laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance 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 safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

EFFECTIVE DATE NOTE: At 80 FR 56145, Sept. 17, 2015, §117.475 was added, effective Nov. 16, 2015, except for paragraph (c)(2). FDA will publish a document in the FEDERAL REGISTER announcing the effective date for this paragraph.

PART 118—PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS

Sec.

AUTHORITY: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

SOURCE: 74 FR 33095, July 9, 2009, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 118 appear at 81 FR 49896, July 29, 2016.

§118.1 Persons covered by the requirements in this part.

(a) If you are a shell egg producer with 3,000 or more laying hens at a particular farm that does not sell all of your eggs directly to consumers and that produces shell eggs for the table market, you are covered by some or all of the requirements in this part, as follows:

(1) If any of your eggs that are produced at a particular farm do not receive a treatment as defined in §118.3,

you must comply with all of the requirements of this part for egg production on that farm.

(2) If all of your eggs that are produced at the particular farm receive a treatment as defined in § 118.3, you must comply only with the refrigeration requirements in § 118.4(e) for production of eggs on that farm and with the registration requirements in § 118.11.

(b) If you transport or hold shell eggs for shell egg processing or egg products facilities, you must comply with the refrigeration requirements in § 118.4(e). This section applies only to eggs from farms with 3,000 or more laying hens.

§ 118.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321) are applicable to such terms when used in this part, except where they are redefined in this part. The following definitions also apply:

Biosecurity means a program, including the limiting of visitors on the farm and in poultry houses, maintaining personnel and equipment practices that will protect against cross contamination from one poultry house to another, preventing stray poultry, wild birds, cats, and other animals from entering poultry houses, and not allowing employees to keep birds at home, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

Egg products facility means a USDA-inspected egg products plant where liquid, frozen, and/or dried egg products are produced.

Farm means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program.

Flock means all laying hens within one poultry house.

Group means all laying hens of the same age within one poultry house.

Induced molting means molting that is artificially initiated.

Laying cycle means the period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production and the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

Molting means a life stage during which hens stop laying eggs and shed their feathers.

Pest means any objectionable animal including, but not limited to, rodents, flies, and larvae.

Positive flock means a flock that has had an egg test that was positive for SE. A flock is considered positive until that flock meets the egg testing requirements in § 118.6(c) to return to table egg production.

Positive poultry house means a poultry house from which there has been an environmental test that was positive for SE at any time during the life of a group in the poultry house until that house is cleaned and disinfected according to § 118.4(d).

Poultry house means a building, other structure, or separate section within a structure used to house poultry. For structures comprising more than one section containing poultry, each section that is separated from the other sections is considered a separate house.

Producer means a person who owns and/or operates a poultry house containing laying hens which produce shell eggs for human consumption.

Shell egg (or egg) means the egg of the domesticated chicken.

Shell egg processing facility means a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market.

Treatment (or treated) means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

§ 118.4 Salmonella Enteritidis (SE) prevention measures.

You must follow the SE prevention measures set forth in this section. In addition, you must have and implement a written SE prevention plan that is specific to each farm where you produce eggs and that includes, at a minimum, the following SE prevention measures:

(a) *Pullets.* You must procure pullets that are SE monitored or raise pullets

under SE monitored conditions. ''SE monitored'' means the pullets are raised under SE control conditions that prevent SE, including:

(1) *Procurement of chicks.* Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for ''U.S. S. Enteritidis Clean'' status (9 CFR 145.23(d)) or equivalent standard;

(2) *Environmental testing.* (i) The pullet environment is tested for SE when pullets are 14 to 16 weeks of age;

(ii) If the environmental test required in paragraph (a)(2)(i) of this section is negative, you do not need to perform any additional testing of those birds or their environment until the environmental test at 40 to 45 weeks of age specified in §118.5(a); and

(iii) If the environmental test required in paragraph (a)(2)(i) of this section is positive, you must begin egg testing, as specified in §118.6, within 2 weeks of the start of egg laying.

