

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 record-keeping 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.

§ 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 bio-surveillance 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.

¹ So in original. Probably should be followed by "of".

(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 agencies, with the food industry, with health care providers, and with the public.

(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 2202 of this title.

(2) Review

In developing of the strategies required by paragraph (1), the Secretary shall, not later than 1 year after January 4, 2011, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to—

(A) staffing levels and expertise available to perform food safety and defense functions;

(B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;

(C) information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level; and

(D) other State and local activities and needs as determined appropriate by the Secretary.

(Pub. L. 111-353, title II, §205, Jan. 4, 2011, 124 Stat. 3937.)

REFERENCES IN TEXT

This Act, referred to in subsec. (a), 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. For complete classification of this Act to the Code, see Short Title note set out under section 2201 of this title and Tables.

The Secretary, referred to in subsecs. (b) and (c)(1), (2)(D), probably means the Secretary of Health and Human Services.

CODIFICATION

Section is comprised of section 205 of Pub. L. 111-353. Subsec. (d) of section 205 of Pub. L. 111-353 amended

section 247b–20 of Title 42, The Public Health and Welfare.

§ 2225. Decontamination and disposal standards and plans

(a) In general

The Administrator of the Environmental Protection Agency (referred to in this section as the “Administrator”), in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Agriculture, shall provide support for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

(b) Development of standards

In carrying out subsection (a), the Administrator, in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of Agriculture, and State, local, and tribal governments, shall develop and disseminate specific standards and protocols to undertake clean-up, clearance, and recovery activities following the decontamination and disposal of specific threat agents and foreign animal diseases.

(c) Development of model plans

In carrying out subsection (a), the Administrator, the Secretary of Health and Human Services, and the Secretary of Agriculture shall jointly develop and disseminate model plans for—

- (1) the decontamination of individuals, equipment, and facilities following an intentional contamination of agriculture or food; and
- (2) the disposal of large quantities of animals, plants, or food products that have been infected or contaminated by specific threat agents and foreign animal diseases.

(d) Exercises

In carrying out subsection (a), the Administrator, in coordination with the entities described under subsection (b), shall conduct exercises at least annually to evaluate and identify weaknesses in the decontamination and disposal model plans described in subsection (c). Such exercises shall be carried out, to the maximum extent practicable, as part of the national exercise program under section 748(b)(1) of title 6.

(e) Modifications

Based on the exercises described in subsection (d), the Administrator, in coordination with the entities described in subsection (b), shall review and modify as necessary the plans described in subsection (c) not less frequently than biennially.

(f) Prioritization

The Administrator, in coordination with the entities described in subsection (b), shall develop standards and plans under subsections (b) and (c) in an identified order of priority that takes into account—

- (1) highest-risk biological, chemical, and radiological threat agents;
- (2) agents that could cause the greatest economic devastation to the agriculture and food system; and

(3) agents that are most difficult to clean or remediate.

(Pub. L. 111–353, title II, §208, Jan. 4, 2011, 124 Stat. 3944.)

SUBCHAPTER III—IMPROVING THE SAFETY OF IMPORTED FOOD

§ 2241. Inspection by the Secretary of Commerce

(1) In general

The Secretary of Commerce, in coordination with the Secretary of Health and Human Services, may send 1 or more inspectors to a country or facility of an exporter from which seafood imported into the United States originates. The inspectors shall assess practices and processes used in connection with the farming, cultivation, harvesting, preparation for market, or transportation of such seafood and may provide technical assistance related to such activities.

(2) Inspection report

(A) In general

The Secretary of Health and Human Services, in coordination with the Secretary of Commerce, shall—

- (i) prepare an inspection report for each inspection conducted under paragraph (1);
- (ii) provide the report to the country or exporter that is the subject of the report; and
- (iii) provide a 30-day period during which the country or exporter may provide a rebuttal or other comments on the findings of the report to the Secretary of Health and Human Services.

(B) Distribution and use of report

The Secretary of Health and Human Services shall consider the inspection reports described in subparagraph (A) in distributing inspection resources under section 350j of this title.

(Pub. L. 111–353, title III, §306(b), Jan. 4, 2011, 124 Stat. 3959.)

§ 2242. Foreign offices of the Food and Drug Administration

(a) In general

The Secretary shall establish offices of the Food and Drug Administration in foreign countries selected by the Secretary, to provide assistance to the appropriate governmental entities of such countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by such country to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entity.

(b) Consultation

In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State, the Secretary of Homeland Security, and the United States Trade Representative.

(c) Report

Not later than October 1, 2011, the Secretary shall submit to Congress a report on the basis