

Environmental Protection Agency

§ 177.125

and the quantity of such food additive required to produce such effect.

(g) The terms of each food additive regulation proposed.

(h) Any other information relevant to the approval of the petition known to the petitioner that is unfavorable to the petition.

(i) A statement of why, in the petitioner's opinion, it would be reasonable for the Administrator to approve the petition, taking into account the terms of the FFDCA and FIFRA, this part, the petition, the data and information submitted or cited in support of the petition, and other information available to the Agency.

(j) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition, and a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice to be furnished to the public under §177.88 or as part of a proposal under §177.130. The summary need not refer to any method or process that is entitled to protection as a trade secret under FFDCA section 301(j).

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.105 Data and information required to support petition to revoke a food additive regulation, to decrease a tolerance, or to add a condition on use.

A petition to revoke a food additive regulation, or to modify such a regulation by decreasing a tolerance for a pesticide residue in or on a processed food or by adding a condition on the use of a food additive, shall include:

(a) The data and information required by §177.102(a), (b), (g), (h), and (i).

(b) Such data and information of the types described in §177.102(c), (d), (e), and (f) as the petitioner chooses to submit.

(c) Information showing what changes, if any, petitioner believes would have to be made in associated registrations of pesticides under FIFRA or in associated tolerance regu-

lations issued under FFDCA section 408 if the petition were granted.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.110 Additional data requirements; waiver of requirements.

(a) The Administrator may require or occasion a petitioner to submit data or information other than that described by this part only if the Administrator finds such data or information to be necessary for the evaluation of the petition.

(b) The Administrator may waive a requirement imposed by this part for the submission of data or information if the Administrator finds such data or information to be unnecessary for the evaluation of the petition.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.116 Sample of food additive.

The Agency may require the petitioner to submit a sample of the food additive or pesticide residue that is a subject of the petition. The Agency shall specify in such request the quantity which it requires.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

Subpart G—Administrative Actions

§ 177.125 Action after review.

(a) After a petition has been accepted for detailed review, the Administrator shall review the petition, the accompanying data and information, and other pertinent data or information available to the Administrator.

(b) Upon completion of such review, the Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a food additive regulation (whether or not in accord with the action proposed by the petitioner), whether to issue an order denying the petition, or whether to publish a proposed food additive regulation and request public comment thereon under §177.130.

(c) The Administrator shall publish in the FEDERAL REGISTER such order or proposed regulation. An order published under this section shall describe

§ 177.130

briefly how to submit objections and requests for a hearing under part 178 of this chapter.

§ 177.130 Issuance of proposed rule on Administrator's initiative or in response to petition, and final action on proposal.

(a) The Administrator may publish in the FEDERAL REGISTER a proposal to establish a food additive regulation or to modify or revoke an existing food additive regulation, on his or her own initiative or in response to a petition.

(b) The Administrator shall provide a period of not less than 30 days for persons to comment on the proposed regulation.

(c) After reviewing any timely comments made, the Administrator may by order establish, modify, or revoke a food additive regulation, or may by order decide that no final action on the proposal is warranted. Each such order and each such regulation shall be published in the FEDERAL REGISTER. An order published under this section shall state that objections and requests for a hearing may be filed as prescribed by part 178 of this chapter.

§ 177.135 Effective date of regulation.

Any final regulation issued under § 177.125 or § 177.130 shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation. The Administrator, in his or her sole discretion, may stay the effective date of the regulation if an adversely affected person files an objection under part 178 of this chapter.

Subpart H—Judicial Review

§ 177.140 Judicial review.

The FFDCFA does not provide for judicial review of an order or regulation issued under this part or of a denial of a petition under this part. However, if an objection to such action is submitted to the Administrator in the manner prescribed by part 178 of this chapter, judicial review may be obtained of the Administrator's action on the objection. (See FFDCFA sections 409(f) and (g).)

40 CFR Ch. I (7-1-02 Edition)

PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

Subpart A—General Provisions

Sec.
178.3 Definitions.

Subpart B—Procedures for Filing Objections and Requests for Hearing

- 178.20 Right to submit objections and requests for a hearing.
- 178.25 Form and manner of submission of objections.
- 178.27 Form and manner of submission of request for evidentiary hearing.
- 178.30 Response by Administrator to objections and to requests for hearing.
- 178.32 Rulings on requests for hearing.
- 178.35 Modification or revocation of regulation.
- 178.37 Order responding to objections on which a hearing was not requested or was denied.

Subpart C [Reserved]

Subpart D—Judicial Review

- 178.65 Judicial review.
- 178.70 Administrative record.

AUTHORITY: 21 U.S.C. 346a, 348, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 178.3 Definitions.

For the purposes of this part:
Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

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

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]