§ 384e. Recognition of foreign government inspections

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 360(i) of this title in order to facilitate risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 360(h) of this title;

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this chapter; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this chapter.

(b) Results of inspection

The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

(1) evidence of compliance with section 351(a)(2)(B) of this title or section 381(r) of this title; and

(2) for any other purposes as determined appropriate by the Secretary.

(June 25, 1938, ch. 675, § 809, as added Pub. L. 112–144, title VII, § 712, July 9, 2012, 126 Stat. 1072; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(X), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title VII, § 701(b), Aug. 18, 2017, 131 Stat. 1055.)

AMENDMENTS

2017—Subsec. (a)(1). Pub. L. 115–52 substituted ''paragraph (2) or (3) of section 360(h)'' for ''section 360(h)(3)''.

2016—Subsec. (a)(2). Pub. L. 114–255 substituted ''conducting'' for ''conduction''.

§ 384f. Strengthening FDA and CBP coordination and capacity

(a) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall coordinate with the Secretary of Homeland Security to carry out activities related to customs and border protection and in response to illegal controlled substances and drug imports, including at sites of import (such as international mail facilities), that will provide improvements to such facilities, technologies, and inspection capacity. Such Secretaries may carry out such activities through a memorandum of understanding between the Food and Drug Administration and the U.S. Customs and Border Protection.

(b) FDA import facilities and inspection capacity

(1) In general

In carrying out this section, the Secretary shall, in collaboration with the Secretary of Homeland Security and the Postmaster General of the United States Postal Service, provide that import facilities in which the Food and Drug Administration operates or carries out activities related to drug imports within the international mail facilities include—

(A) facility upgrades and improved capacity in order to increase and improve inspection and detection capabilities, which may include, as the Secretary determines appropriate—

(i) improvements to facilities, such as upgrades or renovations, and support for the maintenance of existing import facilities and sites to improve coordination between Federal agencies;

(ii) improvements in equipment and information technology enhancement to identify unapproved, counterfeit, or other unlawful controlled substances for destruction;

(iii) the construction of, or upgrades to, laboratory capacity for purposes of detection and testing of imported goods;

(iv) upgrades to the security of import facilities; and

(v) innovative technology and equipment to facilitate improved and near-real-time information sharing between the Food and Drug Administration, the Department of Homeland Security, and the United States Postal Service; and

(B) innovative technology, including controlled substance detection and testing equipment and other applicable technology, in order to collaborate with the U.S. Customs and Border Protection to share near-real-time information, including information about test results, as appropriate.

(2) Innovative technology

Any technology used in accordance with paragraph (1)(B) shall be interoperable with technology used by other relevant Federal agencies, including the U.S. Customs and Border Protection, as the Secretary determines appropriate and practicable.

(c) Report

Not later than 6 months after October 24, 2018, the Secretary, in consultation with the Secretary of Homeland Security and the Postmaster General of the United States Postal Service, shall report to the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate on the implementation of this section, including a summary of progress made toward near-real-time information sharing and the interoperability of such technologies.

(Pub. L. 115–271, title III, § 3014, Oct. 24, 2018, 132 Stat. 3937.)

CODIFICATION

Section was enacted as part of the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, also known as the SCREEN Act, and also as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 384g. Restricting entrance of illicit drugs

(a) Food and Drug Administration and U.S. Customs and Border Protection cooperation

(1) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with the U.S. Customs and Border Protection, shall develop and periodically update a mutually agreed upon list of the controlled substances that the Secretary will refer to U.S. Customs and Border Protection, unless the Secretary and U.S. Customs and Border Protection agree otherwise, when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Secretary shall transfer controlled substances on such list to the U.S. Customs and Border Protection. If the Secretary identifies additional packages that appear to be the same as such package containing a controlled substance, such additional packages may also be transferred to U.S. Customs and Border Protection. The U.S. Customs and Border Protection shall receive such packages consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(2) Report

Not later than 9 months after October 24, 2018, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Secretary of Homeland Security, shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the implementation of this section.

(Pub. L. 115–271, title III, § 3022(a), Oct. 24, 2018, 132 Stat. 3938.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (a)(1), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

The Controlled Substances Import and Export Act, referred to in subsec. (a)(1), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, which is classified principally to subchapter II (§ 951 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 951 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, also known as the SCREEN Act, and also as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER IX—TOBACCO PRODUCTS

PRIOR PROVISIONS

A prior subchapter IX of this chapter, consisting of sections 391 to 399a of this title, was redesignated subchapter X by Pub. L. 111–31, div. A, title I, § 101(b)(1), June 22, 2009, 123 Stat. 1784.

§ 387. Definitions

In this subchapter:

(1) Additive

The term ''additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

(2) Brand

The term ''brand'' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

(3) Cigarette

The term ''cigarette''—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term ''cigarette'' in section 1332(1) of title 15; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) Cigarette tobacco

The term ''cigarette tobacco'' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this subchapter shall also apply to cigarette tobacco.

(5) Commerce

The term ''commerce'' has the meaning given that term by section 1332(2) of title 15.