596	614	632
3	200	300	400	500	600	700	800	900	1,000	1,104

TABLE 7—POTENTIAL NUMBER OF FOREIGN SUPPLIERS (SECTION 806 OF THE FD&C ACT) PARTICIPATING IN VQIP IN ITS INITIAL 10 YEARS

Scenario	Year									
	1	2	3	4	5	6	7	8	9	10
1	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116
2	1,116	1,607	2,098	2,589	3,080	3,136	3,231	3,326	3,426	3,527
3	1,116	1,674	2,232	2,790	3,348	3,906	4,464	5,022	5,580	6,160

TABLE 8—NUMBER OF RESPONDENTS IN THE THIRD-PARTY FINAL RULE

Eligible entities	Scenario 1	Scenario 2	Scenario 3
Section 801(q) of FD&C Act	75	75	75
Section 806 of FD&C Act	1,116	3,527	6,160
Total eligible entities	1,191	3,602	6,235

TABLE 9—NUMBER OF RESPONDENTS TO THE THIRD-PARTY FINAL RULE

Status of ABs/CBs	Number of ABs/CBs		
	Scenario 1	Scenario 2	Scenario 3
ABs seeking recognition	11	17	25
CBs seeking accreditation by recognized ABs	91	140	207
CBs seeking accreditation by FDA	1	1	1
Total CBs accredited	92	141	208

Information Collection Burden Estimate: We estimate the burden for this information collection as follows:

Recordkeeping Burden

In summary, under Scenario 1, total one-time recordkeeping burden by 11 recognized ABs and 92 CBs accredited under the third-party program is

estimated at 25,792 hours (see table 10). Total annual recordkeeping burden by 11 recognized ABs and 92 CBs accredited under the third-party

program is estimated at 2,673 hours (see table 13).

Under Scenario 2, total one-time recordkeeping burden by 17 recognized ABs and 141 CBs accredited under the third-party program is estimated at 41,640 hours (see table 11). Total annual recordkeeping burden by 17 recognized ABs and 141 CBs accredited under the

third-party program is estimated at 4,553 hours (see table 14).

Under Scenario 3, total one-time recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 58,570 hours (see table 12). Total annual recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the

third-party program is estimated at 6,253 hours (see table 15).

For the purpose of this analysis we assume that all ABs that apply for recognition in the program become recognized and all CBs that apply for accreditation are accredited.

TABLE 10—SCENARIO 1, ESTIMATED ONE-TIME RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.615	11	1	11	2	22
§ 1.645	92	1	92	2	184
§ 1.624(d)	11	1	11	160	1,760
§ 1.657(d)	92	1	92	160	14,720
Contract modification	11	8.27	91	2	182
§ 1.651	92	48	4,416	2	8,832
§ 1.653(b)(2)	92	1	92	1	92
Total One-Time Recordkeeping Burden					25,792

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

TABLE 11—SCENARIO 2, ESTIMATED ONE-TIME RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.615	17	1	17	2	34
§ 1.645	141	1	141	2	282
§ 1.624(d)	17	1	17	160	2,720
§ 1.657(d)	141	1	141	160	22,560
Contract modification	17	8.23	140	2	280
§ 1.651	141	55.4	7,811	2	15,623
§ 1.653(b)(2)	141	1	141	1	141
Total One-Time Recordkeeping Burden					41,640

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

TABLE 12—SCENARIO 3, ESTIMATED ONE-TIME RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.615	25	1	25	2	50
§ 1.645	208	1	208	2	416
§ 1.624(d)	25	1	25	160	4,000
§ 1.657(d)	208	1	208	160	33,280
Contract modification	25	8.79	220	2	440
§ 1.651	208	48.5	10,088	2	20,176
§ 1.653(b)(2)	208	1	208	1	208
Total One-Time Recordkeeping Burden					58,570

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

TABLE 13—SCENARIO 1, ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.625	11	397	4,367	0.025 (15 minutes)	1,092
§ 1.624(c)	11	1	11	8	88

TABLE 13—SCENARIO 1, ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.657(d)	92	1	92	8	736
§ 1.652	92	48	4,416	0.083 (5 minutes)	367
§ 1.653(b)(2)	92	48	4,416	0.083 (5 minutes)	367
§ 1.656(c)	92	0.25	23	1	23
Total Annual Recordkeeping Burden					2,673

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

TABLE 14—SCENARIO 2, ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.625	17	456	7,752	0.25 (15 minutes)	1,938
§ 1.624(c)	17	1	17	8	136
§ 1.657(d)	141	1	141	8	1,128
§ 1.652	141	55.4	7,811	0.083 (5 minutes)	648
§ 1.653(b)(2)	141	55.4	7,811	0.083 (5 minutes)	648
§ 1.656(c)	141	0.25	35	1	35
Total Annual Recordkeeping Burden					4,533

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

TABLE 15—SCENARIO 3, ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.625	25	426	10,650	0.25 (15 minutes)	2,663
§ 1.624(c)	25	1	25	8	200
§ 1.657(d)	208	1	208	8	1,664
§ 1.652	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.653(b)(2)	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.656(c)	208	0	52	1	52
Total Annual Recordkeeping Burden					6,253

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

Sections 1.615 and 1.645 of the Third-Party final rule require that at the time an AB submits an application for recognition (under § 1.630 of the Third-Party final rule) or a CB submits an application for direct accreditation (under § 1.660, or where applicable under § 1.670), the AB or CB must demonstrate that it has implemented written procedures to adequately establish, control, and maintain records for the period of time necessary to meet its contractual and legal obligations pertaining to the third-party program.

Currently, ABs maintain recordkeeping protocols relating to their operations; however, we expect that ABs will review their recordkeeping protocols and, if necessary, modify them to meet the requirements of § 1.615 of the Third-Party final rule before submitting applications for recognition. We believe that the records requirements for ABs in § 1.615 and CBs in § 1.645 would constitute a new one-time burden for the 11 to 25 ABs in each of the three considered scenario, and 92 to 208 CBs respectively. We expect that it would

take no more than 2 hours for an AB or a CB to modify its recordkeeping protocol to comply with the written recordkeeping requirements described in §§ 1.615 and 1.645 of the Third-Party final rule (see tables 10 to 12). Therefore, under Scenario 1, we estimate that it would take 22 hours (2 hours/AB × 11 ABs) for ABs to comply with § 1.615 (34 hours under Scenario 2, and 50 hours under Scenario 3) (see tables 10 to 12). We estimate 184 hours (2 hours/CB × 92 CBs) for CBs to comply with § 1.645 of the Third-Party final rule

(282 hours under Scenario 2, and 416 hours under Scenario 3) (see tables 10 to 12).

Section 1.625 of the Third-Party final rule requires that an AB that has been recognized maintain records documenting requests by CBs for accreditation from the AB (per § 1.660), challenges to adverse accreditation decisions (§ 1.620(c)), monitoring activities of its accredited CBs (§ 1.621), self-assessments and corrective actions (§ 1.622), copies of regulatory audit reports submitted by its accredited CBs (§ 1.656), and copies of records of reports or notifications made to us, as required by § 1.623. A recognized AB's requirements for reporting and notifications per § 1.623 of the Third-Party final rule include submission of results of its annual performance assessment of each of its accredited CBs (§ 1.623(a)) and the results of its self-assessment (§ 1.623(b)) (see tables 20 to 22). A recognized AB also must notify us immediately upon granting, withdrawing, suspending, reducing the scope of accreditation of a CB or upon its determination that a CB it accredited issued a food or facility certification in violation of subpart M, pursuant to § 1.623(c) of the Third-Party final rule. Additionally, a recognized AB must notify us within 30 days after making significant changes to its operations that would affect the manner in which it complies with the Third-Party final rule (§ 1.623(d)).

Under current practice, ABs maintain records documenting requests by CBs for accreditation, monitoring activities of CBs they have accredited, and self-assessments and corrective actions. The records currently maintained by ABs are similar to those that would be required of a recognized AB under § 1.623 of the Third-Party final rule. However, CBs do not currently send copies of audit reports of their clients (food facilities) to their ABs. Therefore, an AB's maintenance of records pertaining to regulatory audit reports submitted by CBs they have accredited is considered as a new recordkeeping burden for recognized ABs. We expect that it would take no more than 15 minutes (0.25 hour) for a recognized AB to file a regulatory audit report submitted by its accredited CBs. Under Scenario 1, we estimate the burden for 11 recognized ABs to maintain regulatory audit reports that were submitted to them by their accredited CBs. We estimate that following the implementation of the Third-Party final rule, under Scenario 1, each recognized AB will accredit approximately 8.27 CBs under the program (average of 10-year period) (8.23 CBs/AB under Scenario 2; 8.79

CBs/AB under Scenario 3). In addition, under Scenario 1, we estimate that each CB accredited under the third-party program, on average, will conduct regulatory audits on approximately 48 eligible entities a year (average of 10-year period) (55.4 foreign suppliers per CB under Scenario 2; 48.5 foreign suppliers per CB under Scenario 3). Under Scenario 1, we expect that each recognized AB will receive, on average, 397 regulatory audit reports (48 regulatory audit reports/CB \times 8.27 CBs/AB) from its CBs annually resulting in a total of 4,367 records per year (397 audit reports/AB \times 11 ABs). Under Scenario 2, we expect that each recognized AB will receive, on average, 456 regulatory audit reports (55.4 regulatory audit reports/CB \times 8.23 CBs/AB) from its CBs annually resulting in a total of 7,752 records per year (456 audit reports/AB \times 17 ABs). Under Scenario 3, we expect that each recognized AB will receive, on average, 426 regulatory audit reports (48.5 regulatory audit reports/CB \times 8.79 CBs/AB) from its CBs annually resulting in a total of 10,650 records per year (426 audit reports/AB \times 25 ABs). Total annual burden of recordkeeping requirement for recognized AB under § 1.625 of the Third-Party final rule is estimated at 1,092 hours (4,367 records \times 0.25 hours/record) under Scenario 1 (1,938 hours under Scenario 2; 2,663 hours under Scenario 3) (see tables 13 to 15).

Section 1.624(d) of the Third-Party final rule requires each recognized AB maintain on its Web site an up-to-date list of CBs it has accredited under the Third-Party final rule and for each CB identify the duration and scope of accreditation and date(s) on which the CB paid the AB any fee or reimbursement associated with such accreditation. Recognized ABs must also include information about changes in accreditation status of third-party certification bodies. Our review of AB Web sites found that none of the ABs reviewed publish all the information that is required by § 1.620(d) of the Third-Party final rule on their Web sites. We estimate that each AB, on average, would initially spend approximately 160 hours to update its Web page to conform with this section of the Third-Party final rule. Under Scenario 1, the one-time burden of conforming to § 1.624(d) of the Third-Party final rule by 11 recognized ABs is estimated at approximately 1,760 hours (11 ABs \times 160 hours/AB) (see table 10). Under Scenario 2, the one-time burden of conforming to § 1.624(d) of the Third-Party final rule by 17 recognized ABs is

estimated at approximately 2,720 hours (17 ABs \times 160 hours/AB) (see table 11). Under Scenario 3, the one-time burden of conforming to § 1.624(d) of the Third-Party final rule by 25 recognized ABs is estimated at approximately 4,000 hours (25 ABs \times 160 hours/AB) (see table 12). In addition, we estimate that each recognized AB would spend 8 hours annually, following the initial year, to update information as required by § 1.624(d) of the Third-Party final rule. Under Scenario 1, the annual hourly burden for 11 recognized ABs to update their Web pages to conform to disclosure of information requirement per § 1.624(d) of the Third-Party final rule is estimated at 88 hours (8 hours/AB \times 11 ABs) (136 hours under Scenario 2; 200 hours under Scenario 3) (see tables 13 to 15).

Similarly, § 1.657(d) of the Third-Party final rule requires a CB accredited in compliance with the Third-Party final rule to maintain on its Web site an up-to-date list of eligible entities which it has issued certifications under this subpart. For each such eligible entity the Web site also must identify the duration and scope of the certification and date(s) on which the eligible entity paid the CB accredited under the third-party program any fee or reimbursement associated with such audit or certification. In the Third-Party final Regulatory Impact Analysis, we estimate that following the implementation of the Third-Party final rule and VQIP draft guidance, there will be approximately 91 CBs accredited by recognized ABs and 1 directly-accredited CB under Scenario 1 (140 CBs and one directly-accredited CB under Scenario 2; 207 CBs and 1 directly-accredited CB under Scenario 3). Under Scenario 1, the one-time recordkeeping burden of 92 CBs accredited under the third-party program to comply with § 1.657(d) of the Third-Party final rule is estimated at 14,720 hours (160 hours/CB \times 92 CBs) (22,560 hours under Scenario 2; 33,280 hours under Scenario 3) (see tables 10 to 12). In addition, we estimate that each CB would spend 8 hours annually, following the initial year, to update information as required by § 1.657(d) of the Third-Party final rule. Under Scenario 1, annual hourly burden for 92 CBs accredited under the third-party program to update their Web pages to conform to disclosure of information requirement per § 1.657(d) of the Third-Party final rule is estimated at 736 hours (8 hours/CB \times 92 CBs) (1,128 hours under Scenario 2; 1,664 hours under Scenario 3) (see tables 13 to 15).