(3) *Cleaning and disinfection.* If the environmental test required in paragraph (a)(2) of this section is positive, the pullet environment is cleaned and disinfected, to include:

(i) Removal of all visible manure;

(ii) Dry cleaning the positive pullet house to remove dust, feathers, and old feed; and

(iii) Following cleaning, disinfection of the positive pullet house with spray, aerosol, fumigation, or another appropriate disinfection method.

(b) *Biosecurity.* As part of this program, you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. Among such biosecurity measures you must, at a minimum:

(1) Limit visitors on the farm and in the poultry houses;

(2) Maintain practices that will protect against cross contamination when equipment is moved among poultry houses;

(3) Maintain practices that will protect against cross contamination when persons move between poultry houses;

(4) Prevent stray poultry, wild birds, cats, and other animals from entering poultry houses; and

(5) Not allow employees to keep birds at home.

(c) *Rodents, flies, and other pest control.* As part of this program, you must:

(1) Monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, use appropriate methods to achieve satisfactory rodent control;

(2) Monitor for flies by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable fly activity within a poultry house, use appropriate methods to achieve satisfactory fly control.

(3) Remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests.

(d) *Cleaning and disinfection.* You must clean and disinfect the poultry house according to these procedures before new laying hens are added to the house, if you have had an environmental test or an egg test that was positive for SE at any point during the life of a flock that was housed in the poultry house prior to depopulation. As part of the cleaning and disinfection procedures, you must:

(1) Remove all visible manure;

(2) Dry clean the positive poultry house to remove dust, feathers, and old feed; and

(3) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

(e) *Refrigeration.* You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay. If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then you may then hold them at room temperature for no more than 36 hours just prior to processing to allow an equilibration step to temper the eggs.

§ 118.5 Environmental testing for Salmonella Enteritidis (SE).

(a) *Environmental testing when laying hens are 40 to 45 weeks of age.* As one indicator of the effectiveness of your SE prevention plan, you must perform environmental testing for SE (as described in §§ 118.7 and 118.8) in a poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age.

(1) If an environmental test at 40 to 45 weeks is negative and your laying hens do not undergo induced molting, then you do not need to perform any additional environmental testing within that poultry house, unless the poultry house contains more than one group of laying hens. If the poultry house contains more than one group of laying hens, then you must perform environmental testing on the poultry house when each group of laying hens is 40 to 45 weeks of age.

(2) If the environmental test at 40 to 45 weeks is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing must be obtained within 10-calendar days of receiving notification of the positive environmental test.

(b) *Environmental testing after an induced molting period.* If you induce a molt in a flock or a group in a flock, you must perform environmental testing for SE in the poultry house at 4 to 6 weeks after the end of any molting process.

(1) If an environmental test at 4 to 6 weeks after the end of the molting process is negative and none of your laying hens in that poultry house is molted again, then you do not need to perform any additional environmental testing in that poultry house. Each time a flock or group within the flock is molted, you must perform environmental testing in the poultry house at 4 to 6 weeks after the end of the molting process.

(2) If the environmental test at 4 to 6 weeks after the end of a molting process is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented; and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10-calendar days of receiving notification of the positive environmental test.

§ 118.6 Egg testing for Salmonella Enteritidis (SE).

(a)(1) If the environmental test for pullets at 14 to 16 weeks of age required by § 118.4(a) is positive, you must divert eggs to treatment (defined in § 118.3) for the life of any flock or conduct egg testing within 2 weeks of the start of egg laying, as specified in paragraphs (b) through (e) of this section.

(2) If you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.

(b) Eggs must be sampled as described in § 118.7 and tested using methodology as described in § 118.8.

(c) You must conduct four egg tests, using sampling and methodology in §§ 118.7 and 118.8, on the flock in the positive poultry house at 2-week intervals. If all four tests are negative for SE, you are not required to do further egg testing.

(d) If any of the four egg tests is positive for SE, you must divert, upon receiving notification of an SE-positive egg test, all eggs from that flock to treatment (defined in § 118.3) until the conditions of paragraph (c) of this section are met.

(e) If you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using

sampling and methodology in §§118.7 and 118.8, for the life of the flock.

(1) If all the monthly egg tests in paragraph (e) of this section are negative for SE, you may continue to supply eggs to the table market.

(2) If any of the monthly egg tests in paragraph (e) of this section is positive for SE, you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions of paragraph (c) of this section are met.

