

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.

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.)

REFERENCES IN TEXT

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

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.)

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;

(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.

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

² See References in Text note below.