There are certain provisions within the Third-Party final rule that may require ABs to modify their contracts

with their CBs in order to comply with the Third-Party final rule. Therefore, it is expected that recognized ABs will modify their contracts with their accredited CBs to be able to conduct activities such as conducting unannounced audits of their accredited CBs' facilities. Minor modifications or addenda to contracts with standard language provided by provisions in the Third-Party final rule would consist of no more than 1 hour by an AB executive and 1 hour by a legal counsel representing the AB. As we discussed, following the implementation of the Third-Party final rule, we expect that each recognized AB will accredit approximately 8.27 CBs (8.23 CBs/AB under Scenario 2; 8.79 CBs/AB under Scenario 3). Therefore, under Scenario 1, a total of 91 contracts (8.27 contracts/AB \times 11 ABs) (140 contracts under Scenario 2; 220 contracts under Scenario 3) are expected to be modified to reflect changes in contractual obligations between each recognized AB and its accredited CBs under the Third-Party final rule (see tables 10 to 12). The one-time burden of initial modification of 91 contracts between 11 recognized ABs and their respective accredited CBs is approximately 182 hours (91 contracts \times 2 hours/contract) (280 hours under Scenario 2; 440 hours under Scenario 3) (see tables 10 to 12).

Similarly, CBs accredited by recognized ABs would need to modify or create new contracts with their client eligible entities in order to gain access to any records and any area of the facility, its process(es), and food of the eligible entity relevant to the scope and purpose of audit being performed by the CB (§ 1.651). Considering that each of the expected 92 CBs accredited under the third-party program, under Scenario 1, will each have approximately 48 client eligible entities, we expect that approximately 4,416 contracts (48 contracts/CB \times 92 CBs) between CBs accredited under the third-party program and eligible entities will be modified (7,811 contracts scenario 2; 10,088 contracts under Scenario 3) (see tables 10 to 12). Under Scenario 1, the one-time burden of initial modification of 4,416 contracts between 92 CBs accredited under the third-party program and their respective client eligible entities is approximately 8,832 hours (4,416 contracts \times 2 hours/contract) (15,623 hours under Scenario 2; 20,176 hours under Scenario 3) (see tables 10 to 12).

Section 1.652 of the Third-Party final rule requires that CBs accredited under the third-party program include certain information in reports of food safety audits. We believe that some

information such as the FDA food facility registration number (where applicable) of the facility subject to the audit are currently not included in food safety audits conducted by CBs accredited under other programs. Although this information may not be required as part of the Third-Party program, we have conservatively included the burden of providing such information in this analysis. We expect that it would take about 5 minutes (0.083 hour), on average, by a CB accredited under the third-party program to include additional information, as required in § 1.652, in reports of food safety audits. Therefore, at a minimum, under Scenario 1, each CB accredited under the third-party program must modify a regulatory audit report for each of its 48 eligible entities (55.4 eligible entities per CB in Scenario 2; 48.5 eligible entities per CB in Scenario 3) every year. Under Scenario 1, total annual records of 92 CBs accredited under the third-party program modifying regulatory audit reports of their client eligible entities is estimated at 4,416 records (92 CBs \times 48 eligible entities/CB \times 1 record/eligible entity) (7,811 records under Scenario 2; 10,088 records under Scenario 3). Annual recordkeeping burden of CBs accredited under the third-party program, per § 1.652 of the Third-Party final rule, is estimated at 367 hours (4,416 records \times 0.083 hour/record) for Scenario 1 (648 hours for Scenario 2; 837 hours for Scenario 3) (see tables 13 to 15).

Accredited third-party CBs will incur additional recordkeeping costs associated with modifying existing certification templates to meet the requirements of § 1.653(b)(2). For example, we are requiring accredited CBs to provide a certification number that follows an FDA numeric designation. We have included the burden of providing such information in this analysis because we know that CBs currently do not use an FDA designation in numbering their certificates. To the extent that any of the elements in § 1.653(b)(2) are already included in current certificates issued by some CBs, such as the date(s) and scope of the audit, the recordkeeping burden may be overestimated. We expect that it will take no more than 1 hour, on average, to change the design of certifications issued by CBs accredited under the third-party program. Under Scenario 1, we estimate a one-time recordkeeping burden of modifying the design of the certifications of 92 CBs accredited under the third-party program at 92 hours (92 CBs \times 1 hour/CB) (141 hours under

Scenario 2; 208 hours under Scenario 3) (see tables 16 to 18).

We expect that the burden to fill additional information on a certification that is issued is 5 minutes (0.083 hour). Therefore, under Scenario 1, the annual burden of § 1.653(b)(2) is estimated at 367 hours (92 CBs \times 1 certificate/entity \times 48 entities/CB \times 0.083 hour/certificate) (see table 19). Under Scenario 2, the annual burden of § 1.653(b)(2) is estimated at 648 hours (141 CBs \times 1 certificate/entity \times 55.4 entities/CB \times 0.083 hour/certificate) (see table 20). Finally, under Scenario 3, the annual burden of § 1.653(b)(2) is estimated at 837 hours (208 CBs \times 1 certificate/entity \times 48.5 entities/CB \times 0.083 hour/certificate) (see table 21).

Section 1.656(c) of the Third-Party final rule requires that CBs accredited under the third-party program report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. We believe that these occurrences are rare and may occur once every 4 years, or 0.25 times per year. Reporting serious hazard conditions would consist of the onsite audit agent of a CB accredited under the third-party program to document the event as a record and to immediately submit the record to us. Therefore, under Scenario 1, the annual number of records prepared by 92 CBs accredited under the third-party program is estimated at 23 (0.25 records/CB \times 92 CBs) (35 records under Scenario 2; 52 records under Scenario 3). It is expected that a CB accredited under the third-party program would take no more than 1 hour to prepare such record (notification). Under Scenario 1, annual burden of preparation of records per § 1.656(c) of the Third-Party final rule by 92 CBs accredited under the third-party program is estimated at 23 hours (23 records \times 1 hour/record; see table 13) (35 hours for Scenario 2, and 52 hours for Scenario 3; see tables 14 to 15).

We also acknowledge that an accreditation body seeking to challenge a denial of its application for recognition, renewal of recognition, or reinstatement of recognition will incur costs in compiling information to support its request for reconsideration under § 1.691 or its request for internal Agency review under § 1.692. A third-party certification body seeking to challenge a denial of its application for direct accreditation, renewal of direct accreditation, or reaccreditation as a directly accredited third-party certification body will incur costs in compiling information to support its

request for reconsideration under § 1.691 or its request for internal Agency review under § 1.692, as will any accredited third-party certification body seeking to challenge a denial of its request for a waiver of the conflict of interest requirement of § 1.650(b) or a waiver extension. We anticipate that most accreditation bodies and third-party certification bodies who seek to participate in our program will carefully consider the program requirements before applying to, or joining, the program or before submitting a waiver request. We anticipate the submission of challenges under § 1.691 or § 1.692 to be an infrequent event, and one that most program participants will not encounter. Therefore, we are not calculating costs

associated with the compiling of information to support a request for reconsideration under § 1.691 or a request for internal agency review under § 1.692 by an accreditation body seeking to challenge a denial of its application for recognition, renewal of recognition, or reinstatement of recognition; by an third-party certification body seeking to challenge a denial of its application for direct accreditation, renewal of direct accreditation, or reaccreditation as a directly accredited third-party certification body; or by an accredited third-party certification body seeking to challenge a denial of its request for a waiver of the conflict of interest requirement of § 1.650(b) or a waiver extension.

Reporting Burden

In summary, under Scenario 1, total one-time reporting burden by 11 recognized ABs and 92 CBs accredited under the third-party program is estimated at 960 hours (see table 16). Under Scenario 2, total one-time reporting burden by 17 recognized ABs and 141 CBs accredited under the third-party program is estimated at 1,440 hours (see table 17). Under Scenario 3, total one-time reporting burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 2,080 hours (see table 18). Total annual reporting burden, under Scenarios 1 to 3 is estimated between 3,466 and 7,919 hours (see tables 19 to 21).

TABLE 16—SCENARIO 1, ESTIMATED ONE-TIME REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.630	11	1	11	80	880
§ 1.670(a–b)	1	1	1	80	80
Total One-Time Reporting Burden					960

Note: There are no operations and maintenance costs associated with one-time reporting burden.

TABLE 17—SCENARIO 2, ESTIMATED ONE-TIME REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.630	17	1	17	80	1,360
§ 1.670(a–b)	1	1	1	80	80
Total One-Time Reporting Burden					1,440

Note: There are no operations and maintenance costs associated with one-time reporting burden.

TABLE 18—SCENARIO 3, ESTIMATED ONE-TIME REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.630	25	1	25	80	2,000
§ 1.670(a–b)	1	1	1	80	80
Total One-Time Reporting Burden					2,080

Note: There are no operations and maintenance costs associated with one-time reporting burden.

TABLE 19—SCENARIO 1, ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.634	11	1	11	8	88
§ 1.673	1	1	1	10	10
§ 1.623(a)	11	8.27	91	0.25 (15 minutes)	23
§ 1.623(b)	11	1	11	0.25 (15 minutes)	3

TABLE 19—SCENARIO 1, ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.653(b)(1)	92	48	4,416	0.25 (15 minutes)	1,104
§ 1.656(a) ¹	91	48	4,368	0.25 (15 minutes)	1,092
§ 1.656(a) ²	91	48	4,368	0.25 (15 minutes)	1,092
§ 1.656(a) ³	1	48	48	0.25 (15 minutes)	12
§ 1.656(b) ⁴	91	1	91	0.25 (15 minutes)	23
§ 1.656(b) ⁵	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	92	0.25	23	0.25 (15 minutes)	6
§ 1.656(e) ⁶	92	0.25	23	0.25 (15 minutes)	6
§ 1.656(e) ⁷	91	0.25	23	0.25 (15 minutes)	6
Total Annual Reporting Burden					3,446

Note: There are no operations and maintenance costs associated with annual reporting burden.

¹ Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.

² Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.

³ Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.

⁴ Annual reporting of self-assessment by accredited CBs to their recognized ABs.

⁵ Annual reporting of self-assessment by directly-accredited CBs to the FDA.

⁶ Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.

⁷ Annual reporting of serious risk to public health by accredited CBs to their recognized ABs.

TABLE 20—SCENARIO 2, ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.634	17	1	17	8	136
§ 1.673	1	1	1	10	10
§ 1.623(a)	17	8.23	140	0.25 (15 minutes)	35
§ 1.623(b)	17	1	17	0.25 (15 minutes)	4
§ 1.653(b)(1)	141	55.4	7,811	0.25 (15 minutes)	1,953
§ 1.656(a) ¹	140	55.4	7,756	0.25 (15 minutes)	1,939
§ 1.656(a) ²	140	55.4	7,756	0.25 (15 minutes)	1,939
§ 1.656(a) ³	1	55.4	55	0.25 (15 minutes)	14
§ 1.656(b) ⁴	140	1	140	0.25 (15 minutes)	35
§ 1.656(b) ⁵	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	141	0.25	35	0.25 (15 minutes)	9
§ 1.656(e) ⁶	141	0.25	35	0.25 (15 minutes)	9
§ 1.656(e) ⁷	140	0.25	35	0.25 (15 minutes)	9
Total Annual Reporting Burden					6,093

Note: There are no operations and maintenance costs associated with annual reporting burden.

¹ Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.

² Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.

³ Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.

⁴ Annual reporting of self-assessment by CBs to their recognized ABs.

⁵ Annual reporting of self-assessment by directly-accredited CBs to the FDA.

⁶ Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.

⁷ Annual reporting of serious risk to public health by CBs to their recognized ABs.

TABLE 21—SCENARIO 3, ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
§ 1.634	25	1	25	8	200
§ 1.673	1	1	1	10	10
§ 1.623(a)	25	8.79	220	0.25 (15 minutes)	55
§ 1.623(b)	25	1	25	0.25 (15 minutes)	6
§ 1.653(b)(1)	208	48.5	10,088	0.25 (15 minutes)	2,522
§ 1.656(a) ¹	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) ²	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) ³	1	55.4	55	0.25 (15 minutes)	14
§ 1.656(b) ⁴	207	1	207	0.25 (15 minutes)	52
§ 1.656(b) ⁵	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) ⁶	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) ⁷	207	0.25	52	0.25 (15 minutes)	13
Total Annual Reporting Burden					7,919

Note: There are no operations and maintenance costs associated with annual reporting burden.

¹ Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.

² Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.

³ Annual reporting of regulatory audit reports by directly-accredited CBs to the FDA.

⁴ Annual reporting of self-assessment by CBs to their recognized ABs.

⁵ Annual reporting of self-assessment by directly-accredited CBs to the FDA.

⁶ Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.

⁷ Annual reporting of serious risk to public health by CBs to their recognized ABs.

Section 1.630 of the Third-Party final rule allows for any AB to apply for recognition. Under Scenario 1, we estimate that approximately 11 ABs would apply for recognition. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for recognition. The initial application for recognition is a one-time burden for each AB that applies. Under Scenario 1, the one-time initial application burden for 11 ABs is estimated at 880 hours (11 applications × 80 hours/application) (see table 16). The one-time initial application burden for 17 ABs, under Scenario 2 (25 ABs under Scenario 3), is estimated at 1,360 hours (2,000 hours under Scenario 3) (see tables 17 and 18). The duration of recognition for a recognized AB will not exceed 5 years per § 1.632 of the Third-Party final rule. Therefore, it is expected that each of the recognized ABs would apply to renew its recognition every 5 years per § 1.634 of the Third-Party final rule. We expect that applications for renewal of recognition will take significantly less time to prepare. We use 50 percent of the amount of effort

to prepare and submit an application for renewal of recognition. Therefore, it is expected that, on average, each recognized AB will spend 40 hours every 5 years (after the initial application) to complete and submit an application for renewal of its recognition, or approximately 8 hours per year (40 hours ÷ 5 years) for each AB. Therefore, the annual burden of completing the renewal of recognition application by 11 ABs, under Scenario 1, is 88 hours (11 applications × 8 hours/application) per year (136 hours per year for 17 ABs under Scenario 2; 200 per hour for each of 25 ABs under Scenario 3) (see tables 19 to 21).