(f) If you are diverting eggs, the pallet, case, or other shipping container must be labeled and all documents accompanying the shipment must contain the following statement: ''Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).'' The statement must be legible and conspicuous.

§ 118.7 Sampling methodology for Salmonella Enteritidis (SE).

(a) *Environmental sampling.* An environmental test must be done for each poultry house in accordance with §118.5 (a) and (b). Within each poultry house, you must sample the environment using a sampling plan appropriate to the poultry house layout.

(b) *Egg sampling.* When you conduct an egg test required under §118.6, you must collect and test the following number of eggs from the positive poultry house:

(1) To meet the egg testing requirements of §118.6(c), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production. The 1,000-egg sample must be tested according to §118.8. You must collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

(2) To meet the monthly egg testing requirement of §118.6(e), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production per month for the life of the flock. Eggs must be tested according to §118.8.

§ 118.8 Testing methodology for Salmonella Enteritidis (SE).

(a) *Testing of environmental samples for SE.* Testing to detect SE in environmental samples must be conducted by the method entitled ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses,'' April 2008, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. The April 2008 Environmental Sampling and Detection of *Salmonella* Web site is located at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ ucm114716.htm*, current as of June 26, 2009. The Director of the Federal Register approves the incorporation by reference of ''Environmental Sampling and Detection of *Salmonella* in Poultry Houses,'' April 2008, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. FDA will request approval to incorporate by reference any updates to this Web site. FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS–710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–436–2364, or you may examine a copy at the Food and Drug Administration'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__regulation/ibr__locations.html.*

(b) *Testing of egg samples for SE.* Testing to detect SE in egg samples must be conducted according to Chapter 5 of FDA's Bacteriological Analytical Manual (BAM), December 2007 Edition, or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Chapter 5 of FDA's Bacteriological Analytical Manual, December 2007 Edition, is located at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm070149.htm*, current as of June 26, 2009. The method is incorporated by reference in accordance with 5 U.S.C.

552(a) and 1 CFR part 51. FDA will request approval to incorporate by reference any updates to this Web site. FDA will change the date of the Web site in this paragraph with each update. You may obtain a copy from Division of Microbiology (HFS–710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–436–2364, or you may examine a copy at the Food and Drug Administration'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__regulation/ibr__locations.html.*

[74 FR 33095, July 9, 2009, as amended at 81 FR 5590, Feb. 3, 2016]

§ 118.9 Administration of the Salmonella Enteritidis (SE) prevention plan.

You must have one or more supervisory personnel, who do not have to be on-site employees, to be responsible for ensuring compliance with each farm's SE prevention plan. This person must have successfully completed training on SE prevention measures for egg production that is equivalent to that received under a standardized curriculum recognized by the Food and Drug Administration or must be otherwise qualified through job experience to administer the SE prevention measures. Job experience will qualify this person to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. This person is responsible for:

(a) Development and implementation of an SE prevention plan that is appropriate for your specific farm and meets the requirements of § 118.4;

(b) Reassessing and modifying the SE prevention plan as necessary to ensure that the requirements in § 118.4 are met; and

(c) Review of records created under § 118.10. This person does not need to have performed the monitoring or created the records.

§ 118.10 Recordkeeping requirements for the Salmonella Enteritidis (SE) prevention plan.

(a) *Records:* You must maintain the following records documenting your SE prevention measures:

(1) A written SE prevention plan required by § 118.4;

(2) Documentation that pullets were ''SE monitored'' or were raised under ''SE monitored'' conditions, including environmental testing records for pullets, as required by § 118.4(a)(2);

(3) Records documenting compliance with the SE prevention measures, as follows:

(i) Biosecurity measures;

(ii) Rodent and other pest control measures;

(iii) Cleaning and disinfection procedures performed at depopulation, when applicable;

(iv) Refrigeration requirements;

(v) Environmental and egg sampling procedures, when applicable, performed under § 118.7;

(vi) Results of SE testing, when applicable, performed under § 118.8 as required in §§ 118.4(a)(2), 118.5, and 118.6;

(vii) Diversion of eggs, if applicable, as required in § 118.6; and

(viii) Eggs at a particular farm being given a treatment as defined in § 118.3, if you are a producer complying with the requirements of this section as described in § 118.1(a)(2).

