

this title, and enacted provisions set out as notes under this section and section 350f of this title. For complete classification of title X to the Code, see Tables.

The Dietary Supplement Health and Education Act of 1994, referred to in par. (1), is Pub. L. 103-417, Oct. 25, 1994, 108 Stat. 4325, which enacted sections 343-2 and 350b of this title and section 287c-11 of Title 42, The Public Health and Welfare, amended sections 321, 331, 342, 343, and 350 of this title and section 281 of Title 42, and enacted provisions set out as notes under sections 321 and 343 of this title. For complete classification of this Act to the Code, see Short Title of 1994 Amendments note set out under section 301 of this title and Tables.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act, referred to in par. (2), is Pub. L. 109-462, Dec. 22, 2006, 120 Stat. 3469, which enacted sections 379aa and 379aa-1 of this title, amended sections 331, 343, 352, and 381 of this title, and enacted provisions set out as notes under sections 331, 343, 352, 379aa, and 381 of this title. For complete classification of this Act to the Code, see Short Title of 2006 Amendment note set out under section 301 of this title and Tables.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Pub. L. 110-85, title X, §1005(g), Sept. 27, 2007, 121 Stat. 969, provided that: “Nothing in this title [enacting this chapter and section 350f of this title, amending sections 321 and 331 of this title, and enacting provisions set out as notes under section 350f of this title], or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.”

CHAPTER 27—FOOD SAFETY MODERNIZATION

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SUBCHAPTER I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

§ 2201. Performance standards

(a) In general

The Secretary shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

(b) Guidance documents and regulations

Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 342 of this title or to prevent the spread by food of communicable disease under section 264 of title 42, the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.

(c) No duplication of efforts

The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) Review

The Secretary shall periodically review and revise, as appropriate, the guidance documents, including guidance documents regarding action levels, or regulations promulgated under this section.

(Pub. L. 111-353, title I, §104, Jan. 4, 2011, 124 Stat. 3899.)

Editorial Notes

REFERENCES IN TEXT

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

Statutory Notes and Related Subsidiaries

SHORT TITLE

Pub. L. 111-353, §1(a), Jan. 4, 2011, 124 Stat. 3885, provided that: “This Act [enacting 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, amending sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b-20 of Title 42, and enacting provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title] may be cited as the ‘FDA Food Safety Modernization Act’.”

§ 2202. National Agriculture and Food Defense Strategy

(a) Development and submission of strategy

(1) In general

Not later than 1 year after January 4, 2011, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall prepare and transmit to the relevant committees of Congress, and make publicly available on the Internet Web sites of the Department of Health and Human Services and the Department of Agriculture, the National Agriculture and Food Defense Strategy.

(2) Implementation plan

The strategy shall include an implementation plan for use by the Secretaries described under paragraph (1) in carrying out the strategy.

(3) Research

The strategy shall include a coordinated research agenda for use by the Secretaries described under paragraph (1) in conducting research to support the goals and activities described in paragraphs (1) and (2) of subsection (b).

(4) Revisions

Not later than 4 years after the date on which the strategy is submitted to the relevant committees of Congress under paragraph (1), and not less frequently than every 4 years thereafter, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall revise and submit to the relevant committees of Congress the strategy.

(5) Consistency with existing plans

The strategy described in paragraph (1) shall be consistent with—

- (A) the National Incident Management System;
- (B) the National Response Framework;
- (C) the National Infrastructure Protection Plan;
- (D) the National Preparedness Goals; and
- (E) other relevant national strategies.

(b) Components

(1) In general

The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security—

- (A) to achieve each goal described in paragraph (2); and
- (B) to evaluate the progress made by Federal, State, local, and tribal governments towards the achievement of each goal described in paragraph (2).

(2) Goals

The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security to achieve the following goals:

(A) Preparedness goal

Enhance the preparedness of the agriculture and food system by—

- (i) conducting vulnerability assessments of the agriculture and food system;
- (ii) mitigating vulnerabilities of the system;
- (iii) improving communication and training relating to the system;
- (iv) developing and conducting exercises to test decontamination and disposal plans;
- (v) developing modeling tools to improve event consequence assessment and decision support; and
- (vi) preparing risk communication tools and enhancing public awareness through outreach.

