

**§ 387t. Labeling, recordkeeping, records inspection**

**(a) Origin labeling**

**(1) Requirement**

Beginning 1 year after June 22, 2009, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement “sale only allowed in the United States”. Beginning 15 months after the issuance of the regulations required by section 1333(d) of title 15, as amended by section 201 of Family<sup>1</sup> Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement “Sale only allowed in the United States”.

**(2) Effective date**

The effective date specified in paragraph (1) shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with such paragraph.

**(b) Regulations concerning recordkeeping for tracking and tracing**

**(1) In general**

The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

**(2) Inspection**

In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

**(3) Codes**

The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

**(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,

<sup>1</sup> So in original. Probably should be “the Family”.

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 subsection<sup>1</sup> (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 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 fis-

<sup>1</sup> So in original. Probably should be plural.

cal 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