Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective Oct. 1, 2005, see section 7204 of Pub. L. 109–59, set out as an Effective Date of 2005 Amendment note under section 331 of this title.

REGULATIONS

Pub. L. 111–353, title I, §111(a), Jan. 4, 2011, 124 Stat. 3916, provided that: ''Not later than 18 months after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).''

§ 350f. Reportable food registry

(a) Definitions

In this section:

(1) Responsible party

The term ''responsible party'', with respect to an article of food, means a person that submits the registration under section 350d(a) of this title for a food facility that is required to register under section 350d(a) of this title, at which such article of food is manufactured, processed, packed, or held.

(2) Reportable food

The term ''reportable food'' means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

(b) Establishment

(1) In general

Not later than 1 year after September 27, 2007, the Secretary shall establish within the Food and Drug Administration a Reportable Food Registry to which instances of reportable food may be submitted by the Food and Drug Administration after receipt of reports under subsection (d), via an electronic portal, from—

(A) Federal, State, and local public health officials; or

(B) responsible parties.

(2) Review by Secretary

The Secretary shall promptly review and assess the information submitted under paragraph (1) for the purposes of identifying reportable food, submitting entries to the Reportable Food Registry, acting under subsection (c), and exercising other existing food safety authorities under this chapter to protect the public health.

(c) Issuance of an alert by the Secretary

(1) In general

The Secretary shall issue, or cause to be issued, an alert or a notification with respect to a reportable food using information from the Reportable Food Registry as the Secretary deems necessary to protect the public health.

(2) Effect

Paragraph (1) shall not affect the authority of the Secretary to issue an alert or a notification under any other provision of this chapter.

(d) Reporting and notification

(1) In general

Except as provided in paragraph (2), as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food, the responsible party shall—

(A) submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) (except the elements described in paragraphs (8), (9), and (10) of such subsection); and

(B) investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

(2) No report required

A responsible party is not required to submit a report under paragraph (1) if—

(A) the adulteration originated with the responsible party;

(B) the responsible party detected the adulteration prior to any transfer to another person of such article of food; and

(C) the responsible party—

(i) corrected such adulteration; or

(ii) destroyed or caused the destruction of such article of food.

(3) Reports by public health officials

A Federal, State, or local public health official may submit a report about a reportable food to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) that the official is able to provide.

(4) Report number

The Secretary shall ensure that, upon submission of a report under paragraph (1) or (3), a unique number is issued through the electronic portal established under subsection (b) to the person submitting such report, by which the Secretary is able to link reports about the reportable food submitted and amended under this subsection and identify the supply chain for such reportable food.

(5) Review

The Secretary shall promptly review a report submitted under paragraph (1) or (3).

(6) Response to report submitted by a responsible party

After consultation with the responsible party that submitted a report under paragraph (1), the Secretary may require such responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, 1 or more of the following:

(A) Amend the report submitted by the responsible party under paragraph (1) to include the data element described in subsection (e)(9).

(B) Provide a notification—

(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

(iii) that includes—

(I) the data elements described in subsection (e) that the Secretary deems necessary;

(II) the actions described under paragraph (7) that the recipient of the notification shall perform, as required by the Secretary; and

(III) any other information that the Secretary may require.

(7) Subsequent reports and notifications

Except as provided in paragraph (8), the Secretary may require a responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, after the responsible party receives a notification under subparagraph (C) or paragraph (6)(B), 1 or more of the following:

(A) Submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes those data elements described in subsection (e) and other information that the Secretary deems necessary.

(B) Investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

(C) Provide a notification—

(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

(iii) that includes—

(I) the data elements described in subsection (e) that the Secretary deems necessary;

(II) the actions described under this paragraph that the recipient of the notification shall perform, as required by the Secretary; and

(III) any other information that the Secretary may require.

(8) Amended report

If a responsible party receives a notification under paragraph (6)(B) or paragraph (7)(C) with respect to an article of food after the responsible party has submitted a report to the Food and Drug Administration under paragraph (1) with respect to such article of food—

(A) the responsible party is not required to submit an additional report or make a notification under paragraph (7); and

(B) the responsible party shall amend the report submitted by the responsible party under paragraph (1) to include the data elements described in paragraph (9), and, with respect to both such notification and such report, paragraph (11) of subsection (e).

(e) Data elements

The data elements described in this subsection are the following:

(1) The registration numbers of the responsible party under section 350d(a)(3)[1] of this title.

(2) The date on which an article of food was determined to be a reportable food.

(3) A description of the article of food including the quantity or amount.

(4) The extent and nature of the adulteration.

(5) If the adulteration of the article of food may have originated with the responsible party, the results of the investigation required under paragraph (1)(B) or (7)(B) of subsection (d), as applicable and when known.

(6) The disposition of the article of food, when known.

(7) Product information typically found on packaging including product codes, use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food.

(8) Contact information for the responsible party.

(9) The contact information for parties directly linked in the supply chain and notified under paragraph (6)(B) or (7)(C) of subsection (d), as applicable.

(10) The information required by the Secretary to be included in a notification provided by the responsible party involved under paragraph (6)(B) or (7)(C) of subsection (d) or required in a report under subsection (d)(7)(A).

(11) The unique number described in subsection (d)(4).

(f) Critical information

Except with respect to fruits and vegetables that are raw agricultural commodities, not more than 18 months after January 4, 2011, the Secretary may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include—

(1) a description of the article of food as provided in subsection (e)(3);

(2) as provided in subsection (e)(7), affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food;

(3) contact information for the responsible party as provided in subsection (e)(8); and

(4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

(g) Grocery store notification

(1) Action by Secretary

The Secretary shall—

(A) prepare the critical information described under subsection (f) for a reportable food as a standardized one-page summary;

(B) publish such one-page summary on the Internet website of the Food and Drug Administration in a format that can be easily printed by a grocery store for purposes of consumer notification.

