

that receives and distributes non-alcohol food, provided such food is received and distributed—

- (1) in a prepackaged form that prevents any direct human contact with such food; and
- (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.

(c) Rule of construction

Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214¹ of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act).

(Pub. L. 111-353, title I, §116, Jan. 4, 2011, 124 Stat. 3922.)

REFERENCES IN TEXT

This Act, referred to in subsecs. (a) and (c), is Pub. L. 111-353, Jan. 4, 2011, 124 Stat. 3885, known as the FDA Food Safety Modernization Act, which enacted this chapter and sections 350g to 350l-1, 379j-31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 280g-16 of Title 42, The Public Health and Welfare, amended sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b-20 of Title 42, and enacted provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title. Sections 102, 206, 207, 302, 304, 402, 403, and 404 of the Act enacted sections 350l, 350l-1, 384b, 399d, 2251, and 2252 of this title, amended sections 331, 333, 334, 350d, and 381 of this title, and enacted provisions set out as notes under sections 334, 350d, 350l, and 381 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2201 of this title and Tables.

The Federal Alcohol Administration Act, referred to in subsecs. (a)(1) and (c), is act Aug. 29, 1935, ch. 814, 49 Stat. 977, which is classified generally to subchapter I (§201 et seq.) of chapter 8 of Title 27, Intoxicating Liquors. Section 214 of the Act probably means section 203 of the Act, which is classified to section 214 of Title 27 and defines “alcoholic beverage”. For complete classification of this Act to the Code, see section 201 of Title 27 and Tables.

The Internal Revenue Code of 1986, referred to in subsec. (a)(1), is classified generally to Title 26, Internal Revenue Code.

SUBCHAPTER II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

§ 2221. Food emergency response network

The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal governments shall, not later than 180 days after January 4, 2011, and biennially thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services, a report on the progress in implementing a national food emergency response laboratory network that—

- (1) provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply;

- (2) coordinates the food laboratory capacities of State, local, and tribal food laboratories, including the adoption of novel surveillance and identification technologies and the sharing of data between Federal agencies and State laboratories to develop national situational awareness;

- (3) provides accessible, timely, accurate, and consistent food laboratory services throughout the United States;

- (4) develops and implements a methods repository for use by Federal, State, and local officials;

- (5) responds to food-related emergencies; and

- (6) is integrated with relevant laboratory networks administered by other Federal agencies.

(Pub. L. 111-353, title II, §202(b), Jan. 4, 2011, 124 Stat. 3929.)

REFERENCES IN TEXT

The Secretary, referred to in text, probably means the Secretary of Health and Human Services.

§ 2222. Integrated consortium of laboratory networks

(a) In general

The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency, shall maintain an agreement through which relevant laboratory network members, as determined by the Secretary of Homeland Security, shall—

- (1) agree on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks and facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

- (2) identify means by which laboratory network members could work cooperatively—

- (A) to optimize national laboratory preparedness; and

- (B) to provide surge capacity during emergencies; and

- (3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.

(b) Reporting requirement

The Secretary of Homeland Security shall, on a biennial basis, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the progress of the integrated consortium of laboratory networks, as established under subsection (a), in carrying out this section.

(Pub. L. 111-353, title II, §203, Jan. 4, 2011, 124 Stat. 3929.)

§ 2223. Enhancing tracking and tracing of food and recordkeeping

(a) Pilot projects

(1) In general

Not later than 270 days after January 4, 2011, the Secretary of Health and Human Services

¹ See References in Text note below.

(referred to in this section as the “Secretary”), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(2) Content

The Secretary shall conduct 1 or more pilot projects under paragraph (1) in coordination with the processed food sector and 1 or more such pilot projects in coordination with processors or distributors of fruits and vegetables that are raw agricultural commodities. The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the food supply and include at least 3 different types of foods that have been the subject of significant outbreaks during the 5-year period preceding January 4, 2011, and are selected in order to—

(A) develop and demonstrate methods for rapid and effective tracking and tracing of foods in a manner that is practicable for facilities of varying sizes, including small businesses;

(B) develop and demonstrate appropriate technologies, including technologies existing on January 4, 2011, that enhance the tracking and tracing of food; and

(C) inform the promulgation of regulations under subsection (d).

(3) Report

Not later than 18 months after January 4, 2011, the Secretary shall report to Congress on the findings of the pilot projects under this subsection together with recommendations for improving the tracking and tracing of food.

