

**(c) Required information**

The information to be provided in the notice under subsection (b) is—

(1) the sanitary or phytosanitary standards under consideration or planned for consideration by that organization;

(2) for each sanitary or phytosanitary standard specified in paragraph (1)—

(A) a description of the consideration or planned consideration of the standard;

(B) whether the United States is participating or plans to participate in the consideration of the standard;

(C) the agenda for the United States participation, if any; and

(D) the agency responsible for representing the United States with respect to the standard.

**(d) Public comment**

The agency specified in subsection (c)(2)(D) shall provide an opportunity for public comment with respect to the standards for which the agency is responsible and shall take the comments into account in participating in the consideration of the standards and in proposing matters to be considered by the organization.

(Pub. L. 96-39, title IV, §491, as added Pub. L. 103-465, title IV, §432, Dec. 8, 1994, 108 Stat. 4970.)

**Statutory Notes and Related Subsidiaries****EFFECTIVE DATE**

Section effective on the date of entry into force of the WTO Agreement with respect to the United States (Jan. 1, 1995), except as otherwise provided, see section 451 of Pub. L. 103-465, set out as a note under section 3601 of this title.

**Executive Documents****DESIGNATION OF AGENCY**

Secretary of Agriculture designated under this section as official responsible for informing public of sanitary and phytosanitary standard-setting activities of each international standard-setting organization, see par. (4) of Proc. No. 6780, Mar. 23, 1995, 60 F.R. 15847, set out as a note under section 3511 of this title.

**§ 2578a. Equivalence determinations****(a) In general**

An agency may not determine that a sanitary or phytosanitary measure of a foreign country is equivalent to a sanitary or phytosanitary measure established under the authority of Federal law unless the agency determines that the sanitary or phytosanitary measure of the foreign country provides at least the same level of sanitary or phytosanitary protection as the comparable sanitary or phytosanitary measure established under the authority of Federal law.

**(b) FDA determination**

If the Commissioner proposes to issue a determination of the equivalency of a sanitary or phytosanitary measure of a foreign country to a measure that is required to be promulgated as a rule under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or other statute administered by the Food and Drug Administration, the Commissioner shall issue a proposed

regulation to incorporate such determination and shall include in the notice of proposed rule-making the basis for the determination that the sanitary or phytosanitary measure of a foreign country provides at least the same level of sanitary or phytosanitary protection as the comparable Federal sanitary or phytosanitary measure. The Commissioner shall provide opportunity for interested persons to comment on the proposed regulation. The Commissioner shall not issue a final regulation based on the proposal without taking into account the comments received.

**(c) Notice**

If the Commissioner proposes to issue a determination of the equivalency of a sanitary or phytosanitary measure of a foreign country to a sanitary or phytosanitary measure of the Food and Drug Administration that is not required to be promulgated as a rule under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or other statute administered by the Food and Drug Administration, the Commissioner shall publish a notice in the Federal Register that identifies the basis for the determination that the measure provides at least the same level of sanitary or phytosanitary protection as the comparable Federal sanitary or phytosanitary measure. The Commissioner shall provide opportunity for interested persons to comment on the notice. The Commissioner shall not issue a final determination on the issue of equivalency without taking into account the comments received.

(Pub. L. 96-39, title IV, §492, as added Pub. L. 103-465, title IV, §432, Dec. 8, 1994, 108 Stat. 4971; amended Pub. L. 104-295, §20(d)(1), Oct. 11, 1996, 110 Stat. 3529.)

**Editorial Notes****REFERENCES IN TEXT**

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b) and (c), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

**AMENDMENTS**

1996—Subsec. (c). Pub. L. 104-295 substituted “phytosanitary” for “phystosanitary” before “measure of the Food and Drug Administration”.

**Statutory Notes and Related Subsidiaries****EFFECTIVE DATE**

Section effective on the date of entry into force of the WTO Agreement with respect to the United States (Jan. 1, 1995), except as otherwise provided, see section 451 of Pub. L. 103-465, set out as a note under section 3601 of this title.

**§ 2578b. Definitions****(a) In general**

As used in this part:

**(1) Agency**

The term “agency” means a Federal department or agency (or combination of Federal departments or agencies).

**(2) Commissioner**

The term “Commissioner” means the Commissioner of Food and Drugs.

**(3) International standard-setting organization**

The term “international standard-setting organization” means an organization consisting of representatives of 2 or more countries, the purpose of which is to negotiate, develop, promulgate, or amend an international standard.

