

- (i) processes or production methods relating to such good, or
- (ii) operating methods relating to such service, and

(C) provisions specifying terminology, symbols, packaging, marking, or labelling for—

- (i) a good or its related process or production methods, or
- (ii) a service or its related operating methods,

for common and repeated use, including explanatory and other related provisions set out in a document approved by a standardizing body, with which compliance is not mandatory.

#### **(6) Standards-related measure**

The term “standards-related measure” means a standard, technical regulation, or conformity assessment procedure.

#### **(7) Technical regulation**

The term “technical regulation” means—

- (A) characteristics or their related processes and production methods for a good,
- (B) characteristics for a service or its related operating methods, or
- (C) provisions specifying terminology, symbols, packaging, marking, or labelling for—
  - (i) a good or its related process or production method, or
  - (ii) a service or its related operating method,

set out in a document, including applicable administrative, explanatory, and other related provisions, with which compliance is mandatory.

#### **(8) Telecommunications service**

The term “telecommunications service” means a service provided by means of the transmission and reception of signals by any electromagnetic means, but does not mean the cable, broadcast, or other electromagnetic distribution of radio or television programming to the public generally.

(Pub. L. 96-39, title IV, §473, as added Pub. L. 103-182, title III, §351(a), Dec. 8, 1993, 107 Stat. 2120.)

### **SUBPART 3—PART DEFINITIONS**

#### **§ 2577. Definitions**

Notwithstanding section 2571 of this title, for purposes of this part—

##### **(1) NAFTA**

The term “NAFTA” means the North American Free Trade Agreement.

##### **(2) State**

The term “State” means any of the several States, the District of Columbia, and the Commonwealth of Puerto Rico.

(Pub. L. 96-39, title IV, §481, as added Pub. L. 103-182, title III, §351(a), Dec. 8, 1993, 107 Stat. 2122.)

### **PART F—INTERNATIONAL STANDARD-SETTING ACTIVITIES**

#### **§ 2578. Notice of United States participation in international standard-setting activities**

##### **(a) In general**

The President shall designate an agency to be responsible for informing the public of the sanitary and phytosanitary standard-setting activities of each international standard-setting organization.

##### **(b) Notification**

Not later than June 1 of each year, the agency designated under subsection (a) with respect to each international standard-setting organization shall publish notice in the Federal Register of the information specified in subsection (c) with respect to that organization. The notice shall cover the period ending on June 1 of the year in which the notice is published, and beginning on the date of the preceding notice under this subsection, except that the first such notice shall cover the 1-year period ending on the date of the notice.

##### **(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