(B) Detection goal

Improve agriculture and food system detection capabilities by—

- (i) identifying contamination in food products at the earliest possible time; and
- (ii) conducting surveillance to prevent the spread of diseases.

(C) Emergency response goal

Ensure an efficient response to agriculture and food emergencies by—

- (i) immediately investigating animal disease outbreaks and suspected food contamination;
- (ii) preventing additional human illnesses;
- (iii) organizing, training, and equipping animal, plant, and food emergency response teams of—
 - (I) the Federal Government; and
 - (II) State, local, and tribal governments;
- (iv) designing, developing, and evaluating training and exercises carried out under agriculture and food defense plans; and
- (v) ensuring consistent and organized risk communication to the public by—
 - (I) the Federal Government;
 - (II) State, local, and tribal governments; and
 - (III) the private sector.

(D) Recovery goal

Secure agriculture and food production after an agriculture or food emergency by—

- (i) working with the private sector to develop business recovery plans to rapidly resume agriculture, food production, and international trade;
- (ii) conducting exercises of the plans described in subparagraph (C) with the goal of long-term recovery results;
- (iii) rapidly removing, and effectively disposing of—
 - (I) contaminated agriculture and food products; and
 - (II) infected plants and animals; and
- (iv) decontaminating and restoring areas affected by an agriculture or food emergency.

(3) Evaluation

The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall—

(A) develop metrics to measure progress for the evaluation process described in paragraph (1)(B); and

(B) report on the progress measured in subparagraph (A) as part of the National Agriculture and Food Defense strategy described in subsection (a)(1).

(c) Limited distribution

In the interest of national security, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, may determine the manner and format in which the National Agriculture and Food Defense strategy established under this section is made publicly available on the Internet Web sites of the Department of Health and Human Services, the Department of Homeland Security, and the Department of Agriculture, as described in subsection (a)(1).

(Pub. L. 111-353, title I, §108, Jan. 4, 2011, 124 Stat. 3910.)

Editorial Notes**REFERENCES IN TEXT**

The Secretary, referred to in subsec. (b)(3), probably means the Secretary of Health and Human Services.

§ 2203. Food and Agriculture Coordinating Councils

The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services and the Secretary of Agriculture, shall within 180 days of January 4, 2011, and annually thereafter, 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 activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council, including the progress of such Councils on—

(1) facilitating partnerships between public and private entities to help coordinate and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of—

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

(Pub. L. 111-353, title I, §109, Jan. 4, 2011, 124 Stat. 3912.)

§ 2204. Building domestic capacity**(a) In general****(1) Initial report**

The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall, not later than 2 years after January 4, 2011, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities. Such report shall include a description of the following:

(A) Analysis of the need for further regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 2203 of this title, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

(C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.

(D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.

(E) Surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.

(F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 2202 and 2224 of this title.

(G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.

(H) The impact of requirements under this Act (including amendments made by this Act) on certified organic farms and facilities (as defined in section 350d of this title).¹

(I) Specific efforts taken pursuant to the agreements authorized under section 350j(c) of this title (as added by section 201),² together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

(2) Biennial reports

On a biennial basis following the submission of the report under paragraph (1), the Secretary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

(B) outlines the success of those programs and practices;

¹ So in original. Probably should be “title).”

² See References in Text note below.

(C) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (H) of paragraph (1), as necessary.

(b) Risk-based activities

The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources available to the Secretary for food safety-related activities are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources. The Secretary shall promptly undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

(c) Capability for laboratory analyses; research

The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including commercially-available techniques that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities and progress toward laboratory accreditation under section 350k of this title (as added by section 202).²

(d) Information technology

The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility registration system under section 350d of this title, and the prior notice system under section 381(m) of this title with other information technology systems that are used by the Federal Government for the processing of food offered for import into the United States.

