except the Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health. Test results required to be submitted may be submitted to the Food and Drug Administration through electronic means.

(3) Exception

The Secretary may waive requirements under this subsection if—

(A) a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies; and

(B) the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(c) Review by Secretary

If food sampling and testing performed by a laboratory run and operated by a State or locality that is accredited by a recognized accreditation body on the registry established by the Secretary under subsection (a) result in a State recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall or other compliance and enforcement activities.

(d) No limit on Secretarial authority

Nothing in this section shall be construed to limit the ability of the Secretary to review and act upon information from food testing, including determining the sufficiency of such information and testing.

(June 25, 1938, ch. 675, §422, as added Pub. L. 111–353, title II, §202(a), Jan. 4, 2011, 124 Stat. 3926.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section 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.

§350*l*. Mandatory recall authority

(a) Voluntary procedures

If the Secretary determines, based on information gathered through the reportable food registry under section 350f of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 342 of this title or misbranded under section 343(w) of this title and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 350f of this title) with an opportunity to cease distribution and recall such article.

(b) Prehearing order to cease distribution and give notice

(1) In general

If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to—

(A) immediately cease distribution of such article; and

(B) as applicable, immediately notify all persons—

(i) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and

(ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article.[1]

(2) Required additional information

(A) In general

If an article of food covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the responsible party subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the warehouse-based third party logistics provider to identify the food.

(B) Rules of construction

Nothing in this paragraph shall be construed—

(i) to exempt a warehouse-based third party logistics provider from the requirements of this chapter, including the requirements in this section and section 350c of this title; or

(ii) to exempt a warehouse-based third party logistics provider from being the subject of a mandatory recall order.

(3) Determination to limit areas affected

If the Secretary requires a responsible party to cease distribution under paragraph (1)(A) of an article of food identified in subsection (a), the Secretary may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health.

(c) Hearing on order

The Secretary shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.

[1] So in original. The words ''to immediately cease distribution of such article.'' probably should follow cl. (ii).

(d) Post-hearing recall order and modification of order

(1) Amendment of order

If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that removal of the article from commerce is necessary, the Secretary shall, as appropriate—

(A) amend the order to require recall of such article or other appropriate action;

(B) specify a timetable in which the recall shall occur;

(C) require periodic reports to the Secretary describing the progress of the recall; and

(D) provide notice to consumers to whom such article was, or may have been, distributed.

(2) Vacating of order

If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order.

(e) Rule regarding alcoholic beverages

The Secretary shall not initiate a mandatory recall or take any other action under this section with respect to any alcohol beverage until the Secretary has provided the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall such article under the Alcohol and Tobacco Tax and Trade Bureau authority.

(f) Cooperation and consultation

The Secretary shall work with State and local public health officials in carrying out this section, as appropriate.

(g) Public notification

In conducting a recall under this section, the Secretary shall—

(1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification—

(A) of the recall to consumers and retailers to whom such article was, or may have been, distributed; and

(B) that includes, at a minimum—

(i) the name of the article of food subject to the recall;

(ii) a description of the risk associated with such article; and

(iii) to the extent practicable, information for consumers about similar articles of food that are not affected by the recall;

(2) consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public, as determined appropriate by the Secretary; and

(3) if available, publish on the Internet Web site of the Food and Drug Administration an image of the article that is the subject of the press release described in (1).[2]

[2] So in original. Probably should be ''paragraph (1).''

(h) No delegation

The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

(i) Effect

Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter or under the Public Health Service Act [42 U.S.C. 201 et seq.].

(j) Coordinated communication

(1) In general

To assist in carrying out the requirements of this subsection, the Secretary shall establish an incident command operation or a similar operation within the Department of Health and Human Services that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.

(2) Requirements

To reduce the potential for miscommunication during recalls or regarding investigations of a food borne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Department of Health and Human Services to—

(A) ensure timely and coordinated communication within the Department, including enhanced communication and coordination between different agencies and organizations within the Department;

(B) ensure timely and coordinated communication from the Department, including public statements, throughout the duration of the investigation and related foodborne illness outbreak;

(C) identify a single point of contact within the Department for public inquiries regarding any actions by the Secretary related to a recall;

(D) coordinate with Federal, State, local, and tribal authorities, as appropriate, that have responsibilities related to the recall of a food or a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event such recalled food is a commodity intended for use in a child nutrition program (as identified in section 1769f(b) of title 42); and

(E) conclude operations at such time as the Secretary determines appropriate.

(3) Multiple recalls

The Secretary may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks necessitating such action by the Department of Health and Human Services.

(June 25, 1938, ch. 675, § 423, as added Pub. L. 111–353, title II, § 206(a), Jan. 4, 2011, 124 Stat. 3939.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (i), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section to be construed 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 2251 and 2252 of this title.

SEARCH ENGINE

Pub. L. 111–353, title II, § 206(b), Jan. 4, 2011, 124 Stat. 3942, provided that: ''Not later than 90 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall modify the Internet Web site of the Food and Drug Administration to include a search engine that—

''(1) is consumer-friendly, as determined by the Secretary; and

''(2) provides a means by which an individual may locate relevant information regarding each article of food subject to a recall under section 423 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350*l*] and the status of such recall (such as whether a recall is ongoing or has been completed).''

§ 350*l*–1. Annual report to Congress

(1) In general

Not later than 2 years after January 4, 2011, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 350*l* of this title (as added by subsection (a))[1] and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

(2) Content

The report under paragraph (1) shall include, with respect to the report year—

(A) the identity of each article of food that was the subject of a public health advisory described in paragraph (1), an opportunity to cease distribution and recall under subsection (a) of section 350*l* of this title, or a mandatory recall order under subsection (b) of such section;

(B) the number of responsible parties, as defined in section 350f of this title, formally given the opportunity to cease distribution of an article of food and recall such article, as described in section 350*l*(a) of such title;

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under section 350*l*(a) of this title;

(D) the number of recall orders issued under section 350*l*(b) of this title; and

(E) a description of any instances in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under section 350*l*(b) of this title or a public health advisory described in paragraph (1).

(Pub. L. 111–353, title II, § 206(f), Jan. 4, 2011, 124 Stat. 3943.)

Editorial Notes

REFERENCES IN TEXT

Subsection (a), referred to in par. (1), means subsec. (a) of section 206 of Pub. L. 111–353.

CODIFICATION

Section was enacted as part of the FDA Food Safety Modernization Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section to be construed 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 2251 and 2252 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chap-

[1] See References in Text note below.