(2) for each of fiscal years 2008 and 2009, such sums as are necessary for the operation of the NMIC and Council.


CHAPTER 26—FOOD SAFETY

§ 2101. Findings

Congress finds that—

(1) the safety and integrity of the United States food supply are vital to public health, to public confidence in the food supply, and to the success of the food sector of the Nation’s economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) according to the Economic Research Service of the Department of Agriculture, the United States is increasing the amount of food that it imports such that—

(A) from 2003 to 2007, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average American diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat, and 78.6 percent of fish and shellfish; and

(5) the number of full-time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.


§ 2102. Ensuring the safety of pet food

(a) Processing and ingredient standards

Not later than 2 years after September 27, 2007, the Secretary of Health and Human Services (referred to in this chapter as the “Secretary”), in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) ingredient standards and definitions with respect to pet food;

(2) processing standards for pet food; and

(3) updated standards for the labeling of pet food that include nutritional and ingredient information.

(b) Early warning surveillance systems and notification during pet food recalls

Not later than 1 year after September 27, 2007, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) consider using surveillance and monitoring mechanisms similar to, or in coordination with, those used to monitor human or animal health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet of the Centers for Disease Control and Prevention, the Food Emergency Response Network of the Food and Drug Administration and the Department of Agriculture, and the National Animal Health Laboratory Network of the Department of Agriculture;

(2) consult with relevant professional associations and private sector veterinary hospitals;

(3) work with the National Companion Animal Surveillance Program, the Health Alert Network, or other notification networks as appropriate to inform veterinarians and relevant stakeholders during any recall of pet food; and

(4) use such information and conduct such other activities as the Secretary deems appropriate.


REFERENCES IN TEXT

This chapter, referred to in subsec. (a), was in the original “this title”, meaning title X of Pub. L. 110–85, Sept. 27, 2007, 121 Stat. 962, which enacted this chapter and section 350f of this title, amended sections 321 and 331 of this title, and enacted provisions set out as notes under sections 350f and 2110 of this title. For complete classification of title X to the Code, see Tables.

§ 2103. Ensuring efficient and effective communications during a recall

The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled human and pet foods on the Internet Web site
§ 2104. State and Federal cooperation

(a) In general

The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.

(b) Assistance

The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) Service agreements

The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

(d) Partnerships with States

Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood.

§ 2105. Enhanced aquaculture and seafood inspection

(a) Findings

Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary to perform inspection functions must be enhanced.

(b) Heightened inspections

The Secretary is authorized to enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) Report to Congress

Not later than 180 days after September 27, 2007, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) Partnerships with States

Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood.

§ 2106. Consultation regarding genetically engineered seafood products

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

§ 2107. Sense of Congress

It is the sense of Congress that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration’s ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) Congress should work to develop a comprehensive response to the issue of food safety.

§ 2108. Annual report to Congress

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee
§2109. Publication of annual reports

(a) In general

The Commissioner of Food and Drugs shall annually submit to Congress and publish on the Internet Web site of the Food and Drug Administration, a report concerning the results of the Administration’s pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled “Food and Drug Administration Pesticide Program Residue Monitoring 2003” as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled “Food and Drug Administration Pesticide Program Residue Monitoring 2003”;

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) Initial reports

Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) Memorandum of understanding

The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in par. (3), is act June 29, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.), and enforcement actions used to follow-up on such findings and violations.


§2110. Rule of construction

Nothing in this chapter (or an amendment made by this chapter) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417); or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462).


References in Text

This chapter, referred to in text, was in the original “...this title”, meaning title X of Pub. L. 110–85, Sept. 27, 2007, 121 Stat. 962, which enacted this chapter and section 350f of this title, amended sections 321 and 331 of 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.


CHAPTER 27—FOOD SAFETY MODERNIZATION

SUBCHAPTER I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

(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—

(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.