(e) Automated risk assessment

The report developed under subsection (a)(1) shall include a description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

(f) Traceback and surveillance report

The Secretary shall include in the report developed under subsection (a)(1) an analysis of the Food and Drug Administration's performance in foodborne illness outbreaks during the 5-year period preceding January 4, 2011, involving fruits and vegetables that are raw agricultural commodities (as defined in section 321(r) of this title) and recommendations for enhanced surveillance, outbreak response, and traceability. Such findings and recommendations shall address communication and coordination with the public, industry, and State and local governments, as such communication and coordination relates to outbreak identification and traceback.

(g) Biennial food safety and food defense research plan

The Secretary, the Secretary of Agriculture, and the Secretary of Homeland Security shall, on a biennial basis, submit to Congress a joint food safety and food defense research plan which may include studying the long-term health effects of foodborne illness. Such biennial plan shall include a list and description of projects conducted during the previous 2-year period and the plan for projects to be conducted during the subsequent 2-year period.

(h) Effectiveness of programs administered by the Department of Health and Human Services

(1) In general

To determine whether existing Federal programs administered by the Department of Health and Human Services are effective in achieving the stated goals of such programs, the Secretary shall, beginning not later than 1 year after January 4, 2011—

(A) conduct an annual evaluation of each program of such Department to determine the effectiveness of each such program in achieving legislated intent, purposes, and objectives; and

(B) submit to Congress a report concerning such evaluation.

(2) Content

The report described under paragraph (1)(B) shall—

(A) include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions;

(B) include recommendations for consolidation and elimination to reduce duplication and inefficiencies in such programs at such Department as identified during the evaluation conduct³ under this subsection; and

(C) be made publicly available in a publication entitled “Guide to the U.S. Department of Health and Human Services Programs”.

(i) Unique identification numbers

(1) In general

Not later than 1 year after January 4, 2011, the Secretary, acting through the Commissioner of Food and Drugs, shall conduct a study regarding the need for, and challenges associated with, development and implementation of a program that requires a unique identification number for each food facility registered with the Secretary and, as appropriate, each broker that imports food into the United States. Such study shall include an evaluation of the costs associated with development and implementation of such a system, and make recommendations about what new authorities, if any, would be necessary to develop and implement such a system.

(2) Report

Not later than 15 months after January 4, 2011, the Secretary shall submit to Congress a

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

report that describes the findings of the study conducted under paragraph (1) and that includes any recommendations determined appropriate by the Secretary.

(Pub. L. 111-353, title I, §110, Jan. 4, 2011, 124 Stat. 3913.)

Editorial Notes

REFERENCES IN TEXT

The Secretary, referred to in subsecs. (a), (b), (d), (f), (g), (h)(1), and (i), probably means the Secretary of Health and Human Services.

This Act, referred to in subsec. (a)(1)(H), 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.

Section 350d of this title, referred to in subsec. (a)(1)(H), and section 321(r) of this title, referred to in subsec. (f), were in the original “section 415 (21 U.S.C. 350d)” and “section 201(r) (21 U.S.C. 321(r))”, respectively, and were translated as meaning sections 415 and 201(r) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, to reflect the probable intent of Congress.

Section 201, referred to in subsec. (a)(1)(I), and section 202, referred to in subsec. (c), mean sections 201 and 202, respectively, of Pub. L. 111-353.

§ 2205. Food allergy and anaphylaxis management

(a) Definitions

In this section:

(1) Early childhood education program

The term “early childhood education program” means—

(A) a Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 et seq.);

(B) a State licensed or regulated child care program or school; or

(C) a State prekindergarten program that serves children from birth through kindergarten.

(2) ESEA definitions

The terms “local educational agency”, “secondary school”, “elementary school”, and “parent” have the meanings given the terms in section 7801 of title 20.