Similarly, § 1.670(a) and (b) of the Third-Party final rule allows for CBs to apply to us for direct accreditation, when the criteria for direct accreditation are met. We estimate that approximately one CB would apply for direct accreditation. It is expected that the application for direct accreditation would require the same amount of effort as does an AB's application for recognition. Hence, we estimate that the initial application for direct accreditation would take 80-person

hours. The one-time initial application burden for 1 CB, for each scenario, is estimated at 80 hours (1 application × 80 hours/application) (see tables 16 to 18). The duration of accreditation for a directly-accredited CB will not exceed 4 years, per § 1.671 of the Third-Party final rule. Therefore, it is expected that each of the expected directly-accredited CBs would apply to renew its accreditation every 4 years, per § 1.673 of the Third-Party final rule. We expect that directly accredited CBs use 50 percent amount of effort, or 40 person-hours, for their initial application for direct accreditation, yielding an average of 10 hours per year. Therefore, the annual burden of completing the application for renewal by 1 directly-accredited CB is 10 hours (1 application × 10 hours/application) per year (see tables 19 to 21).

For the purposes of the Third-Party final economic and PRA analyses, we have estimated costs assuming that, during the application process, affected entities will do their paperwork properly and completely the first time. If we assumed a less consistent outcome, one that would result in

recognition denials, the initial burden might increase.

Section 1.623(a) of the Third-Party final rule requires that recognized ABs annually conduct comprehensive assessments of the performance of CBs they have accredited and submit the results of the assessments to us within 45 days of their completion. We expect that it would take no more than 15 minutes (0.25 hour) for a recognized AB to electronically submit the assessment of each its accredited CBs. Following the implementation of the Third-Party final rule and VQIP draft guidance, we expect, on average, each recognized AB would accredit approximately 8.27 CBs (8.23 CBs under Scenario 2; 8.79 under Scenario 3). Therefore, under Scenario 1, each recognized AB would submit, on average, approximately 91 copies of assessments of performance of their accredited CBs (8.27 assessments/AB \times 11 ABs) (140 assessments under Scenario 2; 220 under Scenario 3). Under Scenario 1, annual reporting of 91 assessments by 11 recognized ABs is estimated at 23 hours (91 submission of assessments \times 0.25 hour/submission) (35 hours under Scenario 2; 55 hours under Scenario 3) (see tables 19 to 21).

Section 1.623(b) of the Third-Party final rule requires that recognized ABs annually conduct a self-assessment and submit the assessments within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically submit a copy of its self-assessment. Under Scenario 1, annual reporting of 11 self-assessments by 11 recognized ABs is estimated at 3 hours (11 submission of self-assessments \times 0.25 hour/submission) (4 hours under Scenario 2; 6 hours under Scenario 3) (see tables 10 to 21).

Section 1.656(a) of the Third-Party final rule requires that a CB accredited under the third-party program must submit the regulatory audit reports it conducts to us and to the AB that granted its accreditation (where applicable) within 45 days after completing such audit. In the Third-Party final economic analysis, we estimate that following the implementation of the Third-Party final rule, there will be 11 recognized ABs that accredit 91 CBs (17 recognized ABs and 140 accredited CBs under Scenario 2; 25 recognized ABs and 207 accredited CBs under Scenario 3), and we will directly accredit one CB. In addition, we estimated that each CB accredited under the third-party program, on average, conducts food safety audits and certifies 48 eligible entities under Scenario 1 (55.4 eligible entities/CB under Scenario 2; 48.5 eligible entities/CB under Scenario 3). Therefore, under Scenario

1, CBs accredited by recognized ABs will annually submit 4,368 regulatory audit reports (91 CBs \times 48 reports/CB) to their accrediting ABs and 4,368 reports to us (see table 19). Similarly, under Scenarios 2 and 3, CBs accredited by recognized ABs will annually submit 7,756 and 10,040 regulatory audit reports to their accrediting ABs and the FDA, respectively (see tables 20 and 21). Under Scenario 1, the directly-accredited CB will annually submit 48 regulatory audit reports (1 CB \times 48 reports/CB) (see table 19). The number of eligible entities per directly-accredited CB increases to 55.4 in Scenario 2. We assume that the number of eligible entities per directly-accredited CBs remains the same for Scenario 3. We expect that it would take no more than 15 minutes (0.25 hour) for a CB accredited under the third-party program to electronically submit a copy of the regulatory report it conducts to us and to its AB (where applicable).

Under Scenario 1, annual reporting burden for CBs accredited by recognized ABs is estimated at 1,092 hours (4,368 reports \times 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 1,092 hours for submitting the same records to us (see table 19). Under Scenario 2, annual reporting burden for CBs accredited by recognized ABs is estimated at 1,939 hours (7,756 reports \times 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 1,939 hours for submitting the same records to us (see table 20). Similarly, under Scenario 3, annual reporting burden for CBs accredited by recognized ABs is estimated at 2,510 hours (10,040 reports \times 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 2,510 hours for submitting the same records to us (see table 21). Under Scenario 1, annual burden for submission of regulatory audit reports by directly-accredited CBs is estimated at 12 hours (48 reports \times 0.25 hours/report) (14 hours for Scenarios 2 and 3) (see tables 19 to 21).

Section 1.656(b) of the Third-Party final rule requires CBs accredited under the third-party program to submit reports of their annual self-assessments electronically to their ABs, or in the case of direct accreditation to us, within 45 days of the anniversary date of their accreditation under subpart M. We expect that it would take no more than 15 minutes (0.25 hour) for a CB accredited under the third-party program to electronically send a copy of its annual self-assessment to its AB or

us (as applicable). Under Scenario 1, the annual burden for CBs accredited by recognized ABs is estimated at 23 hours (91 self-assessments \times 0.25 hour/self-assessment; see table 19) (35 hours under Scenario 2 and 52 hours under Scenario 3; see tables 20 and 21). Annual burden for submission of self-assessments by one directly-accredited CB is estimated at 0.25 hour (1 self-assessment \times 0.25 hour/self-assessment; see tables 19 to 21) (rounded to 1 hour).

As we discussed, § 1.656(c) of the Third-Party final rule requires that a CB accredited under the third-party program report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. In the Recordkeeping Burden section above, we estimated that such events are expected to occur once every 4 years, or 0.25 per year. We expect that it would take no more than 15 minutes (0.25 hour) for a CB accredited under the third-party program to electronically send a copy of its notification to us. Therefore, under Scenario 1, the total number of notifications sent to us on an annual basis per § 1.656(c) of the Third-Party final rule is estimated at 23 (92 CBs \times 0.25 records/CB) (35 notifications under Scenario 2; 52 notifications under Scenario 3). Under Scenario 1, annual burden for submitting a notification under § 1.656(c) of the Third-Party final rule to us by CBs accredited under the third-party program is estimated at 6 hours (23 records \times 0.25 hour/record) (9 hours under Scenario 2; 13 hours under Scenario 3) (see tables 19 to 21).

Following reporting under § 1.656(c), a CB accredited under the third-party program is required under § 1.656(e) of the Third-Party final rule to immediately notify the eligible entity and its accrediting AB of any conditions identified during the audit which triggered the reporting requirement per § 1.656(c) of the Third-Party final rule. Under Scenario 1, total number of notification sent to eligible entities by 141 CBs accredited under the third-party program is estimated at 23 (92 CBs \times 0.25 records/CB) (35 notifications under Scenario 2; 52 notifications under Scenario 3) while the number of notifications sent to recognized ABs by their accredited CBs is estimated at 23 (91 CBs \times 0.25 records/CB) (35 under Scenario 2; 52 under Scenario 3). Under Scenario 1, annual burden of submitting a notification under § 1.656(e) of the Third-Party final rule to affected eligible entities and ABs by accredited CBs is estimated at 6 hours (9 hours under Scenario 2; 13 hours under Scenario 3) (see tables 19 to 21).

XVIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIX. Federalism

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

1. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day One, September 19, 2013." Available in Docket No. FDA-2011-N-0143.
2. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day Two, September 20, 2013." Available in Docket No. FDA-2011-N-0143.
3. FDA, "FDA Office of Foods and Veterinary Medicine Memorandum to the Division of Dockets Management on FDA Records of Outreach Sessions," November 21, 2013. Available in Docket No. FDA-2011-N-0920.
4. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC 17000:2004 Conformity Assessment—Vocabulary and General Principles." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case

postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/catalogue_detail.htm?csnumber=29316 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).

5. International Organization for Standardization/International Electrotechnical Commission, ISO/IEC "17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=29332 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
6. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC 17021:2011 Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/publication_item.htm?pid=PUB100353 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
7. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC 17065:2012 Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46568 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
8. International Organization for Standardization, ISO 19011:2011 Guidelines for Auditing Management Systems." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=50675 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
9. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC Guide 65:1996 General Requirements for Bodies Operating Product Certification Systems." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/catalogue_detail.htm?csnumber=26796 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
10. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC 17020:2012 Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=52994 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
11. Global Food Safety Initiative, "Enhancing Food Safety Through Third-Party Certification," March 2011.
12. International Organization for Standardization/International Electrotechnical Commission, "ISO/IEC 17040:2005 Conformity Assessment—General Requirements for Peer Assessment of Conformity Assessment Bodies and Accreditation Bodies." Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=31815 or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
13. International Accreditation Forum, "IAF Endorsed Normative Documents, Issue 4 (IAF PR 4:2007)," http://www.iaf.nu/upFiles/197878.IAF-PR4-2007_Endorsed_NormDocs_Issue_4_Pub.pdf. Accessed on October 26, 2015.
14. Codex Alimentarius Commission, "Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)." http://www.codexalimentarius.org/input/download/standards/37/CXG_020e.pdf. Accessed on October 26, 2015.
15. Armour, S., Lippert, J., and Smith, M., "Food Sickness Millions as Company-Paid Checks Find It Safe," Bloomberg Business, October 11, 2012. <http://www.bloomberg.com/news/articles/2012-10-11/food-sickness-millions-as-industry-paid-inspectors-find-it-safe>. Accessed on October 26, 2015.
16. Zheng, Y., Muth, M.M., Kosa, K., "Economic Analysis of Third-Party Food

- Safety Certification of Imported Food,” RTI International, June 2012.
17. American National Standards Institute, “About ANSI,” http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1. Accessed on May 6, 2015.
 18. United Kingdom Accreditation Service, “About UKAS,” <http://www.ukas.com/about/>. Accessed on October 26, 2015.
 19. Danish Accreditation Fund, “DANAK Home” <http://english.danak.dk/>. Accessed on May 4, 2015.
 20. International Organization for Standards, “ISO/TS 22003:2007 Food Safety Management Systems—Requirements for Bodies Providing Audit and Certification of Food Safety Management Systems.” Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=39834 or may be examined at the Division of Dockets Management (see ADDRESSES) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
 21. International Organization for Standardization/International Electrotechnical Commission, “ISO 22000:2005 Food Safety Management Systems—Requirements for Any Organization in the Food Chain.” Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35466 or may be examined at the Division of Dockets Management (see ADDRESSES) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
 22. British Retail Consortium, “Global Standard for Food Safety, Issue 6,” 2012. Copies are available from the British Retail Consortium, Second Floor, 21 Dartmouth Street, London SW1H 9BP, or may be examined at the Division of Dockets Management (see ADDRESSES) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
 23. Safe Quality Food Institute, “SQF Code, Edition 7.2: A HACCP-Based Supplier Assurance Code for the Food Industry,” July 2014. https://www.sqfi.com/wp-content/uploads/SQF-Code_Ed-7.2-July.pdf. Accessed on October 27, 2015.
 24. International Organization for Standardization, “ISO/TS 22003:2013 Food Safety Management Systems—Requirements for Bodies Providing Audit and Certification of Food Safety Management Systems.” Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland, or on the Internet at http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=60605 or may be examined at the Division of Dockets Management (see ADDRESSES) (Ref. Docket No. FDA-2011-N-0146 and/or RIN 0910-AG66).
 25. FDA, “Tribal Summary Impact Statement: Final Rule on Accreditation of Third-

Party Certification Bodies to Conduct Food Safety Audits and to Issue,” Docket No. FDA-2011-N-0146.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 11, and 16 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

- 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

- 2. Add subpart M, consisting of §§ 1.600 through 1.695, to read as follows:

Subpart M—Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

Sec.

1.600 What definitions apply to this subpart?

1.601 Who is subject to this subpart?

Recognition of Accreditation Bodies Under This Subpart

1.610 Who is eligible to seek recognition?

1.611 What legal authority must an accreditation body have to qualify for recognition?

1.612 What competency and capacity must an accreditation body have to qualify for recognition?

1.613 What protections against conflicts of interest must an accreditation body have to qualify for recognition?

1.614 What quality assurance procedures must an accreditation body have to qualify for recognition?

1.615 What records procedures must an accreditation body have to qualify for recognition?

Requirements for Accreditation Bodies That Have Been Recognized Under This Subpart

1.620 How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation?

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Subpart M—Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

§ 1.600 What definitions apply to this subpart?

(a) The *FD&C Act* means the Federal Food, Drug, and Cosmetic Act.

(b) Except as otherwise defined in paragraph (c) of this section, the definitions of terms in section 201 of the *FD&C Act* apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of this subpart.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the *FD&C Act*.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of this subpart.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party

certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Audit means the systematic and functionally independent examination of an eligible entity under this subpart by an accredited third-party certification body or by FDA. An audit conducted under this subpart is not considered an inspection under section 704 of the *FD&C Act*.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the *FD&C Act*, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of this part.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one

distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food certification means an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

Foreign cooperative means an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and

(ii) The results of which are used in determining eligibility for certification

under section 801(q) or under section 806 of the FD&C Act.

