

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-