(3) School

The term “school” includes public—

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

(4) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

(b) Establishment of voluntary food allergy and anaphylaxis management guidelines

(1) Establishment

(A) In general

Not later than 1 year after January 4, 2011, the Secretary, in consultation with the Secretary of Education, shall—

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs; and

(ii) make such guidelines available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.

(B) Applicability of FERPA

Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of section 1232g of title 20 (commonly referred to as the “Family Educational Rights and Privacy Act of 1974”).

(2) Contents

The voluntary guidelines developed by the Secretary under paragraph (1) shall address each of the following and may be updated as the Secretary determines necessary:

(A) Parental obligation to provide the school or early childhood education program, prior to the start of every school year, with—

(i) documentation from their child’s physician or nurse—

(I) supporting a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

(II) identifying any food to which the child is allergic;

(III) describing, if appropriate, any prior history of anaphylaxis;

(IV) listing any medication prescribed for the child for the treatment of anaphylaxis;

(V) detailing emergency treatment procedures in the event of a reaction;

(VI) listing the signs and symptoms of a reaction; and

(VII) assessing the child’s readiness for self-administration of prescription medication; and

(ii) a list of substitute meals that may be offered to the child by school or early childhood education program food service personnel.

(B) The creation and maintenance of an individual plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any procedures for the self-administration of medication by such children in instances where—

(i) the children are capable of self-administering medication; and

(ii) such administration is not prohibited by State law.

(C) Communication strategies between individual schools or early childhood edu-

cation programs and providers of emergency medical services, including appropriate instructions for emergency medical response.

(D) Strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas such as cafeterias.

(E) The dissemination of general information on life-threatening food allergies to school or early childhood education program staff, parents, and children.

(F) Food allergy management training of school or early childhood education program personnel who regularly come into contact with children with life-threatening food allergies.

(G) The authorization and training of school or early childhood education program personnel to administer epinephrine when the nurse is not immediately available.

(H) The timely accessibility of epinephrine by school or early childhood education program personnel when the nurse is not immediately available.

(I) The creation of a plan contained in each individual plan for food allergy management that addresses the appropriate response to an incident of anaphylaxis of a child while such child is engaged in extracurricular programs of a school or early childhood education program, such as non-academic outings and field trips, before- and after-school programs or before- and after-early child education program programs,¹ and school-sponsored or early childhood education program-sponsored programs held on weekends.

(J) Maintenance of information for each administration of epinephrine to a child at risk for anaphylaxis and prompt notification to parents.

(K) Other elements the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early childhood education programs.

(3) Relation to State law

Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding whether students at risk for anaphylaxis may self-administer medication.

(c) School-based food allergy management grants

(1) In general

The Secretary may award grants to local educational agencies to assist such agencies with implementing voluntary food allergy and anaphylaxis management guidelines described in subsection (b).

(2) Application

(A) In general

To be eligible to receive a grant under this subsection, a local educational agency shall submit an application to the Secretary at such time, in such manner, and including

such information as the Secretary may reasonably require.

(B) Contents

Each application submitted under subparagraph (A) shall include—

(i) an assurance that the local educational agency has developed plans in accordance with the food allergy and anaphylaxis management guidelines described in subsection (b);

(ii) a description of the activities to be funded by the grant in carrying out the food allergy and anaphylaxis management guidelines, including—

(I) how the guidelines will be carried out at individual schools served by the local educational agency;

(II) how the local educational agency will inform parents and students of the guidelines in place;

(III) how school nurses, teachers, administrators, and other school-based staff will be made aware of, and given training on, when applicable, the guidelines in place; and

(IV) any other activities that the Secretary determines appropriate;

(iii) an itemization of how grant funds received under this subsection will be expended;

(iv) a description of how adoption of the guidelines and implementation of grant activities will be monitored; and

(v) an agreement by the local educational agency to report information required by the Secretary to conduct evaluations under this subsection.

(3) Use of funds

Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

(A) Purchase of materials and supplies, including limited medical supplies such as epinephrine and disposable wet wipes, to support carrying out the food allergy and anaphylaxis management guidelines described in subsection (b).