Relinquishment means:

(i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and

(ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

§ 1.601 Who is subject to this subpart?

(a) *Accreditation bodies.* Any accreditation body seeking recognition from FDA to accredit third-party certification bodies to conduct food safety audits and to issue food and facility certifications under this subpart.

(b) *Third-party certification bodies.* Any third-party certification body seeking accreditation from a recognized accreditation body or direct accreditation by FDA for:

(1) Conducting food safety audits; and

(2) Issuing certifications that may be used in satisfying a condition of admissibility of an article of food under section 801(q) of the FD&C Act; or issuing a facility certification for meeting the eligibility requirements for the Voluntary Qualified Importer Program under section 806 of the FD&C Act.

(c) *Eligible entities.* Any eligible entity seeking a food safety audit or a food or facility certification from an accredited third-party certification body under this subpart.

(d) *Limited exemptions from section 801(q) of the FD&C Act—(1) Alcoholic beverages.* (i) Any certification required under section 801(q) of the FD&C Act does not apply with respect to alcoholic beverages from an eligible entity that is a facility that meets the following two conditions:

(A) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(B) Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(ii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to food that is not an alcoholic beverage that is received and distributed by a facility described in paragraph (d)(1)(i) of this section, provided such food:

(A) Is received and distributed in prepackaged form that prevents any direct human contact with such food; and

(B) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(iii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to raw materials or other ingredients that are imported for use in alcoholic beverages provided that:

(A) The imported raw materials or other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(B) Such manufacturing/processing, packing, or holding is performed by the importer;

(C) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(D) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i).

(2) *Certain meat, poultry, and egg products.* Any certification required under section 801(q) of the FD&C Act does not apply with respect to:

(i) Meat food products that at the time of importation are subject to the requirements of the United States Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(ii) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(iii) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

Recognition of Accreditation Bodies Under This Subpart

§ 1.610 Who is eligible to seek recognition?

An accreditation body is eligible to seek recognition by FDA if it can demonstrate that it meets the requirements of §§ 1.611 through 1.615. The accreditation body may use documentation of conformance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, supplemented as necessary, in meeting the applicable requirements of this subpart.

§ 1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

§ 1.612 What competency and capacity must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) The resources required to adequately implement its accreditation program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively evaluate the qualifications of third-party certification bodies seeking accreditation and to effectively monitor the performance of accredited third-party certification bodies; and

(2) Adequate financial resources for its operations; and

(b) The capability to meet the applicable assessment and monitoring requirements, the reporting and notification requirements, and the procedures of this subpart, if recognized.

§ 1.613 What protections against conflicts of interest must an accreditation body have to qualify for recognition?

An accreditation body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such accreditation body; and

(b) The capability to meet the applicable conflict of interest requirements of this subpart, if recognized.

§ 1.614 What quality assurance procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents and its accreditation program, including procedures to:

(1) Identify areas in its accreditation program or performance where deficiencies exist; and

(2) Quickly execute corrective actions that effectively address deficiencies when identified; and

(b) The capability to meet the applicable quality assurance requirements of this subpart, if recognized.

§ 1.615 What records procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for the period of time necessary to meet its contractual and legal obligations pertaining to this subpart and to provide an adequate basis for evaluating its program and performance; and

(b) The capability to meet the applicable reporting and notification requirements of this subpart, if recognized.

Requirements for Accreditation Bodies That Have Been Recognized Under This Subpart

§ 1.620 How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation?

(a) Prior to accrediting a third-party certification body under this subpart, a recognized accreditation body must perform, at a minimum, the following:

(1) In the case of a foreign government or an agency of a foreign government, such reviews and audits of the government's or agency's food safety programs, systems, and standards as are necessary to determine that it meets the eligibility requirements of § 1.640(b).

(2) In the case of a foreign cooperative or any other third-party seeking accreditation as a third-party certification body, such reviews and audits of the training and qualifications of agents conducting audits for such cooperative or other third party (or in the case of a third-party certification body that is an individual, such individual) and such reviews of internal systems and any other investigation of the cooperative or other third party necessary to determine that it meets the eligibility requirements of § 1.640(c).

(3) In conducting a review and audit under paragraph (a)(1) or (2) of this section, an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the third-party

certification body or its agents (or, in the case of a third-party certification body that is an individual, such individual).

(b) A recognized accreditation body must require a third-party certification body, as a condition of accreditation under this subpart, to comply with the reports and notification requirements of §§ 1.652 and 1.656 and to agree to submit to FDA, electronically and in English, any food or facility certifications it issues for purposes of sections 801(q) or 806 of the FD&C Act.

(c) A recognized accreditation body must maintain records on any denial of accreditation (in whole or in part) and on any withdrawal, suspension, or reduction in scope of accreditation of a third-party certification body under this subpart. The records must include the name and contact information for the third-party certification body; the date of the action; the scope of accreditation denied, withdrawn, suspended, or reduced; and the basis for such action.

(d) A recognized accreditation body must notify any third-party certification body of an adverse decision associated with its accreditation under this subpart, including denial of accreditation or the withdrawal, suspension, or reduction in the scope of its accreditation. The recognized accreditation body must establish and implement written procedures for receiving and addressing appeals from any third-party certification body challenging such an adverse decision and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§ 1.692 and 1.693, and include requirements to:

- (1) Make the appeals procedures publicly available;
- (2) Use competent persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not participated in the accreditation decision or be subordinate to a person who has participated in the accreditation decision to investigate and decide appeals;
- (3) Advise third-party certification bodies of the final decisions on their appeals; and
- (4) Maintain records under § 1.625 of appeals, final decisions on appeals, and the bases for such decisions.

§ 1.621 How must a recognized accreditation body monitor the performance of third-party certification bodies it accredited?

(a) A recognized accreditation body must annually conduct a comprehensive assessment of the performance of each

third-party certification body it accredited under this subpart by reviewing the accredited third-party certification body's self-assessments (including information on compliance with the conflict of interest requirements of §§ 1.643 and 1.657); its regulatory audit reports and notifications submitted to FDA under § 1.656; and any other information reasonably available to the recognized accreditation body regarding the compliance history of eligible entities the accredited third-party certification body certified under this subpart; or that is otherwise relevant to a determination whether the accredited third-party certification body is in compliance with this subpart.

(b) No later than 1 year after the initial date of accreditation of the third-party certification body and every 2 years thereafter for duration of its accreditation under this subpart, a recognized accreditation body must conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents) (or, in the case of a third-party certification body that is an individual, such individual) accredited under this subpart and must visit the accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters). The recognized accreditation body will consider the results of such observations and visits in the annual assessment of the accredited third-party certification body required by paragraph (a) of this section.

§ 1.622 How must a recognized accreditation body monitor its own performance?

(a) A recognized accreditation body must annually, and as required under § 1.664(g), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

- (1) The performance of its officers, employees, or other agents involved in accreditation activities and the degree of consistency in conducting accreditation activities;
- (2) The compliance of the recognized accreditation body and its officers, employees, and other agents involved in accreditation activities, with the conflict of interest requirements of § 1.624; and
- (3) If requested by FDA, any other aspects of its performance relevant to a determination whether the recognized accreditation body is in compliance with this subpart.

(b) As a means to evaluate the recognized accreditation body's performance, the self-assessment must include onsite observation of regulatory audits of a representative sample of third-party certification bodies it accredited under this subpart. In meeting this requirement, the recognized accreditation body may use the results of onsite observations performed under § 1.621(b).

(c) Based on the evaluations conducted under paragraphs (a) and (b) of this section, the recognized accreditation body must:

- (1) Identify any area(s) where deficiencies exist;
- (2) Quickly implement corrective action(s) that effectively address those deficiencies; and
- (3) Establish and maintain records of any such corrective action(s) under § 1.625.

(d) The recognized accreditation body must prepare, and as required by § 1.623(b) submit, a written report of the results of its self-assessment that includes the following elements. Documentation of conformance to ISO/IEC 17011:2004 may be used, supplemented as necessary, in meeting the requirements of this paragraph.

- (1) A description of any corrective actions taken under paragraph (c) of this section;
- (2) A statement disclosing the extent to which the recognized accreditation body, and its officers, employees, and other agents involved in accreditation activities, complied with the conflict of interest requirements in § 1.624; and
- (3) A statement attesting to the extent to which the recognized accreditation body complied with applicable requirements of this subpart.

§ 1.623 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *Reporting results of assessments of accredited third-party certification body performance.* A recognized accreditation body must submit to FDA electronically, in English, a report of the results of any assessment conducted under § 1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited third-party certification body to conduct food safety audits under this subpart.

(b) *Reporting results of recognized accreditation body self-assessments.* A recognized accreditation body must submit to FDA electronically, in English:

- (1) A report of the results of an annual self-assessment required under § 1.622, no later than 45 days after completing such self-assessment; and

(2) For a recognized accreditation body subject to § 1.664(g)(1), a report of such self-assessment to FDA within 60 days of the third-party certification body's withdrawal. A recognized accreditation body may use a report prepared for conformance to ISO/IEC 17011:2004, supplemented as necessary, in meeting the requirements this section.

(c) *Immediate notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, immediately upon:

(1) Granting (including expanding the scope of) accreditation to a third-party certification body under this subpart, and include:

(i) The name, address, telephone number, and email address of the accredited third-party certification body;

(ii) The name of one or more officers of the accredited third-party certification body;

(iii) A list of the accredited third-party certification body's audit agents; and

(iv) The scope of accreditation, the date on which it was granted, and its expiration date.

(2) Withdrawing, suspending, or reducing the scope of an accreditation under this subpart, and include:

(i) The basis for such action; and

(ii) Any additional changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(3) Determining that a third-party certification body it accredited failed to comply with § 1.653 in issuing a food or facility certification under this subpart, and include:

(i) The basis for such determination; and

(ii) Any changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(d) *Other notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, within 30 days after:

(1) Denying accreditation (in whole or in part) under this subpart and include:

(i) The name, address, telephone number, and email address of the third-party certification body;

(ii) The name of one or more officers of the third-party certification body;

(iii) The scope of accreditation requested; and

(iv) The scope and basis for such denial.

(2) Making any significant change that would affect the manner in which it complies with the applicable requirements of this subpart and include:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.624 How must a recognized accreditation body protect against conflicts of interest?

(a) A recognized accreditation body must implement a written program to protect against conflicts of interest between the recognized accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such recognized accreditation body, including the following:

(1) Ensuring that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control the third-party certification body (or any affiliate, parent, or subsidiary); and

(2) Prohibiting officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or item of value from the third-party certification body.

(3) The items specified in paragraph (a)(2) of this section do not include:

(i) Money representing payment of fees for accreditation services and reimbursement of direct costs associated with an onsite assessment of the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an assessment and on the premises where the assessment is conducted, if necessary to facilitate the efficient conduct of the assessment.

(b) A recognized accreditation body may accept the payment of fees for accreditation services and the reimbursement of direct costs associated with assessment of a certification body only after the date on which the report of such assessment was completed or the date of which the accreditation was issued, whichever comes later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities will be considered the financial interests of such officers, employees, and other

agents involved in accreditation activities.

(d) A recognized accreditation body must maintain on its Web site an up-to-date list of the third-party certification bodies it accredited under this subpart and must identify the duration and scope of each accreditation and the date(s) on which the accredited third-party certification body paid any fee or reimbursement associated with such accreditation. If the accreditation of a certification body is suspended, withdrawn, or reduced in scope, this list must also include the date of suspension, withdrawal, or reduction in scope and maintain that information for the duration of accreditation or until the suspension is lifted, the certification body is reaccredited, or the scope of accreditation is reinstated, whichever comes first.

§ 1.625 What records requirements must an accreditation body that has been recognized meet?

(a) An accreditation body that has been recognized must maintain electronically for 5 years records created while it is recognized (including documents and data) demonstrating its compliance with this subpart, including records relating to:

(1) Applications for accreditation and renewal of accreditation under § 1.660;

(2) Decisions to grant, deny, suspend, withdraw, or expand or reduce the scope of an accreditation;

(3) Challenges to adverse accreditation decisions under § 1.620(c);

(4) Its monitoring of accredited third-party certification bodies under § 1.621;

(5) Self-assessments and corrective actions under § 1.622;

(6) Regulatory audit reports, including any supporting information, that an accredited third-party certification body may have submitted;

(7) Any reports or notifications to FDA under § 1.623, including any supporting information; and

(8) Records of fee payments and reimbursement of direct costs.

(b) An accreditation body that has been recognized must make records required by paragraph (a) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accreditation body or at a reasonably accessible location. If the records required by paragraph (a) of this section are requested by FDA electronically, the records must be submitted to FDA electronically not later than 10 business days after the date of the request. Additionally, if the requested records are maintained in a language other than

English, the accreditation body must electronically submit an English translation within a reasonable time.

(c) An accreditation body that has been recognized must not prevent or interfere with FDA's access to its accredited third-party certification bodies and the accredited third-party certification body records required by § 1.658.

Procedures for Recognition of Accreditation Bodies Under This Subpart

§ 1.630 How do I apply to FDA for recognition or renewal of recognition?

(a) *Applicant for recognition.* An accreditation body seeking recognition must submit an application demonstrating that it meets the eligibility requirements in § 1.610.

(b) *Applicant for renewal of recognition.* An accreditation body seeking renewal of its accreditation must submit a renewal application demonstrating that it continues to meet the requirements of this subpart.

(c) *Submission.* Recognition and renewal applications and any documents provided as part of the application process must be submitted electronically, in English. An applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during onsite assessments of the applicant by FDA.