REFERENCES IN TEXT

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

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

(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

REFERENCES IN TEXT

Pub. L. 111–353, §1(a), Jan. 4, 2011, 124 Stat. 3885, provided that: ‘‘This Act [enacting this chapter and sections 350g to 350–1, 379j–31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 230c–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, 350f, 350g to 350j, 350l, 350m, and 350n of this title] may be cited as the ‘‘FDA Food Safety Modernization Act.’’’

SUBCHAPTER III—IMPROVING THE SAFETY OF IMPORTED FOOD

(a) In general

The Secretary shall, in coordination with the Secretary of Commerce, identify exports of food that are not subject to United States food safety laws and regulations.

(b) Integrated group plans

The Secretary shall, in coordination with the Secretary of Commerce, coordinate the implementation of the strategies described in paragraph (1) of subsection (a).

(c) Responsibilities

Not later than 1 year after January 4, 2011, the Secretary of Commerce and the Secretary shall jointly prepare and transmit to the relevant committees of Congress, and make publicly available on the Internet Web sites of the Department of Agriculture, the National Agriculture and Food Defense Strategy.

SUBCHAPTER IV—MISCELLANEOUS PROVISIONS

(a) Jurisdiction, authorities

The Secretary shall coordinate with the Secretary of Defense and the Secretary of Homeland Security, the Secretary of Agriculture, and the Secretary of Health and Human Services, to develop uniform policies and standards for the protection of food and the use of federal resources for food defense purposes.

(b) Food and Agriculture Coordinating Councils

The Secretary shall, in coordination with the Secretary of Commerce and the Secretary of Health and Human Services, to establish and maintain a Food and Agriculture Coordinating Council to enhance the coordination among Federal and non-Federal entities involved in the development and implementation of food defense policies and standards.

(c) Building domestic capacity

The Secretary shall, in coordination with the Department of Agriculture, the National Agriculture and Food Defense Strategy, the Food and Drug Administration, and the Secretary of Health and Human Services, to develop and implement a domestic capacity building plan, including training and technical assistance programs, to address the needs of small food businesses, and support the implementation of the Food and Agriculture Coordinating Councils.

(d) Compliance with international agreements

The Secretary shall, in coordination with the Secretary of Commerce and the Secretary of Health and Human Services, to develop and implement a plan to ensure that Federal laws, regulations, and policies do not impose unnecessary barriers to trade and are consistent with the obligations of the United States under international agreements.

(e) Jurisdiction; authorities

The Secretary shall, in coordination with the Secretary of Health and Human Services, to establish and maintain a Food and Agriculture Coordinating Council to enhance the coordination among Federal and non-Federal entities involved in the development and implementation of food defense policies and standards.

(f) Smuggled food

The Secretary shall, in coordination with the Secretary of Commerce and the Secretary of Health and Human Services, to develop and implement a plan to address the problem of smuggled food.

(g) Food allergy and anaphylaxis management

The Secretary shall, in coordination with the Secretary of Health and Human Services, to develop and implement a plan to improve the identification, diagnosis, and management of food allergies and anaphylaxis.

(h) Alcohol-related facilities

The Secretary shall, in coordination with the Secretary of Health and Human Services, to develop and implement a plan to address the problem of alcohol-related facilities.

(i) Decontamination and disposal standards and plans

The Secretary shall, in coordination with the Secretary of Health and Human Services, to develop and implement a plan to address the problem of decontamination and disposal of contaminated food.

(j) Surveillance

The Secretary shall, in coordination with the Secretary of Health and Human Services, to develop and implement a plan to enhance food safety surveillance systems.

§ 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—

(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.


REFERENCES IN TEXT

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

SUBCHAPTER I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

(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

REFERENCES IN TEXT

Pub. L. 111–353, §1(a), Jan. 4, 2011, 124 Stat. 3885, provided that: ‘‘This Act [enacting this chapter and sections 350g to 350–1, 379j–31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 230c–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, 350f, 350g to 350j, 350l, 350m, 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

...