(B) In partnership with local health departments, school nurse, teacher, and personnel training for food allergy management.

(C) Programs that educate students as to the presence of, and policies and procedures in place related to, food allergies and anaphylactic shock.

(D) Outreach to parents.

(E) Any other activities consistent with the guidelines described in subsection (b).

(4) Duration of awards

The Secretary may award grants under this subsection for a period of not more than 2 years. In the event the Secretary conducts a program evaluation under this subsection, funding in the second year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(5) Limitation on grant funding

The Secretary may not provide grant funding to a local educational agency under this

¹ So in original.

subsection after such local educational agency has received 2 years of grant funding under this subsection.

(6) Maximum amount of annual awards

A grant awarded under this subsection may not be made in an amount that is more than \$50,000 annually.

(7) Priority

In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 6333(c) of title 20.

(8) Matching funds

(A) In general

The Secretary may not award a grant under this subsection unless the local educational agency agrees that, with respect to the costs to be incurred by such local educational agency in carrying out the grant activities, the local educational agency shall make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

(B) Determination of amount of non-Federal contribution

Non-Federal funds required under subparagraph (A) may be cash or in kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

(9) Administrative funds

A local educational agency that receives a grant under this subsection may use not more than 2 percent of the grant amount for administrative costs related to carrying out this subsection.

(10) Progress and evaluations

At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide the Secretary with information on how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines described in subsection (b).

(11) Supplement, not supplant

Grant funds received under this subsection shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this subsection.

(12) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection \$30,000,000 for fiscal year 2011 and such sums as may be necessary for each of the 4 succeeding fiscal years.

(d) Voluntary nature of guidelines

(1) In general

The food allergy and anaphylaxis management guidelines developed by the Secretary

under subsection (b) are voluntary. Nothing in this section or the guidelines developed by the Secretary under subsection (b) shall be construed to require a local educational agency to implement such guidelines.

(2) Exception

Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis management guidelines as a condition of the receipt of a grant under subsection (c).

(Pub. L. 111-353, title I, §112, Jan. 4, 2011, 124 Stat. 3916; Pub. L. 114-95, title IX, §9215(jj), Dec. 10, 2015, 129 Stat. 2175.)

Editorial Notes

REFERENCES IN TEXT

The Head Start Act, referred to in subsec. (a)(1)(A), is subchapter B (§635 et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97-35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 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 9801 of Title 42 and Tables.

AMENDMENTS

2015—Subsec. (a)(2). Pub. L. 114-95 made technical amendment to reference in original act which appears in text as reference to section 7801 of title 20.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114-95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114-95, set out as a note under section 6301 of Title 20, Education.

§ 2206. Alcohol-related facilities

(a) In general

Except as provided by sections 102, 206, 207, 302, 304, 402, 403, and 404 of this Act, and the amendments made by such sections, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that—

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and

(2) under section 350d of this title is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.

(b) Limited receipt and distribution of non-alcohol food

Subsection (a) shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that such paragraph shall apply to a facility described in such paragraph 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.)

Editorial Notes

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.)

Editorial Notes

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.)

¹ See References in Text note below.

§ 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 (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 tracing 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 main-

tenance 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

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

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.

(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 busi-

² See References in Text note below.

nesses 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 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.

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

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.)

Editorial Notes

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.

(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.

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

(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.)

Editorial Notes

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, decontami-

nating, 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 Serv-

ices, 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 for the selection by the Secretary of the foreign countries in which the Secretary established offices, the progress which such offices have made with respect to assisting the governments of such countries in providing for the safety of articles of food and other products regulated by the Food and Drug Administration exported to the United States, and the plans of the Secretary for establishing additional foreign offices of the Food and Drug Administration, as appropriate.

(Pub. L. 111-353, title III, § 308, Jan. 4, 2011, 124 Stat. 3966.)

Editorial Notes

REFERENCES IN TEXT

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

§ 2243. Smuggled food

(a) In general

Not later than 180 days after January 4, 2011, the Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.