(4) Records of review and of modifications of the SE prevention plan and corrective actions taken.

(b) *General requirements for records maintained by shell egg producers.* All records required by § 118.10(a) must include:

(1) Your name and the location of your farm,

(2) The date and time of the activity that the record reflects,

(3) The signature or initials of the person performing the operation or creating the record. The written SE prevention plan must be dated and carry the signature(s) (not initials) of the person(s) who administers the plan as described in § 118.9, and

(4) Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records

must contain the actual values observed, if applicable.

(c) *Length of time records must be retained.* You must retain all records required by this part at your place of business, unless stored offsite under §118.10(d), for 1 year after the flock to which they pertain has been taken permanently out of production.

(d) *Offsite storage of records.* You may store the records required by this part, except for the written SE prevention plan, offsite. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(e) *Official review of records.* You must have all records required by this part available for official review and copying at reasonable times.

(f) *Public disclosure of records.* Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

§ 118.11 Registration requirements for shell egg producers covered by the requirements of this part.

(a) Shell egg producers covered under §118.1(a) are required to register their farms with FDA within 30 days of becoming an egg producer or, if already an egg producer, by each farm's applicable compliance date.

(b) Shell egg producers may register their farms by any of the following means:

(1) *Electronic registration.* To register electronically, you must register at *http://www.access.fda.gov*, which will be available for registration 24 hours a day, 7 days a week beginning May 10, 2010. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.

(i) An individual authorized by the owner or operator of a farm, such as an agent in charge, may also register a farm electronically.

(ii) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(iii) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(iv) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(2) *Registration by mail or by fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (b)(1) of this section, an individual authorized by the owner or operator of a farm, such as an agent in charge, may register by mail or fax.

(i) You must register using FDA Form No. 3733. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857, or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(ii) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(2)(i) of this section or fax it to the number on the form.

(iii) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (i.e., by mail or fax).

(iv) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(v) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(vi) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes,

you must update your facility's registration within 60 calendar days.

(vii) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(3) *Registration by CD–ROM for multiple submissions*. If, for example, you do not have reasonable access to the Internet through any of the methods provided under paragraph (b)(1) of this section, you may register by CD–ROM.

(i) Registrants submitting their registrations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(ii) These files must be submitted on a portable document format (PDF) rendition of the registration form (FDA Form No. 3733) and be accompanied by one signed copy of the certification statement that appears on the registration form.

(iii) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on FDA Form No. 3733.

(iv) A CD–ROM may contain registrations for as many facilities as needed up to the CD–ROM's capacity.

(v) The registration on the CD–ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(vi) You must mail the CD–ROM to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857.

(vii) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the submitter unprocessed.

(viii) FDA will enter CD–ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(ix) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(x) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(xi) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language. All information must be submitted using the Latin (Roman) alphabet.

(e) Each registrant must submit the following information through one of the methods described in paragraph (b) of this section:

(1) The name, full address, and phone number of the farm; and

(2) The average or usual number of layers of each house and number of poultry houses on the farm.

(3) A statement in which the shell egg producer certifies that the information submitted is true and accurate. If the individual submitting the form is not the shell egg producer in charge of the farm, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the farm submitting the registration, and the individual's signature (for paper and CD–ROM options).

(f) Registered egg producers must submit an update to a registration within 60-calendar days of any change to any of the information previously submitted by any of the means as provided in § 118.11(b).

(g) Registered egg producers must notify FDA within 120 days of ceasing egg production by completing sections 1b, 1c, and 2 of Form 3733. This notification is not required if you are a seasonal egg producer or you temporarily cease operation due to labor disputes,

fire, natural disasters, or other temporary conditions.

[74 FR 33095, July 9, 2009, as amended at 75 FR 18751, Apr. 13, 2010]

§ 118.12 Enforcement and compliance.

