

Environmental Protection Agency

§ 177.3

SOURCE: 55 FR 50288, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 177.1 Scope and applicability.

(a) This part establishes procedures for the establishment, modification, or revocation by the Administrator of food additive regulations under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348, for food additives which may result in pesticide residues in or on processed food or otherwise affect the characteristics of such food.

(b) Part 178 of this chapter contains procedures for filing objections and requests for hearings under FFDCA section 409(f) on food additive regulations or petition denials issued under this part. Part 179 of this chapter contains rules governing formal evidentiary hearings under FFDCA section 409(f).

(c) Part 180 of this chapter contains regulations establishing tolerances, or exemptions from the necessity for a tolerance, for pesticide residues on raw agricultural commodities under FFDCA section 408. If the use of a pesticide chemical in the production, storage, or transportation of a raw agricultural commodity (RAC) in conformity with such a tolerance or exemption results in the presence of a pesticide residue in or on processed food made from the RAC, FFDCA section 402(a)(2)(C) provides that such pesticide residue shall not be deemed unsafe for the purposes of FFDCA section 409 (despite the absence of a food additive regulation regarding such residue on the processed food) if the residue in or on the RAC has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the RAC. However, a food additive regulation would be required if the level of the pesticide residue in the processed food when ready to eat exceeded the level permitted in the "parent" RAC by the tolerance established under FFDCA section 408. In addition, if a pesticide residue in or on a processed food results from the application of a pesticide during or after processing, the food would be unsafe

within the meaning of FFDCA section 409 unless a food additive regulation permitted that residue in or on the processed food.

§ 177.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or an officer or employee of the Agency to whom the Administrator has delegated the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301-392.

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136-136y.

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food (including any such substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food), except that such term does not include:

(1) A pesticide chemical in or on a raw agricultural commodity.

(2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity.

(3) A color additive.

(4) Any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to the FFDCA, the Poultry Products Inspection Act, or the Federal Meat Inspection Act.

(5) A new animal drug.

(6) A substance that is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

Food additive regulation means a regulation issued pursuant to FFDCA section 409 that states the conditions under which a food additive may be safely used. A food additive regulation under this part ordinarily establishes a tolerance for pesticide residues in or on a particular processed food or a group of such foods. It may also specify:

- (1) The particular food or classes of food in or on which a food additive may be used.
- (2) The maximum quantity of the food additive which may be used in or on such food.
- (3) The manner in which the food additive may be added to or used in or on such food.
- (4) Directions or other labeling or packaging requirements for the food additive.

Pesticide chemical means any substance which alone, or in chemical combination with or in formulation with one or more other substances, is a "pesticide" within the meaning of FIFRA and which is used in the production, storage, or transportation of any raw agricultural commodity or processed food. The term includes any substance that is an active ingredient, intentionally-added inert ingredient, or impurity of such a "pesticide."

Pesticide residue means a residue of a pesticide chemical or of any metabolite or degradation product of a pesticide chemical.

Tolerance means:

- (1) The amount of a pesticide residue that legally may be present in or on a raw agricultural commodity under the terms of a tolerance under FFDCA section 408 or a processed food under the terms of a food additive regulation under FFDCA section 409. Tolerances are usually expressed in terms of parts of the pesticide residue per million parts of the food (ppm), by weight.

- (2) [Reserved]

Subparts B-D [Reserved]

Subpart E—Procedures for Filing Petitions

§ 177.81 Petition for establishment, modification, or revocation of a food additive regulation.

(a) *Who may submit a petition.* Any person may submit a petition requesting the Agency to issue a regulation to establish, modify, or revoke a food additive regulation.

(b) *Where to submit petition.* A petition shall be submitted to: Office of Pesticide Programs (H7504C), Document Processing Desk - PETN, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(c) *Identification of petitioner.* A petition must be signed by the petitioner or the petitioner's authorized representative, and must state the petitioner's mailing address and telephone number.

(d) *Material to be in English language.* The petition shall be written in the English language. If any part of the accompanying material is written in a language other than English, it shall be accompanied by an accurate and complete English translation.

(e) *Format for data submission.* Data and information submitted in support of a petition shall be on separate sheets or sets of sheets of paper, suitably identified. If an item of data has already been submitted to the Agency, the petitioner may cite it rather than resubmitting it. The data shall be submitted in the manner specified by § 158.32 of this chapter.

(f) *Confidentiality of data and information in petition, amendment, or supplement—(1) Asserting confidentiality claims.* A petitioner may assert a claim that data and information in a petition, or any amendment or supplement to a petition, other than the summary described in § 177.102(j), are entitled to confidential treatment under part 2 of this chapter. To assert such a claim, the petitioner must mark those portions of the petition, amendment, or supplement, and those portions of any