(b) Notification to Homeland Security

Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 350f(n) of this title describing the smuggled food and, if available, the names of the individuals or entities that attempted to import such food into the United States.

(c) Public notification

If the Secretary—

- (1) identifies a smuggled food;
- (2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and
- (3) reasonably believes that the food has entered domestic commerce and is likely to be consumed,

the Secretary shall promptly issue a press release describing that food and shall use other emergency communication or recall networks, as appropriate, to warn consumers and vendors about the potential threat.

(d) Effect of section

Nothing in this section shall affect the authority of the Secretary to issue public notifications under other circumstances.

(e) Definition

In this subsection, the term “smuggled food” means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.

(Pub. L. 111-353, title III, § 309, Jan. 4, 2011, 124 Stat. 3966.)

Editorial Notes

REFERENCES IN TEXT

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

SUBCHAPTER IV—MISCELLANEOUS PROVISIONS

§ 2251. Jurisdiction; authorities

Nothing in this Act, or an amendment made by this Act, shall be construed to—

- (1) alter the jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services, under applicable statutes, regulations, or agreements regarding

voluntary inspection of non-amenable species under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.);

(2) alter the jurisdiction between the Alcohol and Tobacco Tax and Trade Bureau and the Secretary of Health and Human Services, under applicable statutes and regulations;

(3) limit the authority of the Secretary of Health and Human Services under—

(A) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before January 4, 2011; or

(B) the Public Health Service Act [42 U.S.C. 201 et seq.] as in effect on the day before January 4, 2011;

(4) alter or limit the authority of the Secretary of Agriculture under the laws administered by such Secretary, including—

(A) the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(B) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);

(C) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(D) the United States Grain Standards Act (7 U.S.C. 71 et seq.);

(E) the Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.);

(F) the United States Warehouse Act (7 U.S.C. 241 et seq.);

(G) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.); and

(H) the Agricultural Adjustment Act (7 U.S.C. 601 et seq.), reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937; or

(5) alter, impede, or affect the authority of the Secretary of Homeland Security under the Homeland Security Act of 2002 (6 U.S.C. 101 et seq.) or any other statute, including any authority related to securing the borders of the United States, managing ports of entry, or agricultural import and entry inspection activities.

(Pub. L. 111-353, title IV, § 403, Jan. 4, 2011, 124 Stat. 3972.)

Editorial Notes

REFERENCES IN TEXT

This Act, referred to in text, 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 Agricultural Marketing Act of 1946, referred to in pars. (1) and (4)(G), is title II of act Aug. 14, 1946, ch. 966, 60 Stat. 1087, which is classified generally to chapter 38 (§1621 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 1621 of Title 7 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in par. (3)(A), is act June 25, 1938, ch. 675, 52 Stat.

1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Public Health Service Act, referred to in par. (3)(B), 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.

The Federal Meat Inspection Act, referred to in par. (4)(A), is titles I to V of act Mar. 4, 1907, ch. 2907, as added Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, and Pub. L. 110-246, title XI, §11015(a), June 18, 2008, 122 Stat. 2124, which are classified generally to subchapters I to IV-A (§601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

The Poultry Products Inspection Act, referred to in par. (4)(B), is Pub. L. 85-172, Aug. 28, 1957, 71 Stat. 441, which is classified generally to chapter 10 (§451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Egg Products Inspection Act, referred to in par. (4)(C), is Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which is classified principally to chapter 15 (§1031 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables.

The United States Grain Standards Act, referred to in par. (4)(D), is part B of act Aug. 11, 1916, ch. 313, 39 Stat. 482, which is classified generally to chapter 3 (§71 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see section 71 of Title 7 and Tables.

The Packers and Stockyards Act, 1921, referred to in par. (4)(E), is act Aug. 15, 1921, ch. 64, 42 Stat. 159, which is classified generally to chapter 9 (§181 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see section 181 of Title 7 and Tables.

The United States Warehouse Act, referred to in par. (4)(F), is part C of act Aug. 11, 1916, ch. 313, 39 Stat. 486, which is classified generally to chapter 10 (§241 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 241 of Title 7 and Tables.

