

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.

(Pub. L. 110-85, title X, §1008, Sept. 27, 2007, 121 Stat. 970.)

§ 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 on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and enforcement actions used to follow-up on such findings and violations.

(Pub. L. 110-85, title X, §1009, Sept. 27, 2007, 121 Stat. 970.)

Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in par. (3), 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.

§ 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.

(Pub. L. 110-85, title X, §1010, Sept. 27, 2007, 121 Stat. 970.)

§ 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).

(Pub. L. 110-85, title X, §1011, Sept. 27, 2007, 121 Stat. 971.)

Editorial Notes

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.

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’.”