

(4) Size of business

The Secretary shall take into account the size of a business in promulgating regulations under this section.

(5) Recordkeeping by retailers

The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

(c) Records inspection

If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

(d) Knowledge of illegal transaction**(1) Notification**

If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

(2) Knowledge defined

For purposes of this subsection, the term “knowledge” as applied to a manufacturer or distributor means—

(A) the actual knowledge that the manufacturer or distributor had; or

(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(e) Consultation

In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.

(June 25, 1938, ch. 675, §920, as added Pub. L. 111-31, div. A, title III, §301, June 22, 2009, 123 Stat. 1850.)

REFERENCES IN TEXT

Section 201 of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a)(1), is section 201 of div. A of Pub. L. 111-31.

§ 387u. Studies of progress and effectiveness**(a) FDA report**

Not later than 3 years after June 22, 2009, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 387j of this title and modified risk product applications received under section 387k of this title, and the number of applications acted on under each category; and

(4) data on the number of full time equivalents engaged in implementing this division.

(b) GAO report

Not later than 5 years after June 22, 2009, the Comptroller General of the United States shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) Public availability

The Secretary of Health and Human Services and the Comptroller General of the United States, respectively, shall make the reports required under subsection¹ (a) and (b) available to the public, including by posting such reports on the respective Internet websites of the Food and Drug Administration and the Government Accountability Office.

(Pub. L. 111-31, div. A, title I, §106, June 22, 2009, 123 Stat. 1841.)

REFERENCES IN TEXT

This division, referred to in subsecs. (a)(1), (2), (4) and (b)(1), is div. A of Pub. L. 111-31, June 22, 2009, 123 Stat. 1776, known as Family Smoking Prevention and Tobacco Control Act. For complete classification of division A to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act, and not as part of

¹ So in original. Probably should be plural.

the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in div. A of Pub. L. 111-31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111-31, set out as a note under section 387 of this title.

SUBCHAPTER X—MISCELLANEOUS

CODIFICATION

Former subchapter IX of this chapter was redesignated as this subchapter.

§ 391. Separability clause

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

(June 25, 1938, ch. 675, §1001, formerly §901, 52 Stat. 1059; renumbered §1001, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 392. Exemption of meats and meat food products

(a) Law determinative of exemption

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended [21 U.S.C. 601 et seq.].

(b) Laws unaffected

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act [42 U.S.C. 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832-833) [21 U.S.C. 151 et seq.]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 [21 U.S.C. 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C. 141 et seq.].

(June 25, 1938, ch. 675, §1002(b), (c), formerly §902(b), (c), 52 Stat. 1059; Pub. L. 90-399, §107, July 13, 1968, 82 Stat. 353; renumbered §1002(b), (c), Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to

subchapters I to IV (§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.

Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended. The provisions of such act referred to relating to viruses, etc., applicable to domestic animals, are contained in the eighth paragraph under the heading "Bureau of Animal Industry", 37 Stat. 832, as amended, popularly known as the Virus-Serum-Toxin Act, which is classified generally to chapter 5 (§151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, as amended, which had been classified to chapter 10 (§1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et seq. of Title 26 by Pub. L. 93-490, §3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, as amended, which is classified generally to chapter 3 (§61 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 61 of this title and Tables.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, as amended, which is classified generally to subchapter IV (§141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 141 of this title and Tables.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of section 1002 of act June 25, 1938. Subsecs. (a) and (d) of section 1002 of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90-399 substituted "section 262 of title 42 (relating to viruses, serums, toxins, and analogous products applicable to man)" for "the virus serum, and toxin Act of July 1, 1902" and inserted reference to "the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Act June 25, 1938, ch. 675, §1002(d), formerly §902(d), 52 Stat. 1059; renumbered §1002(d), Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784, provided that: "In order to carry out the provisions of this Act which take effect [see section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title] prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [former sections 1 to 5 and 7 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions."