

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.

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.