The Agricultural Adjustment Act (7 U.S.C. 601 et seq.), reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937, referred to in par. (4)(H), is title I of act May 12, 1933, ch. 25, 48 Stat. 31, which is classified generally to chapter 26 (§601 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 601 of Title 7 and Tables.

The Homeland Security Act of 2002, referred to in par. (5), is Pub. L. 107-296, Nov. 25, 2002, 116 Stat. 2135, which is classified principally to chapter 1 (§101 et seq.) of Title 6, Domestic Security. For complete classification of this Act to the Code, see Short Title note set out under section 101 of Title 6 and Tables.

§ 2252. Compliance with international agreements

Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

(Pub. L. 111-353, title IV, § 404, Jan. 4, 2011, 124 Stat. 3972.)

Editorial Notes

REFERENCES IN TEXT

This Act, referred to in text, 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 350j-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.

CHAPTER 28—SANCTIONS WITH RESPECT TO FOREIGN TRAFFICKERS OF ILLICIT SYNTHETIC OPIOIDS

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TERMINATION OF CHAPTER

For termination of chapter 7 years after Dec. 20, 2019, see section 2334 of this title.

§ 2301. Sense of Congress

It is the sense of Congress that—

(1) the United States should apply economic and other financial sanctions to foreign traffickers of illicit opioids to protect the national security, foreign policy, and economy of the United States and the health of the people of the United States;

(2) it is imperative that the People's Republic of China follow through on full implementation of the new regulations, adopted May 1, 2019, to treat all fentanyl analogues as controlled substances under the laws of the People's Republic of China, including by devoting sufficient resources for implementation and strict enforcement of the new regulations; and

(3) the effective enforcement of the new regulations should result in diminished trafficking of illicit fentanyl originating from the People's Republic of China into the United States.

(Pub. L. 116-92, div. F, title LXXII, § 7202, Dec. 20, 2019, 133 Stat. 2262.)

Statutory Notes and Related Subsidiaries

SHORT TITLE

Pub. L. 116-92, div. F, title LXXII, § 7201, Dec. 20, 2019, 133 Stat. 2262, provided that: "This title [enacting this

chapter and amending section 2291h of Title 22, Foreign Relations and Intercourse] may be cited as the 'Fentanyl Sanctions Act'."

§ 2302. Definitions

In this chapter:

(1) Alien; national; national of the United States

The terms "alien", "national", and "national of the United States" have the meanings given those terms in section 1101 of title 8.

(2) Appropriate congressional committees and leadership

The term "appropriate congressional committees and leadership" means—

(A) the Committee on Appropriations, the Committee on Armed Services, the Committee on Banking, Housing, and Urban Affairs, the Committee on Foreign Relations, the Committee on Homeland Security and Governmental Affairs, the Committee on the Judiciary, the Select Committee on Intelligence, and the majority leader and the minority leader of the Senate; and

(B) the Committee on Appropriations, the Committee on Armed Services, the Committee on Financial Services, the Committee on Foreign Affairs, the Committee on Homeland Security, the Committee on the Judiciary, the Committee on Oversight and Reform, the Permanent Select Committee on Intelligence, and the Speaker and the minority leader of the House of Representatives.

(3) Controlled substance; listed chemical

The terms "controlled substance", "listed chemical", "narcotic drug", and "opioid" have the meanings given those terms in section 802 of this title.

(4) Entity

The term "entity" means a partnership, joint venture, association, corporation, organization, network, group, or subgroup, or any form of business collaboration.

(5) Foreign opioid trafficker

The term "foreign opioid trafficker" means any foreign person that the President determines plays a significant role in opioid trafficking.

(6) Foreign person

The term "foreign person"—

(A) means—

(i) any citizen or national of a foreign country; or

(ii) any entity not organized under the laws of the United States or a jurisdiction within the United States; and

(B) does not include the government of a foreign country.

(7) Knowingly

The term "knowingly", with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result.