**(4) Sanitary or phytosanitary standard**

The term “sanitary or phytosanitary standard” means a standard intended to form a basis for a sanitary or phytosanitary measure.

**(5) International standard**

The term “international standard” means a standard, guideline, or recommendation—

(A) regarding food safety, adopted by the Codex Alimentarius Commission, including a standard, guideline, or recommendation regarding decomposition elaborated by the Codex Committee on Fish and Fishery Products, food additives, contaminants, hygienic practice, and methods of analysis and sampling;

(B) regarding animal health and zoonoses, developed under the auspices of the International Office of Epizootics;

(C) regarding plant health, developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with the North American Plant Protection Organization; or

(D) established by or developed under any other international organization agreed to by the USMCA countries (as defined in section 4502 of this title) or by the WTO members (as defined in section 3501(10) of this title).

**(b) Other definitions**

The definitions set forth in section 2575b of this title apply for purposes of this part except that in applying paragraph (7) of section 2575b of this title with respect to a sanitary or phytosanitary measure of a foreign country, any reference in such paragraph to the United States shall be deemed to be a reference to that foreign country.

(Pub. L. 96-39, title IV, §493, as added Pub. L. 103-465, title IV, §432, Dec. 8, 1994, 108 Stat. 4972; amended Pub. L. 116-260, div. O, title VI, §602(f), Dec. 27, 2020, 134 Stat. 2154.)

**Editorial Notes****AMENDMENTS**

2020—Subsec. (a)(5)(D). Pub. L. 116-260 substituted “the USMCA countries (as defined in section 4502 of this title)” for “the NAFTA countries (as defined in section 2(4) of the North American Free Trade Agreement Implementation Act)”.

**Statutory Notes and Related Subsidiaries****EFFECTIVE DATE OF 2020 AMENDMENT**

Pub. L. 116-260, div. O, title VI, §602(g), Dec. 27, 2020, 134 Stat. 2154, provided that: “This section [amending this section, sections 2702 to 2703a, 3721, 3722, and 4362 of

this title, section 11 of Title 35, Patents, and section 2296b of Title 42, The Public Health and Welfare] and the amendments made by this section shall take effect on July 1, 2020.”

**EFFECTIVE DATE**

Section effective on the date of entry into force of the WTO Agreement with respect to the United States (Jan. 1, 1995), except as otherwise provided, see section 451 of Pub. L. 103-465, set out as a note under section 3601 of this title.

**SUBCHAPTER III—MISCELLANEOUS PROVISIONS****§ 2581. Auction of import licenses****(a) In general**

Notwithstanding any other provision of law, the President may sell import licenses at public auction under such terms and conditions as he deems appropriate. Regulations prescribed under this subsection shall, to the extent practicable and consistent with efficient and fair administration, insure against inequitable sharing of imports by a relatively small number of the larger importers.

**(b) “Import license” defined**

For purposes of this section, the term “import license” means any documentation used to administer a quantitative restriction imposed or modified after July 26, 1979 under—

(1) section 125, 203, 301, or 406 of the Trade Act of 1974 (19 U.S.C. 2135, 2253, 2411, or 2436),

(2) the International Emergency Economic Powers Act (50 U.S.C. 1701–1706),

(3) authority under the notes of the Harmonized Tariff Schedule of the United States, but not including any quantitative restriction imposed under section 22 of the Agricultural Adjustment Act of 1934 (7 U.S.C. 624),

(4) the Trading With the Enemy Act (50 U.S.C. App. 1-44),<sup>1</sup>

(5) section 204 of the Agricultural Act of 1956 (7 U.S.C. 1854) other than for meat or meat products, or

(6) any Act enacted explicitly for the purpose of implementing an international agreement to which the United States is a party, including such agreements relating to commodities, but not including any agreement relating to cheese or dairy products.

(Pub. L. 96-39, title XI, §1102, July 26, 1979, 93 Stat. 307; Pub. L. 100-418, title I, §1214(k), Aug. 23, 1988, 102 Stat. 1158.)

**Editorial Notes****REFERENCES IN TEXT**

The International Emergency Economic Powers Act, referred to in subsec. (b)(2), is Pub. L. 95-223, title II, Dec. 28, 1977, 91 Stat. 1626, which is classified generally to chapter 35 (§1701 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1701 of Title 50 and Tables.

The Harmonized Tariff Schedule of the United States, referred to in subsec. (b)(3), is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of this title.

The Trading With the Enemy Act, referred to in subsec. (b)(4), is act Oct. 6, 1917, ch. 106, 40 Stat. 411, which

<sup>1</sup> See References in Text note below.