(d) *Signature.* Recognition and renewal applications must be signed in the manner designated by FDA, by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.631 How will FDA review my application for recognition or renewal of recognition and what happens once FDA decides on my application?

(a) *Review of recognition or renewal application.* FDA will examine an accreditation body's recognition or renewal application for completeness and notify the applicant of any deficiencies. FDA will review an accreditation body's recognition or renewal application on a first in, first out basis according to the date on which the completed application was submitted; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of recognition or renewal.* FDA will evaluate any completed recognition or renewal application to determine whether the applicant meets the applicable requirements of this subpart. Such evaluation may include an onsite assessment of the accreditation body.

FDA will notify the applicant, in writing, regarding whether the application has been approved or denied. FDA may make such notification electronically. If FDA does not reach a final decision on a renewal application before an accreditation body's recognition terminates by expiration, FDA may extend such recognition for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Issuance of recognition.* FDA will notify an applicant that its recognition or renewal application has been approved through issuance of recognition that will list any limitations associated with the recognition.

(d) *Issuance of denial of recognition or renewal application.* FDA will notify an applicant that its recognition or renewal application has been denied through issuance of a denial of recognition or denial of a renewal application that will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(e) *Notice of records custodian after denial of an application for renewal of recognition.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.625(a) and make them available to FDA as required by § 1.625(b). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.625(a) will be located.

(f) *Effect of denial of an application for renewal of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the denial of a recognition renewal to any third-party certification bodies accredited by the accreditation body whose renewal application was denied. The third-party certification body's accreditation will remain in effect so long as the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of the denial of recognition renewal, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after issuance of the notice of denial of recognition renewal or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized

accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(g) *Effect of denial of an application for renewal of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of a denial of the renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in the voluntary qualified importer program (VQIP).

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide notice on the Web site described in § 1.690 of the date of issuance of a denial of a renewal application and will describe the basis for the denial.

§ 1.632 What is the duration of recognition?

FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition.

§ 1.633 How will FDA monitor recognized accreditation bodies?

(a) FDA will evaluate the performance of each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment must occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. FDA may conduct additional assessments of a recognized accreditation body at any time.

(b) An FDA assessment of a recognized accreditation body may include onsite assessments of a representative sample of third-party certification bodies the recognized accreditation body accredited and onsite audits of a representative sample of eligible entities certified by such third-party certification bodies under this subpart. These may be conducted at any time and, as FDA determines necessary

or appropriate, may occur without the recognized accreditation body or, in the case of an audit of an eligible entity, the accredited third-party certification body present.

§ 1.634 When will FDA revoke recognition?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body found not to be in compliance with the requirements of this subpart, including for any one or more of the following:

(1) Refusal by the accreditation body to allow FDA to access records required by § 1.625, or to conduct an assessment or investigation of the accreditation body or of a third-party certification body it accredited to ensure the accreditation body's continued compliance with the requirements of this subpart.

(2) Failure to take timely and necessary corrective action when:

(i) The accreditation of a third-party certification body it accredited is withdrawn by FDA under § 1.664(a);

(ii) A significant deficiency is identified through self-assessment under § 1.622, monitoring under § 1.621, or self-assessment by one or more of its accredited third-party certification bodies under § 1.655; or

(iii) Directed to do so by FDA to ensure compliance with this subpart.

(3) A determination by FDA that the accreditation body has committed fraud or has submitted material false statements to the Agency.

(4) A determination by FDA that there is otherwise good cause for revocation, including:

(i) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(ii) Failure to adequately support one or more decisions to grant accreditation under this subpart.

(b) *Records request associated with revocation.* To assist in determining whether revocation is warranted under paragraph (a) of this section, FDA may request records of the accreditation body required by § 1.625 or the records, required by § 1.658, of one or more of the third-party certification bodies it accredited under this subpart.

(c) *Issuance of revocation of recognition.* (1) FDA will notify an accreditation body that its recognition has been revoked through issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under § 1.693 on the revocation, and the procedures for requesting reinstatement of recognition under § 1.636.

(2) Within 10 business days of the date of issuance of the revocation, the

accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain the records and make them available to FDA as required by § 1.625. The contact information for the custodian must provide, at a minimum, an email address and the physical address where the records will be located.

(d) *Effect of revocation of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the revocation of recognition to any accredited third-party certification body accredited by the accreditation body whose recognition was revoked. The third-party certification body's accreditation will remain in effect if the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of revocation, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after issuance of the notice of the revocation, or the original date of expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(e) *Effect of revocation of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of the revocation of recognition will remain in effect until the certificate terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(f) *Public notice of revocation of recognition.* FDA will provide notice on the Web site described in § 1.690 of the issuance of the revocation of recognition of an accreditation body and will describe the basis for revocation.

§ 1.635 What if I want to voluntarily relinquish recognition or do not want to renew recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* A recognized accreditation body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing recognition or before allowing recognition to expire without seeking renewal. The recognized accreditation body must provide the name and contact information of the custodian who will maintain the records required under § 1.625(a) after the date of relinquishment or the date recognition expires, as applicable, and make them available to FDA as required by § 1.625(b). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.625(a) will be located.

(b) *Notice to accredited third-party certification bodies of intent to relinquish or not to renew recognition.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the recognized accreditation body must notify any currently accredited third-party certification body that it intends to relinquish recognition or to allow its recognition to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625.

(c)(1) *Effect of voluntary relinquishment or expiration of recognition on third-party certification bodies.* The accreditation of a third-party certification body issued prior to the relinquishment or expiration of its accreditation body's recognition will remain in effect, so long as the third-party certification body:

(i) No later than 60 days after the date of relinquishment or the date of expiration of the recognition, conducts a self-assessment under § 1.655 and reports the results of the self-assessment to FDA under § 1.656(b); and

(ii) No later than 1 year after the date of relinquishment or the date of expiration of recognition, or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under § 1.664(c).

(d) *Effect of voluntary relinquishment or expiration of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to relinquishment or expiration of its recognition will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(e) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of recognition of an accreditation body under this subpart.

§ 1.636 How do I request reinstatement of recognition?

(a) *Application following revocation.* An accreditation body that has had its recognition revoked may seek reinstatement by submitting a new application for recognition under § 1.630. The accreditation body must submit evidence that the grounds for revocation have been resolved, including evidence addressing the cause or conditions that were the basis for revocation and identifying measures that have been implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

(b) *Application following relinquishment.* An accreditation body that previously relinquished its recognition under § 1.635 may seek recognition by submitting a new application for recognition under § 1.630.

Accreditation of Third-Party Certification Bodies Under This Subpart

§ 1.640 Who is eligible to seek accreditation?

(a) A foreign government, agency of a foreign government, foreign cooperative, or any other third party may seek accreditation from a recognized accreditation body (or, where direct accreditation is appropriate, FDA) to conduct food safety audits and to issue food and facility certifications to eligible entities under this subpart. An accredited third-party certification body may use documentation of conformance with ISO/IEC 17021: 2011 or ISO/IEC

17065: 2012, supplemented as necessary, in meeting the applicable requirements of this subpart.

(b) A foreign government or an agency of a foreign government is eligible for accreditation if it can demonstrate that its food safety programs, systems, and standards meet the requirements of §§ 1.641 through 1.645.

(c) A foreign cooperative or other third party is eligible for accreditation if it can demonstrate that the training and qualifications of its agents used to conduct audits (or, in the case of a third-party certification body that is an individual, such individual) and its internal systems and standards meet the requirements of §§ 1.641 through 1.645.

§ 1.641 What legal authority must a third-party certification body have to qualify for accreditation?

(a) A third-party certification body seeking accreditation from a recognized accreditation body or from FDA must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform such examinations of facilities, their process(es), and food(s) as are necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and conformance with applicable industry standards and practices and to issue certifications where appropriate based on a review of the findings of such examinations. This includes authority to:

- (1) Review any relevant records;
- (2) Conduct onsite audits of an eligible entity; and
- (3) Suspend or withdraw certification for failure to comply with applicable requirements.

(b) A third-party certification body seeking accreditation must demonstrate that it is capable of exerting the authority (as a governmental entity or as legal entity with contractual rights) necessary to meet the applicable requirements of accreditation under this subpart if accredited.

§ 1.642 What competency and capacity must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

- (a) The resources necessary to fully implement its certification program, including:
 - (1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA

regulations, conformance with applicable industry standards and practices, and issuance of valid and reliable certifications; and

(2) Adequate financial resources for its operations; and

(b) The competency and capacity to meet the applicable requirements of this subpart, if accredited.

§ 1.643 What protections against conflicts of interest must a third-party certification body have to qualify for accreditation?

A third-party certification body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and clients seeking examinations or certification from, or audited or certified by, such third-party certification body; and

(b) The capability to meet the conflict of interest requirements in § 1.657, if accredited.

§ 1.644 What quality assurance procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities, including procedures to:

- (1) Identify deficiencies in its auditing and certification program or performance; and
- (2) Quickly execute corrective actions that effectively address any identified deficiencies; and

(b) The capability to meet the quality assurance requirements of § 1.655, if accredited.

§ 1.645 What records procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for evaluating its program and performance; and

(b) Is capable of meeting the reporting, notification, and records requirements of this subpart, if accredited.

Requirements for Third-Party Certification Bodies That Have Been Accredited Under This Subpart

§ 1.650 How must an accredited third-party certification body ensure its audit agents are competent and objective?

(a) An accredited third-party certification body that uses audit agents to conduct food safety audits must ensure that each such audit agent meets the following requirements with respect to the scope of its accreditation under this subpart. If the accredited third-party certification body is an individual, that individual is also subject to the following requirements, as applicable:

(1) Has relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Has been determined by the accredited third-party certification body, through observations of a representative sample of audits, to be competent to conduct food safety audits under this subpart relevant to the audits they will be assigned to perform;

(3) Has completed annual food safety training that is relevant to activities conducted under this subpart;

(4) Is in compliance with the conflict of interest requirements of § 1.657 and has no other conflicts of interest with the eligible entity to be audited that might impair the audit agent's objectivity; and

(5) Agrees to notify its accredited third-party certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health.

(b) In assigning an audit agent to conduct a food safety audit at a particular eligible entity, an accredited third-party certification body must determine that the audit agent is qualified to conduct such audit under the criteria established in paragraph (a) of this section and based on the scope and purpose of the audit and the type of facility, its process(es), and food.

(c) An accredited third-party certification body cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited third-party certification body demonstrates to FDA, under § 1.663, there is insufficient

access to audit agents in the country or region where the eligible entity is located. If the accredited third-party certification body is an individual, that individual is also subject to such limitations.

§ 1.651 How must an accredited third-party certification body conduct a food safety audit of an eligible entity?

(a) *Audit planning.* Before beginning to conduct a food safety audit under this subpart, an accredited third-party certification body must:

(1) Require the eligible entity seeking a food safety audit to:

(i) Identify the scope and purpose of the food safety audit, including the facility, process(es), or food to be audited; whether the food safety audit is to be conducted as a consultative or regulatory audit subject to the requirements of this subpart, and if a regulatory audit, the type(s) of certification(s) sought; and

(ii) Provide a 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit; and

(2) Determine whether the requested audit is within its scope of accreditation.

(b) *Authority to audit.* In arranging a food safety audit with an eligible entity under this subpart, an accredited third-party certification body must ensure it has authority, whether contractual or otherwise, to:

(1) Conduct an unannounced audit to determine whether the facility, process(es), and food of the eligible entity (within the scope of the audit) comply with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of such audit;

(3) When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with:

(i) ISO/IEC 17025:2005; or

(ii) Another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results.

(4) Notify FDA immediately if, at any time during a food safety audit, the accredited third-party certification body (or its audit agent, where applicable) discovers a condition that could cause

or contribute to a serious risk to the public health and provide information required by § 1.656(c);

(5) Prepare reports of audits conducted under this subpart as follows:

(i) For consultative audits, prepare reports that contain the elements specified in § 1.652(a) and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and

(ii) For regulatory audits, prepare reports that contain the elements specified in § 1.652(b) and submit them to FDA and to its recognized accreditation body (where applicable) under § 1.656(a); and

(6) Allow FDA and the recognized accreditation body that accredited such third-party certification body, if any, to observe any food safety audit conducted under this subpart for purposes of evaluating the accredited third-party certification body's performance under §§ 1.621 and 1.662 or, where appropriate, the recognized accreditation body's performance under §§ 1.622 and 1.633.

(c) *Audit protocols.* An accredited third-party certification body (or its audit agent, where applicable) must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation.

(1) With the exception of records review, which may be scheduled, the audit must be conducted without announcement during the 30-day timeframe identified under paragraph (a)(1)(ii) of this section and must be focused on determining whether the facility, its process(es), and food are in compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices that are within the scope of the audit.

(2) The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph (b)(3) of this section. The audit may include any other activities necessary to determine compliance with applicable food safety requirements of the FD&C Act and FDA regulations, and, for consultative audits, also includes conformance with

applicable industry standards and practices.

(3) The audit must be sufficiently rigorous to allow the accredited third-party certification body to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and for consultative audits, also includes conformance with applicable industry standards and practices, at the time of the audit; and for a regulatory audit, whether the eligible entity, given its food safety system and practices would be likely to remain in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under this subpart. An accredited third-party certification body (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

(4) Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by § 1.652 and maintained as a record under § 1.658.

§ 1.652 What must an accredited third-party certification body include in food safety audit reports?