(a) *Authority*. This part is established under authority of the Public Health Service Act (the PHS Act). Under the FFDCA, the Food and Drug Administration (FDA) can enforce the food adulteration provisions under 21 U.S.C. 331 through 334 and 342. Under the PHS Act (42 U.S.C. 264), FDA has the authority to make and enforce regulations for the control of communicable diseases. FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon a finding that any shell eggs have been produced or held in violation of this part, an authorized FDA representative or a State or local representative in accordance with paragraph (c) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction under the PHS Act*. Any district office of FDA or any State or locality acting under paragraph (c) of this section, upon finding shell eggs that have been produced or held in violation of this regulation, may serve a written order upon the person in whose possession the eggs are found requiring that the eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-long destruction of SE or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order, unless under paragraph (a)(2)(iii) of this section, a hearing is held, in which case the eggs must be diverted or destroyed consistent with the decision of the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA District Director under paragraph (a)(2)(v) of this section. The order must include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs must not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (a)(1)(iv) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency issuing the order and the name of its Director.

(ii) *Approval of District Director*. An order, before issuance, must be approved by FDA's District Director or the Acting District Director. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum as soon as possible.

(iii) *Labeling or marking of shell eggs under order*. An FDA, State, or local representative issuing an order under paragraph (a)(1)(i) of this section must label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs must not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroy them or

(*2*) Move them to another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act (42 U.S.C. 271)).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(iv) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order must not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until receiving a notice that the order is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local representative, in writing, to:

(A) Divert or destroy them as specified in paragraph (a)(1)(i) of this section, or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to an Office of Regulatory Affairs Program Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal must be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing must be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which must not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order must state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA District Director determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the presiding FDA official determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing must be conducted by the Office of Regulatory Affairs Program Director or another FDA official senior to an FDA District Director, and a written summary of the proceedings must be prepared by the presiding FDA official.

(A) The presiding FDA official may direct that the hearing be conducted in any suitable manner permitted by law and by this section. The presiding FDA official has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action that is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at

the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding FDA official's report of the hearing.

(E) The presiding FDA official must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the presiding FDA official may give the parties the opportunity to review and comment on the report of the hearing.

(F) The presiding FDA official 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 recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the presiding FDA official must render a decision on the appeal affirming or revoking the detention order within 5-working days after the receipt of the appeal.

(v) *Presiding FDA official's decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the presiding FDA official finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the presiding FDA official must issue a written notice that the prior order is withdrawn. If the presiding FDA official affirms the order, he must order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The presiding FDA official's decision must be accompanied by a statement of the reasons for the decision. The decision of the presiding FDA official constitutes final agency action, subject to judicial review.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the presiding FDA official after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(b) *Inspection.* Persons engaged in production of shell eggs must permit authorized representatives of FDA to make, at any reasonable time, an inspection of the egg production establishment in which shell eggs are being produced. Such inspection includes the inspection and sampling of shell eggs and the environment, the equipment related to production of shell eggs, the equipment in which shell eggs are held, and examination and copying of any records relating to such equipment or eggs, as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(c) *State and local cooperation.* Under sections 311 and 361 of the Public Health Service Act, any State or locality that is willing and able to assist the agency in the enforcement of §§ 118.4 through 118.10, and is authorized to inspect or regulate egg production establishments, may, in its own jurisdiction, enforce §§ 118.4 through 118.10 through inspections under paragraph (b) of this section and through administrative enforcement remedies specified in paragraph (a) of this section unless FDA notifies the State or locality in writing that such assistance is no longer needed. A state or locality may substitute, where necessary, appropriate State or local officials for designated FDA officials in this section. When providing assistance under paragraph (a) of this section, a State or locality may follow the hearing procedures set out in paragraphs (a)(2)(iii) through (a)(2)(v) of this section, or may

utilize comparable State or local hearing procedures if such procedures satisfy due process.

(d) *Preemption.* No State or local governing entity shall establish, or continue in effect any law, rule, regulation, or other requirement regarding prevention of SE in shell eggs during production, storage, or transportation that is less stringent than those required by this part.

[74 FR 33095, July 9, 2009, as amended at 82 FR 14146, Mar. 17, 2017]

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

AUTHORITY: 21 U.S.C. 321, 342, 343, 371.

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

Sec.

Subpart B—Pathogen Reduction

AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 2421, 264.

SOURCE: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.