

emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant acting under authority of FIFRA section 18 either has requested an emergency exemption, has stated its intention to issue a crisis exemption, or has issued a crisis exemption for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

§ 176.7 Information needed to establish a tolerance.

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into account the limited duration and emergency nature of a section 18 application, and based on the available data the Agency cannot conclude that there is a reasonable certainty that no harm will result from the use proposed by the applicant or granted pursuant to a crisis exemption, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

§ 176.9 Publication of a tolerance.

(a) If EPA issues an emergency exemption or crisis exemption under FIFRA section 18, and EPA concludes that the tolerance for residues resulting from use of the pesticide under the exemption will be safe, then EPA will establish the tolerance by publishing an amendment to 40 CFR part 180 in the FEDERAL REGISTER.

(b) A tolerance under this part may be established without prior publication of a proposed tolerance or comment period.

§ 176.11 Duration of a tolerance.

(a) Tolerances issued under this part will become effective upon publication

in the FEDERAL REGISTER, unless otherwise specified by the Administrator.

(b) Unless extended, tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the final rule published in FEDERAL REGISTER.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

§ 176.13 Modification of a time-limited tolerance.

If additional emergency or crisis exemptions are authorized that would extend use beyond the date originally authorized, or if EPA determines that the duration of a time-limited tolerance is insufficient to allow treated commodities to clear the channels of trade, EPA may modify the time-limited tolerance by publication of a final rule in the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

Subpart A—General Provisions

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178.3 Definitions.

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

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Subpart C [Reserved]

Subpart D—Judicial Review

178.65 Judicial review.

178.70 Administrative record.

AUTHORITY: 21 U.S.C. 346a, 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 Chemical Safety and Pollution Prevention, or any officer or employee of the Agency's Office of Chemical Safety and Pollution Prevention 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; 77 FR 46292, Aug. 3, 2012]

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 60th day after the date of publication in the FEDERAL REGISTER of an order under part 180 of this chapter establishing, modifying, or revoking a regulation, or 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.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 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 60th day following the date of the publication in the FEDERAL REGISTER of the order to which the objection is taken (or, if such 60th day is a Saturday, Sunday, or Federal holiday, not later than the close of business of the next government business day after such 60th day).

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

(1) Mailed submissions should be addressed to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(2) For hand/courier delivery the Office of the Hearing Clerk is located at Suite 350, 1099 14th St., NW., Washington, DC 20005.

[55 FR 50291, Dec. 5, 1990, as amended at 69 FR 39864, July 1, 2004; 70 FR 33359, June 8, 2005; 71 FR 35546, June 21, 2006]

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§ 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

§ 178.35

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 or prior order.

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

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lish an order setting forth any revision to the regulation or prior order that the Administrator has found to be warranted.

(b) The Administrator will provide an opportunity for objections and requests for hearing on such order 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.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 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 FFDC section 408(g)(2)(B) or section 408(g)(2)(C) 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.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

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 FFDC section 408(h),

as of the date of publication of the order in the FEDERAL REGISTER. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

[70 FR 33359, June 8, 2005]

§ 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 § 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.

(3) 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.

(4) 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.

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

(6) 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.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

PART 179—FORMAL EVIDENTIARY PUBLIC HEARING

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