

**§ 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 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 FFDCA 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 FFDCA sections 409(f) and (g).)

**PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS****Subpart A—General Provisions**

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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.

*FFDCA* 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]

**Subpart B—Procedures for Filing Objections and Requests for Hearing**

**§ 178.20 Right to submit objections and requests for a hearing.**

(a) On or before the 30th day after the date of publication in the FEDERAL REGISTER of an order under part 177 or part 180 of this chapter establishing, modifying, or revoking a regulation, or an order under part 177 of this chapter denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an

evidentiary hearing on such objection in accordance with § 178.27

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

**§ 178.25 Form and manner of submission of objections.**

(a) To be considered by the Administrator, an objection must:

- (1) Be in writing.
- (2) Specify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought.
- (3) Be signed by the objector.
- (4) State the objector's name and mailing address.
- (5) Be accompanied by the fee prescribed by § 180.33(i) of this chapter, if the objection is to an order or regulation issued under part 180 of this chapter.

(6) Be submitted to the hearing clerk.

(7) Be received by the hearing clerk not later than the close of business of the 30th day following the date of the publication in the FEDERAL REGISTER of the order to which the objection is taken (or, if such 30th day is a Saturday, Sunday, or Federal holiday, not later than the close of business of the next government business day after such 30th day).

(b) Submissions to the hearing clerk shall be made as follows:

(1) Mailed submissions should be addressed to: Office of the Hearing Clerk (A-110), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(2) For personal delivery, the Office of the Hearing Clerk is located at: room M3708, Waterside Mall, 401 M St., SW., Washington, DC.

**§ 178.27 Form and manner of submission of request for evidentiary hearing.**

To be considered by the Administrator, a request for an evidentiary hearing must meet the criteria in § 178.32, and must:

(a) Be submitted as a part of, and specifically request an evidentiary hearing on an objection that complies with the requirements of § 178.25.

(b) Include a statement of the factual issue(s) on which a hearing is requested and the requestor's contentions on each such issue.

(c) Include a copy of any report, article, survey, or other written document (or the pertinent pages thereof) upon which the objector relies to justify an evidentiary hearing, unless the document is an EPA document that is routinely available to any member of the public.

(d) Include a summary of any evidence not described in paragraph (a)(3) of this section upon which the objector relies to justify an evidentiary hearing.

(e) Include a discussion of the relationship between the factual issues and the relief requested by the objection.

**§ 178.30 Response by Administrator to objections and to requests for hearing.**

The Administrator will respond to objections, and to requests for a hearing on such objections, as set forth in this section.

(a) *Denial of objections that are improperly submitted or that seek an unavailable form of relief.* The Administrator will by order issued under § 178.37 deny each objection and each request for a hearing that is included with such an objection, if:

(1) The objection is found not to conform to § 178.25.

(2) The action requested by the objection is inconsistent with any provision of FFDCA.

(3) The action requested by the objection is inconsistent with any generic, e.g., non-chemical specific, interpretation of a provision of FFDCA in any regulation in this chapter (the proper procedure in such a case is for the person to petition for an amendment of the regulation involved).

(b) *Denial of improperly submitted requests for hearing.* The Administrator will then determine whether any objection that has not been denied under paragraph (a) of this section was accompanied by a request for an evidentiary hearing that conforms to § 178.27. The Administrator will deny under § 178.37 each request that does not conform to § 178.27.

(c) *Grouping of certain related objections.* If the Administrator then finds (1) That two or more undenied objections are substantially similar, or are related in such a way that any judicial review of the Administrator's action on those objections should occur at the same time, and (2) that one or more of those objections was accompanied by an undenied request for an evidentiary hearing on that objection, the Administrator will treat those objections as a group and will rule on them only after ruling under § 178.32 on the associated request for hearing.

(d) *Rulings on objections for which a request for hearing has been granted.* If the Administrator rules under § 178.32 that an evidentiary hearing should be held on an objection, the Administrator will resolve the issues raised by any other objection grouped with it under paragraph (c) of this section in conjunction with the evidentiary hearing upon which the hearing request was granted, unless the Administrator for good cause determines otherwise.