(a) *Consultative audits.* An accredited third-party certification body must prepare a report of a consultative audit not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report under § 1.658, subject to FDA access in accordance with the requirements of section 414 of the FD&C Act. A consultative audit report must include:

(1) The identity of the site or location where the consultative audit was conducted, including:

(i) The name, address and the FDA Establishment Identifier of the facility subject to the consultative audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, the FDA Establishment Identifier and unique facility identifier, if designated by FDA,

and, where applicable, registration number under subpart H of this part;

(3) The name(s) and telephone number(s) of the person(s) responsible for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations

(4) The dates and scope of the consultative audit;

(5) The process(es) and food(s) observed during such consultative audit; and

(6) Any deficiencies observed that relate to or may influence a determination of compliance with the applicable food safety requirements of the FD&C Act and FDA regulations that require corrective action, the corrective action plan, and the date on which such corrective actions were completed. Such consultative audit report must be maintained as a record under § 1.658 and must be made available to FDA in accordance with section 414 of the FD&C Act.

(b) *Regulatory audits.* An accredited third-party certification body must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to its recognized accreditation body (or, in the case of direct accreditation, only to FDA) and must provide to the eligible entity a report of such regulatory audit that includes the following information:

(1) The identity of the site or location where the regulatory audit was conducted, including:

(i) The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and

(ii) Where applicable, the FDA registration number assigned to the facility under subpart H of this part;

(2) The identity of the eligible entity, if different from the facility, including the name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, and, where applicable, registration number under subpart H of this part;

(3) The dates and scope of the regulatory audit;

(4) The process(es) and food(s) observed during such regulatory audit;

(5) The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations;

(6) Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product:

(i) Will cause serious adverse health consequences or death to humans and animals; or

(ii) May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death to humans or animals is remote;

(7) The corrective action plan for addressing each deficiency identified under paragraph (b)(6) of this section, unless corrective action was implemented immediately and verified onsite by the accredited third-party certification body (or its audit agent, where applicable);

(8) Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is performed in or used by the facility; and

(9) Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the 2 years preceding the regulatory audit.

(c) *Submission of regulatory audit report.* An accredited third-party certification body must submit a completed regulatory audit report as required by paragraph (b) of this section, regardless of whether the certification body issued a food or facility certification to the eligible entity.

(d) *Notice and appeals of adverse regulatory audit results.* An accredited third-party certification body must notify an eligible entity of a denial of certification and must establish and implement written procedures for receiving and addressing appeals from eligible entities challenging such adverse regulatory audit results and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§ 1.692 and 1.693, including requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the accredited third-party certification body, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;

(3) Advise the eligible entity of the final decision on its appeal; and

(4) Maintain records under § 1.658 of the appeal, the final decision, and the basis for such decision.

§ 1.653 What must an accredited third-party certification body do when issuing food or facility certifications?

(a) *Basis for issuance of a food or facility certification.* (1) Prior to issuing a food or facility certification to an eligible entity, an accredited third-party

certification body (or, where applicable, an audit agent on its behalf) must complete a regulatory audit that meets the requirements of § 1.651 and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

(2) If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, an accredited third-party certification body may not issue a food or facility certification to such entity until after the accredited third-party certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies that are the subject of a notification under § 1.656(c).

(3) An accredited third-party certification body must consider each observation and the data and other information from a regulatory audit and other activities conducted under § 1.651 to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification issued under this subpart.

(4) A single regulatory audit may result in issuance of one or more food or facility certifications under this subpart, provided that the requirements of issuance are met as to each such certification.

(5) Where an accredited third-party certification body uses an audit agent to conduct a regulatory audit of an eligible entity under this subpart, the accredited third-party certification body (and not the audit agent) must make the determination whether to issue a food or facility certification based on the results of such regulatory audit.

(b) *Issuance of a food or facility certification and submission to FDA.* (1) Any food or facility certification issued under this subpart must be submitted to FDA electronically and in English. The accredited third-party certification body may issue a food or facility certification under this subpart for a term of up to 12 months.

(2) A food or facility certification must contain, at a minimum, the following elements:

(i) The name and address of the accredited third-party certification body

and the scope and date of its accreditation under this subpart;

(ii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the eligible entity to which the food or facility certification was issued;

(iii) The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the facility where the regulatory audit was conducted, if different than the eligible entity;

(iv) The scope and date(s) of the regulatory audit and the certification number;

(v) The name of the audit agent(s) (where applicable) conducting the regulatory audit; and

(vi) The scope of the food or facility certification, date of issuance, and date of expiration.

(3) FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines, that such food or facility certification is not valid or reliable because, for example:

(i) The certification is offered in support of the admissibility of a food that was not within the scope of the certification;

(ii) The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation under this subpart; or

(iii) The certification was issued without reliable demonstration that the requirements of paragraph (a) of this section were met.

§ 1.654 When must an accredited third-party certification body monitor an eligible entity that it has issued a food or facility certification?

If an accredited third-party certification body has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited third-party certification body must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited third-party certification body must immediately notify FDA, under § 1.656(d), if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The accredited third-party certification body must maintain records of such monitoring under § 1.658.

§ 1.655 How must an accredited third-party certification body monitor its own performance?

(a) An accredited third-party certification body must annually, upon FDA request made for cause, or as required under § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in auditing and certification activities, including the performance of audit agents in examining facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations;

(2) The degree of consistency among its officers, employees, or other agents involved in auditing and certification activities, including evaluating whether its audit agents interpreted audit protocols in a consistent manner;

(3) The compliance of the accredited third-party certification body and its officers, employees, and other agents involved in auditing and certification activities, with the conflict of interest requirements of § 1.657;

(4) Actions taken in response to the results of any assessments conducted by FDA or, where applicable, the recognized accreditation body under § 1.621; and

(5) As requested by FDA, any other aspects of its performance relevant to a determination of whether the accredited third-party certification body is in compliance with this subpart.

(b) As a means to assess its performance, the accredited third-party certification body may evaluate the compliance of one or more of eligible entities to which a food or facility certification was issued under this subpart.

(c) Based on the assessments and evaluations conducted under paragraphs (a) and (b) of this section, the accredited third-party certification body must:

(1) Identify any deficiencies in complying with the requirements of this subpart;

(2) Quickly implement corrective action(s) that effectively address the identified deficiencies; and

(3) Under § 1.658, establish and maintain records of such corrective action(s).

(d) The accredited third-party certification body must prepare a written report of the results of its self-assessment that includes:

(1) A description of any corrective action(s) taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the accredited third-party certification body, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements in § 1.657; and

(3) A statement attesting to the extent to which the accredited third-party certification body complied with the applicable requirements of this subpart.

(e) An accredited third-party certification body may use a report, supplemented as necessary, on its conformance to ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012 in meeting the requirements of this section.

§ 1.656 What reports and notifications must an accredited third-party certification body submit?

(a) *Reporting results of regulatory audits.* An accredited third-party certification body must submit a regulatory audit report, as described in § 1.652(b), electronically, in English, to FDA and to the recognized accreditation body that granted its accreditation (where applicable), no later than 45 days after completing such audit.

(b) *Reporting results of accredited third-party certification body self-assessments.* An accredited third-party certification body must submit the report of its annual self-assessment required by § 1.655 electronically to its recognized accreditation body (or, in the case of direct accreditation, electronically and in English, to FDA), within 45 days of the anniversary date of its accreditation under this subpart. For an accredited third-party certification body subject to an FDA request for cause, or § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits under this subpart.

(c) *Notification to FDA of a serious risk to public health.* An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

(1) The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to

the audit, and, where applicable, the registration number under subpart H of this part;

(2) The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility under subpart H of this part; and

(3) The condition for which notification is submitted.

(d) *Immediate notification to FDA of withdrawal or suspension of a food or facility certification.* An accredited third-party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

(e) *Notification to its recognized accreditation body or an eligible entity.* (1) After notifying FDA under paragraph (c) of this section, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify the recognized accreditation body that granted its accreditation, except for third-party certification bodies directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA.

(2) An accredited third-party certification body must notify its recognized accreditation body (or, in the case of direct accreditation, FDA) electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements of this subpart and must include with such notification the following information:

- (i) A description of the change; and
- (ii) An explanation for the purpose of the change.

§ 1.657 How must an accredited third-party certification body protect against conflicts of interest?

(a) An accredited third-party certification body must implement a written program to protect against conflicts of interest between the accredited third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and an eligible entity seeking a food safety audit or food or facility certification from, or audited or certified by, such accredited third-party certification body, including the following:

(1) Ensuring that the accredited third-party certification body and its officers, employees, or other agents involved in auditing and certification activities do not own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity;

(2) Ensuring that the accredited third-party certification body and, its officers, employees, or other agents involved in auditing and certification activities are not owned, managed, or controlled by any person that owns or operates an eligible entity to be certified;

(3) Ensuring that an audit agent of the accredited third-party certification body does not own, operate, have a financial interest in, manage, or otherwise control an eligible entity or any affiliate, parent, or subsidiary of the entity that is subject to a consultative or regulatory audit by the audit agent; and

(4) Prohibiting an accredited third-party certification body's officer, employee, or other agent involved in auditing and certification activities from accepting any money, gift, gratuity, or other item of value from the eligible entity to be audited or certified under this subpart.

(5) The items specified in paragraph (a)(4) of this section do not include:

- (i) Money representing payment of fees for auditing and certification services and reimbursement of direct costs associated with an onsite audit by the third-party certification body; or
- (ii) Lunch of de minimis value provided during the course of an audit and on the premises where the audit is conducted, if necessary to facilitate the efficient conduct of the audit.

(b) An accredited third-party certification body may accept the payment of fees for auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity only after the date on which the report of such audit was completed or the date a food or facility certification was issued, whichever is later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of accredited third-party certification body's officers, employees, and other agents involved in auditing and certification activities will be considered the financial interests of such officers, employees, and other agents involved in auditing and certification activities.

(d) An accredited third-party certification body must maintain on its Web site an up-to-date list of the eligible

entities to which it has issued food or facility certifications under this subpart. For each such eligible entity, the Web site also must identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification.

§ 1.658 What records requirements must a third-party certification body that has been accredited meet?

(a) A third-party certification body that has been accredited must maintain electronically for 4 years records created during its period of accreditation (including documents and data) that document compliance with this subpart, including:

(1) Any audit report and other documents resulting from a consultative audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit;

(2) Any request for a regulatory audit from an eligible entity;

(3) Any audit report and other documents resulting from a regulatory audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit, and, when sampling and analysis is conducted, laboratory testing records and results from a laboratory that is accredited in accordance with § 1.651(b)(3), and documentation demonstrating such laboratory is accredited in accordance with § 1.651(b)(3);

(4) Any notification submitted by an audit agent to the accredited third-party certification body in accordance with § 1.650(a)(5);

(5) Any challenge to an adverse regulatory audit decision and the disposition of the challenge;

(6) Any monitoring it conducted of an eligible entity to which food or facility certification was issued;

(7) Its self-assessments and corrective actions taken to address any deficiencies identified during a self-assessment; and

(8) Significant changes to its auditing or certification program that might affect compliance with this subpart.

(b) An accredited third-party certification body must make the records of a consultative audit required by paragraph (a)(1) of this section available to FDA in accordance with section 414 of the FD&C Act.

(c) An accredited third-party certification body must make the records required by paragraphs (a)(2) through (8) of this section available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accredited third-party certification body or at a reasonably accessible location. If such records are requested by FDA electronically, the records must be submitted electronically not later than 10 business days after the date of the request. Additionally, if the records are maintained in a language other than English, an accredited third-party certification body must electronically submit an English translation within a reasonable time.

Procedures for Accreditation of Third-Party Certification Bodies Under This Subpart

§ 1.660 Where do I apply for accreditation or renewal of accreditation by a recognized accreditation body and what happens once the recognized accreditation body decides on my application?

(a) *Submission of accreditation or renewal application to a recognized accreditation body.* A third-party certification body seeking accreditation or renewal of accreditation by a recognized accreditation body identified on the Web site described in § 1.690.

(b) *Notice of records custodian after denial of application for renewal of accreditation.* An applicant whose renewal application was denied by a recognized accreditation body must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of accreditation or denial of the renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(c) *Effect of denial of an application for renewal of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification

in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of denial of an application for renewal of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the date of issuance of a denial of renewal of accreditation of a third-party certification body that had previous been accredited.

§ 1.661 What is the duration of accreditation by a recognized accreditation body?

A recognized accreditation body may grant accreditation to a third-party certification body under this subpart for a period not to exceed 4 years.

§ 1.662 How will FDA monitor accredited third-party certification bodies?

(a) FDA will periodically evaluate the performance of each accredited third-party certification body to determine whether the accredited third-party certification body continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the accredited third-party certification body that, if not corrected, would warrant withdrawal of its accreditation under § 1.664. FDA will evaluate each directly accredited third-party certification body annually. For a third-party certification body accredited by a recognized accreditation body, FDA will evaluate an accredited third-party certification body not later than 3 years after the date of accreditation for a 4-year term of accreditation, or by no later than the mid-term point for accreditation granted for less than 4 years. FDA may conduct additional performance assessments of an accredited third-party certification body at any time.

(b) In evaluating the performance of an accredited third-party certification body under paragraph (a) of this section, FDA may review any one or more of the following:

(1) Regulatory audit reports and food and facility certifications;

(2) The accredited third-party certification body's self-assessments under § 1.655;

(3) Reports of assessments by a recognized accreditation body under § 1.621;

(4) Documents and other information relevant to a determination of the accredited third-party certification body's compliance with the applicable requirements of this subpart; and

(5) Information obtained by FDA, including during inspections, audits,

onsite observations, or investigations, of one or more eligible entities to which a food or facility certification was issued by such accredited third-party certification body.

