

lateral arrangements regarding standards-related measures, and the provisions of those systems and arrangements;

(2) the location of notices of the type required under article 909 of the NAFTA, or where the information contained in such notice can be obtained; and

(3) the Federal agency procedures for assessment of risk, and factors the agency considers in conducting the assessment and establishing the levels of protection that the agency considers appropriate.

(Pub. L. 96-39, title IV, §472, as added Pub. L. 103-182, title III, §351(a), Dec. 8, 1993, 107 Stat. 2120.)

§ 2576b. Subpart definitions

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

(1) Approval procedure

The term “approval procedure” means any registration, notification, or other mandatory administrative procedure for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions.

(2) Conformity assessment procedure

The term “conformity assessment procedure” means any procedure used, directly or indirectly, to determine that a technical regulation or standard is fulfilled, including sampling, testing, inspection, evaluation, verification, monitoring, auditing, assurance of conformity, accreditation, registration, or approval used for such a purpose, but does not mean an approval procedure.

(3) Objective

The term “objective” includes—

- (A) safety,
- (B) protection of human, animal, or plant life or health, the environment or consumers, including matters relating to quality and identifiability of goods or services, and
- (C) sustainable development,

but does not include the protection of domestic production.

(4) Service

The term “service” means a land transportation service or a telecommunications service.

(5) Standard

The term “standard” means—

- (A) characteristics for a good or a service,
- (B) characteristics, rules, or guidelines for—

- (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) of this section

with respect to each international standard-setting organization shall publish notice in the Federal Register of the information specified in subsection (c) of this section 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) of this section 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) of this section 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.)

EFFECTIVE DATE

Part 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.

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.)

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, as amended, 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”.

§ 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 consist-