

ments 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 phyto-

sanitary 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 “phyto-sanitary” 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 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 NAFTA countries (as defined in section 3301(4) of this title) or by the WTO