(b) Additional data gathering

(1) In general

The Secretary, in coordination with the Secretary of Agriculture and multiple representatives of State departments of health and agriculture, shall assess—

(A) the costs and benefits associated with the adoption and use of several product tracing technologies, including technologies used in the pilot projects under subsection (a);

(B) the feasibility of such technologies for different sectors of the food industry, including small businesses; and

(C) whether such technologies are compatible with the requirements of this subsection.

(2) Requirements

To the extent practicable, in carrying out paragraph (1), the Secretary shall—

(A) evaluate domestic and international product tracing practices in commercial use;

(B) consider international efforts, including an assessment of whether product trac-

ing requirements developed under this section are compatible with global tracing systems, as appropriate; and

(C) consult with a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers, and nongovernmental organizations that represent the interests of consumers.

(c) Product tracing system

The Secretary, in consultation with the Secretary of Agriculture, shall, as appropriate, establish within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States. Prior to the establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.

(d) Additional recordkeeping requirements for high risk foods

(1) In general

In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 342 of this title or misbranded under section 343(w) of this title, not later than 2 years after January 4, 2011, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 350c of this title and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations), for facilities that manufacture, process, pack, or hold foods that the Secretary designates under paragraph (2) as high-risk foods. The Secretary shall set an appropriate effective date of such additional requirements for foods designated as high risk that takes into account the length of time necessary to comply with such requirements. Such requirements shall—

(A) relate only to information that is reasonably available and appropriate;

(B) be science-based;

(C) not prescribe specific technologies for the maintenance of records;

(D) ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements;

(E) be scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens, and not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business;

(F) minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food;

(G) to the extent practicable, not require a facility to change business systems to comply with such requirements;

(H) allow any person subject to this subsection to maintain records required under this subsection at a central or reasonably accessible location provided that such records can be made available to the Secretary not later than 24 hours after the Secretary requests such records; and¹

(I) include a process by which the Secretary may issue a waiver of the requirements under this subsection if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility;

(J) be commensurate with the known safety risks of the designated food;

(K) take into account international trade obligations;

(L) not require—

(i) a full pedigree, or a record of the complete previous distribution history of the food from the point of origin of such food;

(ii) records of recipients of a food beyond the immediate subsequent recipient of such food; or

(iii) product tracking to the case level by persons subject to such requirements; and

(M) include a process by which the Secretary may remove a high-risk food designation developed under paragraph (2) for a food or type of food.

(2) Designation of high-risk foods

(A) In general

Not later than 1 year after January 4, 2011, and thereafter as the Secretary determines necessary, the Secretary shall designate high-risk foods for which the additional recordkeeping requirements described in paragraph (1) are appropriate and necessary to protect the public health. Each such designation shall be based on—

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

(B) List of high-risk foods

At the time the Secretary promulgates the final rules under paragraph (1), the Secretary shall publish the list of the foods designated under subparagraph (A) as high-risk foods on the Internet website of the Food and Drug Administration. The Secretary may update the list to designate new high-risk foods and to remove foods that are no longer deemed to be high-risk foods, provided that each such update to the list is consistent with the requirements of this subsection and notice of such update is published in the Federal Register.

(3) Protection of sensitive information

In promulgating regulations under this subsection, the Secretary shall take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section, including periodic risk assessment and planning to prevent unauthorized release and controls to—

(A) prevent unauthorized reproduction of trade secret or confidential information;

(B) prevent unauthorized access to trade secret or confidential information; and

(C) maintain records with respect to access by any person to trade secret or confidential information maintained by the agency.

(4) Public input

During the comment period in the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(5) Retention of records

Except as otherwise provided in this subsection, the Secretary may require that a facility retain records under this subsection for not more than 2 years, taking into consideration the risk of spoilage, loss of value, or loss of palatability of the applicable food when determining the appropriate timeframes.

(6) Limitations

(A) Farm to school programs

In establishing requirements under this subsection, the Secretary shall, in consultation with the Secretary of Agriculture, consider the impact of requirements on farm to school or farm to institution programs of the Department of Agriculture and other farm to school and farm to institution programs outside such agency, and shall modify the requirements under this subsection, as appropriate, with respect to such programs so that the requirements do not place undue burdens on farm to school or farm to institution programs.

¹ So in original. The word "and" probably should not appear.

(B) Identity-preserved labels with respect to farm sales of food that is produced and packaged on a farm

The requirements under this subsection shall not apply to a food that is produced and packaged on a farm if—

(i) the packaging of the food maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(ii) the labeling of the food includes the name, complete address (street address, town, State, country, and zip or other postal code), and business phone number of the farm, unless the Secretary waives the requirement to include a business phone number of the farm, as appropriate, in order to accommodate a religious belief of the individual in charge of such farm.