(e) *Rulings on objections for which no request for hearing was received, or for which each request for hearing was denied.* Except as provided in paragraphs (c) and (d) of this section, if no hearing was requested on an objection, or if each such request that was made is denied under the criteria of paragraphs (a) or (b) of this section or § 178.32(b), the Administrator will rule on the objection under § 178.37.

**§ 178.32 Rulings on requests for hearing.**

(a) In the case of each request for an evidentiary hearing that was not denied under § 178.30(a) or (b), the Administrator will determine whether such a hearing on one or more of the objections is justified, and will publish in the FEDERAL REGISTER the determination in an order issued under § 178.37 or

a Notice of Hearing issued under § 179.20 of this chapter. If some requests for a hearing are denied and others pertaining to the same order or regulation are granted, the denial order and the hearing notice may be combined into a single document and shall be issued at the same time unless the Administrator for good cause determines otherwise.

(b) A request for an evidentiary hearing will be granted if the Administrator determines that the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(c) Where appropriate, the Administrator will make rulings on any issues raised by an objection which are necessary for resolution prior to determining whether a request for an evidentiary hearing should be granted.

**§ 178.35 Modification or revocation of regulation.**

(a) If the Administrator determines upon review of an objection or request for hearing that the regulation in question should be modified or revoked, the Administrator will by order publish ap-

propriate rulemaking documents in the FEDERAL REGISTER.

(b) The Administrator will provide an opportunity for objections and requests for hearing on such rule to the extent required by law. Such objections to the modification or revocation of the regulation, and requests for a hearing on such objections, may be submitted under §§ 178.20 through 178.27.

(c) Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in accordance with this part.

**§ 178.37 Order responding to objections on which a hearing was not requested or was denied.**

(a) The Administrator will publish in the FEDERAL REGISTER an order under FFDCA section 408(d)(5) or 409(f)(1) setting forth the Administrator's determination on each denial of a request for a hearing, and on each objection submitted under § 178.20 on which:

(1) A hearing was not requested.

(2) A hearing was requested, but denied.

(b) Each order published under paragraph (a) of this section must state the reasons for the Administrator's determination. If the order denies a request for a hearing on the objection, the order also must state the reason for that denial (e.g., why the request for a hearing did not conform to § 178.27, or why the request was denied under § 178.32).

(c) Each order published under paragraph (a) of this section must state its effective date, which must not be earlier than the 90th day after the order is published unless the order contains the Administrator's findings as to the existence of emergency conditions that necessitate an earlier effective date.

**Subpart C [Reserved]**

**Subpart D—Judicial Review**

**§ 178.65 Judicial review.**

An order issued under § 178.37 is final agency action reviewable in the courts as provided by FFDCA sections 408(i) or 409(g)(1), as of the date of entry of the order, which shall be determined in accordance with §§ 23.10 and 23.11 of this

chapter. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the entry of the order constitutes a waiver under FFDCA section 408(i) or 409(g)(1) of the right to judicial review of the order and of any regulation promulgated by the order.

#### **§ 178.70 Administrative record.**

(a) For purposes of judicial review, the record of an administrative proceeding that culminates in an order under § 178.37 consists of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under § 177.125 of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(3) Any order issued under § 177.130 of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(4) Any order issued under § 180.7(g) of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(5) Any order issued under § 180.29(f) of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(6) Any comments submitted by members of the public in response to the Notice of Filing or Notice of Proposed Rulemaking, any data or information submitted as part of the comments, the Administrator's response to

comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(7) All other documents or information submitted to the docket for the rulemaking in question.

(8) The order issued under § 178.37.

(b) The record will be closed as of the date of the Administrator's decision unless another date for closing of the record is specified in the order issued under § 178.37.

## **PART 179—FORMAL EVIDENTIARY PUBLIC HEARING**

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