

*Food additive regulation* means a regulation issued pursuant to FFDCFA 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 FFDCFA section 408 or a processed food under the terms of a food additive regulation under FFDCFA 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

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data and information submitted in support of the petition, amendment, or supplement, with the words "trade secret," "proprietary," or other words that indicate the data or information are claimed to be confidential business information. If the data and information have also been submitted to EPA under FIFRA, the person shall assert the confidentiality claim in accordance with § 158.33 of this chapter.

(2) *Effect of asserting confidentiality claim.* If a petitioner asserts a confidentiality claim in accordance with this paragraph for any data or information in a petition, amendment, or supplement, the Agency will disclose that data or information only in accordance with parts 2, 158, 178, and 179, of this chapter, and FIFRA and FFDCa, as applicable.

(3) *Failure to assert confidentiality claim.* If a petitioner does not assert a claim that specific data and information in a petition, or any amendment or supplement to a petition, are entitled to confidential treatment under part 2 of this chapter in accordance with paragraph (e)(1) of this section at the time of submission of the petition, amendment, or supplement, the Agency will treat that data and information as available for disclosure to the public without further notice to the petitioner.

### § 177.84 Deficient or incomplete petitions.

(a) After a preliminary review of the petition, the Administrator may notify the petitioner that the Agency has found the petition to be incomplete or deficient, i.e., that it does not comply with the requirements of § 177.102 or § 177.105, and that it will not be accepted for detailed review.

(b) A petitioner who receives a notice under paragraph (a) of this section may supplement the petition, in which case the Agency shall conduct a further preliminary review of the petition as supplemented and take action under paragraph (a) of this section or under § 177.86.

### § 177.86 Acceptance for review.

Unless the Administrator notifies the petitioner under § 177.84 that the petition is incomplete or deficient, the Ad-

ministrator shall accept the petition for detailed review.

### § 177.88 Publication of notice.

Within 30 days of acceptance of a petition for detailed review, the Administrator shall publish in the FEDERAL REGISTER a notice which includes the name of the petitioner and the summary submitted in accordance with § 177.102(j).

### § 177.92 Amendments or supplements to petitions.

After a notice of a petition has been published, the petitioner may submit additional information or data in support of the petition, or may amend the petition. Any such submission or amendment shall be accompanied by an informative summary of its contents that may be published in the FEDERAL REGISTER. The Administrator shall publish a notice in the FEDERAL REGISTER to supplement the notice published under § 177.88 if:

(a) The petitioner seeks to amend the petition by:

(1) Increasing a requested tolerance, by identifying any additional food additive or additional pesticide residues to which the requested food additive regulation would apply.

(2) Identifying any additional processed food to which the requested food additive regulation would apply.

(3) Changing the method for detecting or measuring pesticide residues to be used for enforcement purposes.

(b) The Administrator finds that publication of such a notice otherwise would be in the public interest.

### § 177.98 Withdrawal of petitions.

A petitioner may withdraw a petition. The Agency may retain a copy of a withdrawn petition and any supporting data and information.

### § 177.99 Demand for action.

A petitioner may demand action on a petition if the Administrator has not acted on the petition within the timeframes in FFDCa section 409(c)(2). Upon receipt of such a demand, the Administrator shall take appropriate action under FFDCa section 409(c)(1).