(C) Fishing vessels

The requirements under this subsection with respect to a food that is produced through the use of a fishing vessel (as defined in section 1802(18) of title 16) shall be limited to the requirements under subparagraph (F) until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.

(D) Commingled raw agricultural commodities

(i) Limitation on extent of tracing

Recordkeeping requirements under this subsection with regard to any commingled raw agricultural commodity shall be limited to the requirements under subparagraph (F).

(ii) Definitions

For the purposes of this subparagraph—

(I) the term “commingled raw agricultural commodity” means any commodity that is combined or mixed after harvesting, but before processing;

(II) the term “commingled raw agricultural commodity” shall not include types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that standards promulgated under section 350h of this title (as added by section 105)² would minimize the risk of serious adverse health consequences or death; and

(III) the term “processing” means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

(E) Exemption of other foods

The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect to, or exempt a food or a type of facility from, the requirements of this subsection (other than the requirements under subparagraph (F), if applicable) if the Secretary determines that

product tracing requirements for such food (such as bulk or commingled ingredients that are intended to be processed to destroy pathogens) or type of facility is not necessary to protect the public health.

(F) Recordkeeping regarding previous sources and subsequent recipients

In the case of a person or food to which a limitation or exemption under subparagraph (C), (D), or (E) applies, if such person, or a person who manufactures, processes, packs, or holds such food, is required to register with the Secretary under section 350d of this title with respect to the manufacturing, processing, packing, or holding of the applicable food, the Secretary shall require such person to maintain records that identify the immediate previous source of such food and the immediate subsequent recipient of such food.

(G) Grocery stores

With respect to a sale of a food described in subparagraph (H) to a grocery store, the Secretary shall not require such grocery store to maintain records under this subsection other than records documenting the farm that was the source of such food. The Secretary shall not require that such records be kept for more than 180 days.

(H) Farm sales to consumers

The Secretary shall not require a farm to maintain any distribution records under this subsection with respect to a sale of a food described in subparagraph (I) (including a sale of a food that is produced and packaged on such farm), if such sale is made by the farm directly to a consumer.

(I) Sale of a food

A sale of a food described in this subparagraph is a sale of a food in which—

(i) the food is produced on a farm; and

(ii) the sale is made by the owner, operator, or agent in charge of such farm directly to a consumer or grocery store.

(7) No impact on non-high-risk foods

The recordkeeping requirements established under paragraph (1) shall have no effect on foods that are not designated by the Secretary under paragraph (2) as high-risk foods. Foods described in the preceding sentence shall be subject solely to the recordkeeping requirements under section 350c of this title and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations).

(e) Evaluation and recommendations

(1) Report

Not later than 1 year after the effective date of the final rule promulgated under subsection (d)(1), the Comptroller General of the United States shall submit to Congress a report, taking into consideration the costs of compliance and other regulatory burdens on small businesses and Federal, State, and local food safety practices and requirements, that evaluates the public health benefits and risks, if any, of limiting—

(A) the product tracing requirements under subsection (d) to foods identified

² See References in Text note below.

under paragraph (2) of such subsection, including whether such requirements provide adequate assurance of traceability in the event of intentional adulteration, including by acts of terrorism; and

(B) the participation of restaurants in the recordkeeping requirements.

(2) Determination and recommendations

In conducting the evaluation and report under paragraph (1), if the Comptroller General of the United States determines that the limitations described in such paragraph do not adequately protect the public health, the Comptroller General shall submit to Congress recommendations, if appropriate, regarding recordkeeping requirements for restaurants and additional foods, in order to protect the public health.

(f) Farms

(1) Request for information

Notwithstanding subsection (d), during an active investigation of a foodborne illness outbreak, or if the Secretary determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak, the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, may request that the owner, operator, or agent of a farm identify potential immediate recipients, other than consumers, of an article of the food that is the subject of such investigation if the Secretary reasonably believes such article of food—

(A) is adulterated under section 342 of this title;

(B) presents a threat of serious adverse health consequences or death to humans or animals; and

(C) was adulterated as described in subparagraph (A) on a particular farm (as defined in section 1.227 of chapter³ 21, Code of Federal Regulations (or any successor regulation)).

(2) Manner of request

In making a request under paragraph (1), the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, shall issue a written notice to the owner, operator, or agent of the farm to which the article of food has been traced. The individual providing such notice shall present to such owner, operator, or agent appropriate credentials and shall deliver such notice at reasonable times and within reasonable limits and in a reasonable manner.