(c) FDA may conduct its evaluation of an accredited third-party certification body through a site visit to an accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters), through onsite observation of an accredited third party certification body's performance during a food safety audit of an eligible entity, or through document review.

§ 1.663 How do I request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits?

(a) An accredited third-party certification body may submit a request to FDA to waive the requirements of § 1.650(c) preventing an audit agent from conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months. The accredited third-party certification body seeking a waiver or waiver extension must demonstrate there is insufficient access to audit agents and any third-party certification bodies that are comprised of an individual in the country or region where the eligible entity is located.

(b) Requests for a waiver or waiver extension and all documents provided in support of the request must be submitted to FDA electronically, in English. The requestor must provide such translation and interpretation services as are needed by FDA to process the request.

(c) The request must be signed by the requestor or by any individual authorized to act on behalf of the requestor for purposes of seeking such waiver or waiver extension.

(d) FDA will review requests for waivers and waiver extensions on a first in, first out basis according to the date on which the completed submission is received; however, FDA may prioritize the review of specific requests to meet the needs of the program. FDA will evaluate any completed waiver request to determine whether the criteria for waiver have been met.

(e) FDA will notify the requestor whether the request for a waiver or waiver extension is approved or denied.

(f) If FDA approves the request, issuance of the waiver will state the duration of the waiver and list any limitations associated with it. If FDA

denies the request, the issuance of a denial of a waiver request will state the basis for denial and will provide the address and procedures for requesting reconsideration of the request under § 1.691.

(g) Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in § 1.650(c) has elapsed.

§ 1.664 When would FDA withdraw accreditation?

(a) *Mandatory withdrawal.* FDA will withdraw accreditation from a third-party certification body:

(1) Except as provided in paragraph (b) of this section, if the food or facility certified under this subpart is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(2) Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this subpart; or

(3) Following its refusal to allow FDA to access records under § 1.658 or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this subpart.

(b) *Exception.* FDA may waive mandatory withdrawal under paragraph (a)(1) of this section, if FDA:

(1) Conducts an investigation of the material facts related to the outbreak of human or animal illness;

(2) Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

(3) Determines that the accredited third-party certification body satisfied the requirements for issuance of certification under this subpart.

(c) *Discretionary withdrawal.* FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked under § 1.634, if FDA determines there is good cause for withdrawal, including:

(1) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(2) Performance that calls into question the validity or reliability of its food safety audits or certifications.

(d) *Records access.* FDA may request records of the accredited third-party certification body under § 1.658 and,

where applicable, may request records under § 1.625 of an accreditation body that has been recognized under § 1.625, when considering withdrawal under paragraph (a)(1), (a)(2), or (c) of this section.

(e) *Notice to the third-party certification body of withdrawal of accreditation.* (1) FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing under § 1.693 on the withdrawal, and the procedures for requesting reaccreditation under § 1.666.

(2) Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by § 1.658, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(f) *Effect of withdrawal of accreditation on eligible entities.* A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(g) *Effect of withdrawal of accreditation on recognized accreditation bodies.* (1) FDA will notify a recognized accreditation body if the accreditation of a third-party certification body it accredited is withdrawn by FDA. Such accreditation body's recognition will remain in effect if, no later than 60 days after withdrawal, the accreditation body conducts a self-assessment under § 1.622 and reports the results of the self-assessment to FDA as required by § 1.623(b).

(2) FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under § 1.634.

(h) *Public notice of withdrawal accreditation.* FDA will provide notice on the Web site described in § 1.690 of its withdrawal of accreditation of a third-party certification body and

provide a description of the basis for withdrawal.

§ 1.665 What if I want to voluntarily relinquish accreditation or do not want to renew accreditation?

(a) *Notice to FDA of intent to relinquish or not to renew accreditation.* A third-party certification body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required under § 1.658(a) after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(b) *Notice to recognized accreditation body and eligible entities of intent to relinquish or not to renew accreditation.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the certification body must notify its recognized accreditation body and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625(a).

(c) *Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of voluntary relinquishment or expiration of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of accreditation of a certification body under this subpart.

§ 1.666 How do I request reaccreditation?

(a) *Application following withdrawal.* FDA will reinstate the accreditation of a third-party certification body for which it has withdrawn accreditation:

(1) If, in the case of direct accreditation, FDA determines, based on evidence presented by the third-party certification body, that the third-party certification body satisfies the applicable requirements of this subpart and adequate grounds for withdrawal no longer exist; or

(2) In the case of a third-party certification body accredited by an accreditation body for which recognition has been revoked under § 1.634:

(i) If the third-party certification body becomes accredited by another recognized accreditation body or by FDA through direct accreditation no later than 1 year after withdrawal of accreditation, or the original date of the expiration of accreditation, whichever comes first; or

(ii) Under such conditions as FDA may impose in withdrawing accreditation.

(b) *Application following voluntary relinquishment.* A third-party certification body that previously relinquished its accreditation under § 1.665 may seek accreditation by submitting a new application for accreditation under § 1.660 or, where applicable, § 1.670.

Additional Procedures for Direct Accreditation of Third-Party Certification Bodies Under This Subpart

§ 1.670 How do I apply to FDA for direct accreditation or renewal of direct accreditation?

(a) *Eligibility.* (1) FDA will accept applications from third-party certification bodies for direct accreditation or renewal of direct accreditation only if FDA determines that it has not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing the accredited third-party audits and certification program. Such FDA determination may apply, as appropriate, to specific types of third-party certification bodies, types of expertise, or geographic location; or through identification by FDA of any requirements of section 808 of the FD&C Act not otherwise met by previously recognized accreditation bodies. FDA will only accept applications for direct accreditation and renewal applications that are within the scope of the determination.

(2) FDA may revoke or modify a determination under paragraph (a)(1) of this section if FDA subsequently identifies and recognizes an accreditation body that affects such determination.

(3) FDA will provide notice on the Web site described in § 1.690 of a determination under paragraph (a)(1) of this section and of a revocation or modification of the determination under paragraph (a)(1) of this section, as described in paragraph (a)(2) of this section.

(b) *Application for direct accreditation or renewal of direct accreditation.* (1) A third-party certification body seeking direct accreditation or renewal of direct accreditation must submit an application to FDA, demonstrating that it is within the scope of the determination issued under paragraph (a)(1) of this section, and it meets the eligibility requirements of § 1.640.

(2) Applications and all documents provided as part of the application process must be submitted electronically, in English. An applicant must provide such translation and interpretation services as are needed by FDA to process the application, including during an onsite audit of the applicant.

(3) The application must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking or renewing direct accreditation.

§ 1.671 How will FDA review my application for direct accreditation or renewal of direct accreditation and what happens once FDA decides on my application?

(a) *Review of a direct accreditation or renewal application.* FDA will examine a third-party certification body's direct accreditation or renewal application for completeness and notify the applicant of any deficiencies. FDA will review applications for direct accreditation and for renewal of direct accreditation on a first in, first out basis according to the date the completed submission is received; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of a direct accreditation or renewal application.* FDA will evaluate any completed application to determine whether the applicant meets the requirements for direct accreditation under this subpart. If FDA does not reach a final decision on a renewal application before the expiration of the direct accreditation, FDA may extend the duration of such direct accreditation for a specified

period of time or until the Agency reaches a final decision on the renewal application.

(c) *Notice of approval or denial.* FDA will notify the applicant that its direct accreditation or renewal application has been approved through issuance of or denied.

(d) *Issuance of direct accreditation.* If an application has been approved, the issuance of the direct accreditation that will list any limitations associated with the accreditation.

(e) *Issuance of denial of direct accreditation.* If FDA issues a denial of direct accreditation or denial of a renewal application, the issuance of the denial of direct accreditation will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(f) *Notice of records custodian after denial of application for renewal of direct accreditation.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(b) will be located.

(g) *Effect of denial of renewal of direct accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(h) *Public notice of denial of renewal of direct accreditation.* FDA will provide notice on the Web site described in § 1.690 of the issuance of a denial of renewal application for direct accreditation under this subpart.

§ 1.672 What is the duration of direct accreditation?

FDA will grant direct accreditation of a third-party certification body for a period not to exceed 4 years.

Requirements for Eligible Entities Under This Subpart

§ 1.680 How and when will FDA monitor eligible entities?

FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited third-party certification body under this subpart. Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present. An FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

§ 1.681 How frequently must eligible entities be recertified?

An eligible entity seeking recertification of a food or facility certification under this subpart must apply for recertification prior to the expiration of its certification. For certifications used in meeting the requirements of section 801(q) or 806 of the FD&C Act, FDA may require an eligible entity to apply for recertification at any time FDA determines appropriate under such section.

General Requirements of This Subpart

§ 1.690 How will FDA make information about recognized accreditation bodies and accredited third-party certification bodies available to the public?

FDA will place on its Web site a registry of recognized accreditation bodies and accredited third-party certification bodies, including the name, contact information, and scope and duration of recognition or accreditation. The registry may provide information on third-party certification bodies accredited by recognized accreditation bodies through links to the Web sites of such recognized accreditation bodies. FDA will also place on its Web site a list of accreditation bodies for which it has denied renewal of recognition, for which FDA has revoked recognition, and that have relinquished their recognition or have allowed their recognition to expire. FDA will also place in its Web site a list of certification bodies whose renewal of accreditation has been denied, for which FDA has withdrawn accreditation, and that have relinquished their accreditations or have allowed their accreditations to expire. FDA will place on its Web site determinations under § 1.670(a)(1) and modifications of such determinations under § 1.670(a)(2).

§ 1.691 How do I request reconsideration of a denial by FDA of an application or a waiver request?

(a) An accreditation body may seek reconsideration of the denial of an application for recognition, renewal of recognition, or reinstatement of recognition no later than 10 business days after the date of the issuance of such denial.

(b) A third-party certification body may seek reconsideration of the denial of an application for direct accreditation, renewal of direct accreditation, reaccreditation of directly accredited third-party certification body, a request for a waiver of the conflict of interest requirement in § 1.650(b), or a waiver extension no later than 10 business days after the date of the issuance of such denial.

(c) A request to reconsider an application or waiver request under paragraph (a) or (b) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for reconsideration. The request must be submitted electronically in English and must comply with the procedures described in the notice.

(d) After completing its review and evaluation of the request for reconsideration, FDA will notify the requestor through the issuance of the recognition, direct accreditation, or waiver upon reconsideration or through the issuance of a denial of the application or waiver request under paragraph (a) or (b) of this section upon reconsideration.

§ 1.692 How do I request internal agency review of a denial of an application or waiver request upon reconsideration?

(a) No later than 10 business days after the date of issuance of a denial of an application or waiver request upon reconsideration under § 1.691, the requestor may seek internal agency review of such denial under § 10.75(c)(1) of this chapter.

(b) The request for internal agency review under paragraph (a) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for internal review. The request must be submitted electronically in English to the address specified in the denial upon reconsideration and must comply with procedures it describes.

(c) Under § 10.75(d) of this chapter, internal agency review of such denial must be based on the information in the administrative file, which will include any supporting information submitted under § 1.691(c).

(d) After completing the review and evaluation of the administrative file, FDA will notify the requestor of its decision to overturn the denial and grant the application or waiver request through issuance of an application or waiver request upon reconsideration or to affirm the denial of the application or waiver request upon reconsideration through issuance of a denial of an application or waiver request upon reconsideration.

(e) Issuance by FDA of a denial of an application or waiver request upon reconsideration constitutes final agency action under 5 U.S.C. 702.

§ 1.693 How do I request a regulatory hearing on a revocation of recognition or withdrawal of accreditation?

(a) *Request for hearing on revocation.* No later than 10 business days after the date of issuance of a revocation of recognition of an accreditation body under § 1.634, an individual authorized to act on the accreditation body's behalf may submit a request for a regulatory hearing on the revocation under part 16 of this chapter. The issuance of revocation issued under § 1.634 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Request for hearing on withdrawal.* No later than 10 business days after the date of issuance of a withdrawal of accreditation of a third-party certification body under § 1.664, an individual authorized to act on the third-party certification body's behalf may submit a request for a regulatory hearing on the withdrawal under part 16 of this chapter. The issuance of withdrawal under § 1.664 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of opportunity of hearing under part 16 of this chapter.

(c) *Submission of request for regulatory hearing.* The request for a regulatory hearing under paragraph (a) or (b) of this section must be submitted with a written appeal that responds to the basis for the FDA decision, as described in the issuance of revocation or withdrawal, as appropriate, and includes any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the address specified in the notice and must comply with the procedures it describes.

(d) *Effect of submission of request on FDA decision.* The submission of a request for a regulatory hearing under

paragraph (a) or (b) of this section will not operate to delay or stay the effect of a decision by FDA to revoke recognition of an accreditation body or to withdraw accreditation of a third-party certification body unless FDA determines that a delay or a stay is in the public interest.

(e) *Presiding officer.* The presiding officer for a regulatory hearing for a revocation or withdrawal under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(f) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing for a revocation or withdrawal under § 16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(g) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing for a revocation or withdrawal, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by requestor, the presiding officer, and FDA.

(2) The presiding officer must conduct the regulatory hearing for revocation or withdrawal under part 16 of this chapter, except that, under § 16.5(b) of this chapter, such procedures apply only to the extent that the procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 are inapplicable to regulatory hearings under this subpart: § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or the withdrawal of accreditation is considered a final agency action under 5 U.S.C. 702.

§ 1.694 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that

also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 1.695 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 4. In § 11.1, add paragraph (m) to read as follows:

§ 11.1 Scope.