(2) Action by grocery store

A notification described under paragraph (1)(B) shall include the date and time such

[1] See References in Text note below.

summary was posted on the Internet website of the Food and Drug Administration.

(h) Consumer notification

(1) In general

If a grocery store sold a reportable food that is the subject of the posting and such establishment is part of[2] chain of establishments with 15 or more physical locations, then such establishment shall, not later than 24 hours after a one page summary described in subsection (g) is published, prominently display such summary or the information from such summary via at least one of the methods identified under paragraph (2) and maintain the display for 14 days.

(2) List of conspicuous locations

Not more than 1 year after January 4, 2011, the Secretary shall develop and publish a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least one, for providing the notification required in paragraph (1). Such list shall include—

(A) posting the notification at or near the register;

(B) providing the location of the reportable food;

(C) providing targeted recall information given to customers upon purchase of a food; and

(D) other such prominent and conspicuous locations and manners utilized by grocery stores as of January 4, 2011, to provide notice of such recalls to consumers as considered appropriate by the Secretary.

(i) Coordination of Federal, State, and local efforts

(1) Department of Agriculture

In implementing this section, the Secretary shall—

(A) share information and coordinate regulatory efforts with the Department of Agriculture; and

(B) if the Secretary receives a report submitted about a food within the jurisdiction of the Department of Agriculture, promptly provide such report to the Department of Agriculture.

(2) States and localities

In implementing this section, the Secretary shall work with the State and local public health officials to share information and coordinate regulatory efforts, in order to—

(A) help to ensure coverage of the safety of the food supply chain, including those food establishments regulated by the States and localities that are not required to register under section 350d of this title; and

(B) reduce duplicative regulatory efforts.

(j) Maintenance and inspection of records

The responsible party shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section for 2 years. A responsible party shall, at the request of the Secretary, permit inspection of such records as provided for section[3] 350c of this title.

(k) Request for information

Except as provided by section 350d(a)(4)[1] of this title, section 552 of title 5 shall apply to any request for information regarding a record in the Reportable Food Registry.

***(l)* Safety report**

A report or notification under subsection (d) shall be considered to be a safety report under section 379v of this title and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report or the notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

(m) Admission

A report or notification under this section shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness.

(n) Homeland Security notification

If, after receiving a report under subsection (d), the Secretary believes such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make relevant information from the Reportable Food Registry available to the Secretary of Homeland Security.

(June 25, 1938, ch. 675, §417, as added Pub. L. 110–85, title X, §1005(b), Sept. 27, 2007, 121 Stat. 965; amended Pub. L. 111–353, title II, §211(a), Jan. 4, 2011, 124 Stat. 3951.)

Editorial Notes

REFERENCES IN TEXT

Section 350d(a)(3), (4) of this title, referred to in subsecs. (e)(1) and (k), was redesignated section 350d(a)(4), (5), respectively, of this title by Pub. L. 111–353, title I, §102(a)(2), Jan. 4, 2011, 124 Stat. 3887.

AMENDMENTS

2011—Subsecs. (f) to (n). Pub. L. 111–353 added subsecs. (f) to (h) and redesignated former subsecs. (f) to (k) as (i) to (n), respectively.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 110–85, title X, §1005(e), Sept. 27, 2007, 121 Stat. 969, provided that: ''The requirements of section 417(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350f(d)], as added by subsection (a) [probably should be (b)], shall become effective 1 year after the date of the enactment of this Act [Sept. 27, 2007].''

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

[2] So in original. Probably should be followed by ''a''.

[3] So in original. Probably should be ''in section''.

FINDINGS

Pub. L. 110–85, title X, § 1005(a), Sept. 27, 2007, 121 Stat. 964, provided that: ''Congress makes the following findings:

''(1) In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417) [see Short Title of 1994 Amendments note set out under section 301 of this title] to provide the Food and Drug Administration the legal framework which is intended to ensure that dietary supplements are safe and properly labeled foods.

''(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462) [see Short Title of 2006 Amendment note set out under section 301 of this title] to establish a mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements sold and consumed in the United States.

''(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act is intended to serve as an early warning system for potential public health issues associated with the use of these products.

''(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health.''

GUIDANCE

Pub. L. 110–85, title X, § 1005(f), Sept. 27, 2007, 121 Stat. 969, provided that: ''Not later than 9 months after the date of the enactment of this Act [Sept. 27, 2007], the Secretary [of Health and Human Services] shall issue a guidance to industry about submitting reports to the electronic portal established under section 417 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350f] (as added by this section) and providing notifications to other persons in the supply chain of an article of food under such section 417.''

§ 350g. Hazard analysis and risk-based preventive controls

(a) In general

The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 342 of this title or misbranded under section 343(w) of this title, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

(b) Hazard analysis

The owner, operator, or agent in charge of a facility shall—

(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

(B) hazards that occur naturally, or may be unintentionally introduced; and

(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

(3) develop a written analysis of the hazards.

(c) Preventive controls

The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;

(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 350i of this title, as applicable; and

(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(d) Monitoring of effectiveness

The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

(e) Corrective actions

The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

(2) all affected food is evaluated for safety; and

(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(f) Verification

The owner, operator, or agent in charge of a facility shall verify that—

(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e);

(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

(5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

(g) Recordkeeping

The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the pre-