(3) Delivery of information requested

The owner, operator, or agent of a farm shall deliver the information requested under paragraph (1) in a prompt and reasonable manner. Such information may consist of records kept in the normal course of business, and may be in electronic or non-electronic format.

(4) Limitation

A request made under paragraph (1) shall not include a request for information relating to

the finances, pricing of commodities produced, personnel, research, sales (other than information relating to shipping), or other disclosures that may reveal trade secrets or confidential information from the farm to which the article of food has been traced, other than information necessary to identify potential immediate recipients of such food. Section 331(j) of this title and the Freedom of Information Act [5 U.S.C. 552] shall apply with respect to any confidential commercial information that is disclosed to the Food and Drug Administration in the course of responding to a request under paragraph (1).

(5) Records

Except with respect to identifying potential immediate recipients in response to a request under this subsection, nothing in this subsection shall require the establishment or maintenance by farms of new records.

(g) No Limitation on commingling of food

Nothing in this section shall be construed to authorize the Secretary to impose any limitation on the commingling of food.

(h) Small entity compliance guide

Not later than 180 days after promulgation of a final rule under subsection (d), the Secretary shall issue a small entity compliance guide setting forth in plain language the requirements of the regulations under such subsection in order to assist small entities, including farms and small businesses, in complying with the recordkeeping requirements under such subsection.

(i) Flexibility for small businesses

Notwithstanding any other provision of law, the regulations promulgated under subsection (d) shall apply—

(1) to small businesses (as defined by the Secretary in section 350g of this title, not later than 90 days after January 4, 2011) beginning on the date that is 1 year after the effective date of the final regulations promulgated under subsection (d); and

(2) to very small businesses (as defined by the Secretary in section 350g of this title, not later than 90 days after January 4, 2011) beginning on the date that is 2 years after the effective date of the final regulations promulgated under subsection (d).

(Pub. L. 111–353, title II, §204, Jan. 4, 2011, 124 Stat. 3930.)

REFERENCES IN TEXT

Section 105, referred to in subsec. (d)(6)(D)(ii)(II), means section 105 of Pub. L. 111–353.

Section 350g of this title, referred to in subsec. (i), was in the original “section 103”, meaning section 103 of Pub. L. 111–353, which enacted section 350g of this title, amended section 331 of this title, and enacted provisions set out as notes under sections 342, 350d, and 350g of this title, and was translated as section 350g of this title to reflect the probable intent of Congress because section 350g(n) of this title directs the Secretary of Health and Human Services to define “small business” and “very small business”.

CODIFICATION

Section is comprised of section 204 of Pub. L. 111–353. Subsec. (j) of section 204 of Pub. L. 111–353 amended sections 331 and 381 of this title.

³ So in original. Probably should be “title”.

§ 2224. Surveillance**(a) Definition of foodborne illness outbreak**

In this Act, the term “foodborne illness outbreak” means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food.

(b) Foodborne illness surveillance systems**(1) In general**

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses by—

(A) coordinating Federal, State and local foodborne illness surveillance systems, including complaint systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories;

(B) facilitating sharing of surveillance information on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, the Department of Homeland Security, and State and local agencies, and with the public;

(C) developing improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases;

(D) augmenting such systems to improve attribution of a foodborne illness outbreak to a specific food;

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of identification practices, including fingerprinting strategies, for foodborne infectious agents, in order to identify new or rarely documented causes of foodborne illness and submit standardized information to a centralized database;

(F) allowing timely public access to aggregated, de-identified surveillance data;

(G) at least annually, publishing current reports on findings from such systems;

(H) establishing a flexible mechanism for rapidly initiating scientific research by academic institutions;

(I) integrating foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center; and

(J) other activities as determined appropriate by the Secretary.

(2) Working group

The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food and food testing industries, consumer organizations, and academia. Such working group shall provide the Secretary, through at least annual

meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the improvement of foodborne illness surveillance and implementation of this section, including advice and recommendations on—

(A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;

(B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;

(C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the working group’s recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

(3) Authorization of appropriations

To carry out the activities described in paragraph (1), there is authorized to be appropriated \$24,000,000 for each¹ fiscal years 2011 through 2015.

(c) Improving food safety and defense capacity at the State and local level**(1) In general**

The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals:

(A) Improve foodborne illness outbreak response and containment.

(B) Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories, and conducting more standardized illness outbreak interviews.

(C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.

(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness.

(E) Share information on a timely basis among public health and food regulatory

¹ So in original. Probably should be followed by “of”.