* * * * *

(m) This part does not apply to records required to be established or maintained by subpart M of part 1 of this chapter. Records that satisfy the requirements of subpart M of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. In § 16.1(b)(2), add the following entry in numerical order to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 1.634 and 1.664, relating to revocation of recognition of an accreditation body and withdrawal of accreditation of third-party certification bodies that conduct food safety audits of eligible entities in the food import supply chain and issue food and facility certifications.

* * * * *

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28160 Filed 11–13–15; 8:45 am]

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 112

Final Environmental Impact Statement and Record of Decision for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Availability; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2014-N-2244]

RIN 0910-AG35

Final Environmental Impact Statement and Record of Decision for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) has made available for public review the Final Environmental Impact Statement (EIS) and Record of Decision (ROD) for the standards for the growing, harvesting, packing, and holding of produce for human consumption. FDA prepared the Final EIS after taking into account public comment received on the corresponding Draft EIS and is publishing the ROD at the time of our decision. The Final EIS and ROD documents are available in Docket No. FDA-2014-N-2244.

DATES: FDA announces the availability of the EIS and ROD on November 27, 2015.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1057.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. As part of our implementation of FSMA, we published the proposed rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as “the 2013 proposed rule”) on January 16, 2013, to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce (78 FR 3504). On September 29, 2014, FDA issued a

supplemental notice of proposed rulemaking (“the supplemental proposed rule”), amending certain specific provisions of the 2013 proposed rule (79 FR 58434). Taken together, these publications constitute FDA’s proposed standards for the growing, harvesting, packing, and holding of produce for human consumption (“the Produce Safety proposed rule”).

FDA announced a “Notice of Intent” (NOI) to prepare an EIS to evaluate the potential environmental effects of the Produce Safety Proposed Rule in the **Federal Register** on August 19, 2013 (78 FR 50358). In the NOI, FDA also announced the beginning of the scoping process and solicited public comments to identify issues to be analyzed in an EIS. The NOI asked for public comment by November 15, 2013, and FDA later extended the deadline for the comment period to March 15, 2014 (78 FR 69006; November 18, 2013), and then April 18, 2014 (79 FR 13593; March 11, 2014).

A public scoping meeting was held on April 4, 2014, in College Park, MD. FDA prepared a Draft EIS for the Produce Safety proposed rule and, on January 14, 2015, published a “Notification of public meeting” in the **Federal Register** to: (1) Announce the availability of the Draft EIS for public review and comment and (2) announce a public meeting to inform the public of the findings in the Draft EIS, provide information about the EIS process, solicit oral stakeholder and public comments on the Draft EIS, and provide clarification, as needed, about the contents of the Draft EIS (80 FR 1852). The public meeting was held on February 10, 2015, in College Park, MD. The comment period on the Draft EIS closed on March 13, 2015. FDA is now announcing the availability of the Final EIS, which FDA prepared, taking into account public comment received on the Draft EIS, and the ROD, which details FDA’s final decision, taking into account the findings of the Final EIS and the Agency’s stated purpose and need.

In the Produce Safety proposed rule, FDA proposed science-based minimum standards for the safe production and harvesting of produce. As discussed in the Final EIS (Ref. 1), out of these standards, we identified four provisions that could potentially significantly affect the quality of the human environment, if finalized (hereinafter referred to as “potentially significant provisions”). For each of the potentially significant provisions, FDA then identified alternative provisions to consider. The potentially significant provisions are: (1) Standards directed to agricultural water, (2) standards

directed to biological soil amendments (BSA) of animal origin, (3) standards directed to domesticated and wild animals, and (4) general provisions (*i.e.*, cumulative impacts). Additionally, an overarching “No Action” alternative was considered for the purpose of evaluating conditions in the absence of any final rule.

For standards directed to agricultural water, we considered the following alternatives: (1) As proposed by FDA, *i.e.*, a statistical threshold value (STV) not exceeding 410 colony forming units (CFU) of generic *Escherichia coli* per 100 milliliters (ml) of water and a geometric mean (GM) not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing (proposed 21 CFR 112.44(c)); (2) a microbial quality standard of no more than 235 CFU (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as was proposed in the 2013 proposed rule; (3) as proposed (*i.e.*, Alternative 1), but with an additional criterion establishing a maximum generic *E. coli* threshold; and (4) for each of the previous alternatives, consider the environmental impacts if each alternative includes root crops that are irrigated using low-flow methods.

For standards directed to BSAs of animal origin, FDA considered standards for both untreated and treated BSAs. For untreated BSAs of animal origin, the alternatives considered included a range of minimal application intervals (the time between application and harvest) when the BSA is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. The alternative application intervals evaluated were: (1) 9 months; (2) 0 months; (3) 90 and 120 days; consistent with the National Organic Program’s regulations in 7 CFR 205.203(c)(1); (4) 6 months; and (5) 12 months. For standards directed to treated BSAs, the alternatives considered included a range of application intervals when the BSA is composted in accordance with the requirements proposed in § 112.54(c) and applied in a manner that minimizes the potential for contact with covered produce during and after application.

The application intervals evaluated were: (1) As proposed by FDA, 0 days (proposed § 112.56(a)(4)(i)); (2) 45 days; and (3) 90 days.

For standards directed at domesticated animals, we considered alternatives under which, if working animals are used in a growing area where a crop has been planted, measures would be required to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce with the waiting period between grazing and harvesting varying by alternative. The following alternatives were evaluated: (1) As proposed by FDA, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop (proposed § 112.82(a)); (2) a minimum waiting period of 9 months; and (3) a minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (applying the timeframes for raw manure set forth in the National Organic Program's regulations in 7 CFR 205.203(c)(1)). For standards directed to wild animals, we considered alternatives to the proposed requirement that under circumstances when there is a reasonable probability that animal intrusion will contaminate covered produce, the grower would be required to monitor those areas that are used for a covered activity for evidence of animal intrusion: (1) As needed during the growing season based on (i) the grower's covered produce and (ii) the grower's observations and experience; and (2) immediately prior to harvest. The alternatives evaluated were: (1) As proposed by FDA, if animal intrusion occurs—as made evident by observation of significant quantities of animals, animal excreta, or crop destruction via grazing—the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112 (proposed § 112.83(a) and (b)); and (2) if animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

The cumulative impacts of the proposed rule were considered using a range of alternatives to the general provision in proposed § 112.4, which would specify the farms that would be covered under the rule based on the farm's annual sales of produce. The alternatives evaluated were to cover those farms that have: (1) As proposed by FDA, an average annual monetary value of produce sold during the previous 3-year period of more than

\$25,000 (on a rolling basis) (proposed § 112.4); (2) an average annual monetary value of food sold during the previous 3-year period of more than \$50,000 (on a rolling basis); (3) an average annual monetary value of food sold during the previous 3-year period of more than \$100,000 (on a rolling basis); and (4) an average annual monetary value of covered produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis).

In the Final EIS, FDA identifies the "Agency's preferred alternative," *i.e.*, the alternative which the Agency believes will fulfill its statutory mission and responsibilities for this rulemaking, giving consideration to economic, environmental, technical, and other factors. Slight modifications to the preferred alternative were made in the ROD to reflect the Agency's final action. The Agency's preferred alternative, as described in the ROD, is comprised of the following alternatives for each of the potentially significant provisions listed previously:

For agricultural water and including root crops irrigated using low-flow methods, generic *E. coli*: GM of 126 CFU/100 ml and STV of 410 CFU/100 ml, with additional flexibility for microbial die-off and/or removal (§§ 112.44(b) and 112.45(b));

For treated biological soil amendments of animal origin, 0 day application interval (§ 112.56(a)(2)); and
For domesticated animals (grazing and working) and animal intrusion, visual assessment for significant evidence of animal potential contamination as needed during the growing season to identify and not harvest produce that is or is likely to be contaminated (§§ 112.83, 112.84, and 112.112).

As discussed in the supplemental proposed rule, FDA has chosen to defer decision on a minimum application interval for untreated BSAs of animal origin that are applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application (79 FR 58434) and, therefore, has not identified an alternative that would best meet the statutory mission and responsibilities. For the purpose of the aggregate environmental impact analysis in the Final EIS, in the absence of a decision on the alternative that would fulfill the statutory mission, the impacts associated with the 0-day application interval were included as the environmental impacts associated with this alternative.

FDA has made the Final EIS and ROD available for public review in Docket

No. FDA-2014-N-2244 (see Ref. 1 and 2).

Waiver of 30-Day Review of Final EIS

Under CEQ regulation 40 CFR 1506.10(b)(2), no decision on the proposed action shall be made or recorded by a Federal Agency under 40 CFR 1505.2 until 30 days after publication of the notice for a Final EIS. However, 40 CFR 1506.10(b)(2) also provides the following exception from the rules of timing: An agency engaged in rulemaking under the Administrative Procedure Act or other statute for the purpose of protecting the public health or safety, may waive the time period in paragraph (b)(2) and publish a decision on the final rule simultaneously with publication of the notice of the availability of the final environmental impact statement.

Consistent with the circumstances in 40 CFR 1506.10(b)(2) under which a waiver may be used, FDA is waiving the 30-day time period between the publication of the Final EIS and FDA's decision on the Produce Safety final rule. FDA is publishing this notice of availability of the Final EIS simultaneously with the publication of the Produce Safety final rule and ROD. FDA considers the use of the waiver to be appropriate, in order to enhance food safety and protect public health, consistent with the purpose of FSMA and the Produce Safety final rule and the urgency for its release. We explain our reasons as follows:

The Produce Safety final rule establishes standards to minimize the risk of serious adverse health consequences or death (SAHCOD) resulting from contaminated produce. This rule implements section 419 of the FD&C Act (21 U.S.C. 350h), which requires FDA to adopt a final produce safety regulation based on known safety risks, that sets forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342).

The history of foodborne illness outbreaks, including outbreaks resulting in severe illnesses and death associated with contaminated produce, make clear that produce-related outbreaks are a serious and ongoing food safety problem. From 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,132 outbreak-related illnesses; 1,360 hospitalizations; and 27 deaths.

These outbreaks were associated with approximately 20 different produce commodities (Ref. 3). Even after enactment of FSMA outbreaks from produce continue to occur, between January 2011 and 2014, there were 44 outbreaks; 3,120 illnesses; 735 hospitalizations; and 42 deaths associated with produce (Ref. 4). These outbreaks were associated with approximately 10 different produce commodities. The illness numbers cited previously are the reported illnesses; the Centers for Disease Control estimates that only a fraction of foodborne illness is reported (<http://www.cdc.gov/foodborneburden/estimates-overview.html>).

This history of produce-related outbreaks was the impetus for Congress, in FSMA, to require Federal produce safety standards to establish requirements for prevention-focused regulation in a sector of the food industry that had previously seen little Federal food safety oversight and underscores the urgent public health need for implementation of FDA produce safety standards to begin. Annualizing benefits over the first 10 years after publication of the rule, we expect benefits of the Produce Safety final rule to be approximately 362,059 illnesses averted per year, valued at \$976 million annually (see the Regulatory Impact Analysis accompanying the rule for additional information (Ref. 5)).

There is a public health need to publish the Produce Safety final rule and begin implementation of the produce safety standards. Congress conveyed its sense of urgency in the timeframes established in FSMA for the Produce Safety final rule: 1 year after enactment of FSMA for a proposed rule (section 419(a)(1)(A) of the FD&C Act) and 1 year after the close of the comment period for a final rule (section 419(b)(1) of the FD&C Act). Congress recognized the urgent need to establish standards for produce safety to prevent SAHCOD hazards and, therefore, included specific timeframes for issuance of the proposed and final produce safety rules within the statute. Although FDA was unable to meet these statutory timeframes, FDA has nonetheless acted as swiftly as possible to complete the rulemaking process to

establish the produce safety regulation in 21 CFR part 112.

Formulating the produce safety standards involved highly complex scientific, regulatory, and practical considerations. For example, establishing the appropriate microbial quality criteria for agricultural water that is used during growing activities involved extensive review of scientific literature on pathogen presence, transmission, and survival under various conditions; other relevant national and international standards; diverse uses and methods of application of water; and the wide array of commodities and practices that affect potential risk of contamination of produce. As another example, we considered various options before adopting a regulatory framework that is based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce, rather than one that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. FDA's integrated approach to produce safety standards draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. Through this rule (along with other FSMA rules) FDA is putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices.

The rule notably sets standards in an area that is extremely diverse. Therefore, FDA has spent considerable time to achieve the right balance in establishing standards that would adequately protect public health and yet be flexible and practicable to be implemented successfully by the highly diverse produce industry. This necessitated enormous outreach, including numerous farm visits all over the United States, throughout the rulemaking process, to solicit and consider stakeholder input in preparing the final rule. We believe we have acted responsibly in taking the time to craft a

regulation that provides critical public health protection and also is implementable by the produce industry. Implementation of the produce safety standards by covered farms engaged in the growing, harvesting, packing, and/or holding of produce is critical to achieve the public health goals set out in FSMA and, therefore, we set reasonable timeframes for compliance with the rule. It is important for FDA to finalize the rule as quickly as possible to enable farmers, packers, handlers, and others covered under the rule to begin taking the steps that will safeguard public health and safety.

II. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Final Environmental Impact Statement for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, <http://www.fda.gov/food/guidanceregulation/fsma/ucm396564.htm>.
2. Record of Decision. Final Environmental Impact Statement—Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, October 2015.
3. D'Lima, C., K. Vierk, and FDA, "Memorandum to the Record", 2011.
4. Merriweather, C., T. C. Cloyd, C. Robinson, D. Gubernot, and FDA, 2011–2014 Produce Related Outbreaks and Illnesses [Memorandum]. May 8, 2015.
5. FDA, "Final Regulatory Impact Analysis: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28161 Filed 11–13–15; 8:45 am]

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