

## § 180.8

*www.regulations.gov* where the full text of the summary required in paragraph (b) of this section is located, and refer interested parties to this document for further information on the petition. The full text of the summary may be omitted from the notice.

(g) The Administrator may request a sample of the pesticide chemical at any time while a petition is under consideration. The Administrator shall specify in its request for a sample of the pesticide chemical, a quantity which it deems adequate to permit tests of analytical methods used to determine residues of the pesticide chemical and of methods proposed by the petitioner for removing any residues of the chemical that exceed the tolerance proposed.

(h) The Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a tolerance regulation (whether or not in accord with the action proposed by the petitioner), whether to publish a proposed tolerance regulation and request public comment thereon under § 180.29, or whether to deny the petition. The Administrator shall publish in the FEDERAL REGISTER such order or proposed regulation. After receiving comments on any proposed regulation, the Administrator may issue an order that establishes, modifies, or revokes a tolerance 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. A regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation.

[70 FR 33360, June 8, 2005, as amended at 73 FR 75600, Dec. 12, 2008]

### § 180.8 Withdrawal of petitions without prejudice.

In some cases the Administrator will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of

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additional data. This withdrawal may be without prejudice to a future filing. A deposit for fees as specified in § 180.33 shall accompany the resubmission of the petition.

[70 FR 33361, June 8, 2005]

### § 180.9 Substantive amendments to petitions.

After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date.

[70 FR 33361, June 8, 2005]

### § 180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.

(a) Upon the Administrator's own initiative, the Administrator may propose, under FFDCA section 408(e), the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance, or a regulation modifying or revoking an existing tolerance or exemption.

(b) The Administrator shall provide a period of not less than 60 days for persons to comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(c) After reviewing any timely comments received, the Administrator may by order establish, modify, or revoke a tolerance regulation, which order and regulation shall be published in the FEDERAL REGISTER. An order published under this section shall state that persons may submit objections and requests for a hearing in the manner described in part 178 of this chapter.

(d) Any final regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation.

[70 FR 33361, June 8, 2005]

### § 180.30 Judicial review.

(a) Under FFDCA section 408(h), judicial review is available in the United

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States Courts of Appeal as to the following actions:

(1) Regulations establishing general procedures and requirements under FFDCA section 408(e)(1)(C).

(2) Orders issued under FFDCA section 408(f)(1)(C) requiring the submission of data.

(3) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to establishment, modification, or revocation of a tolerance or exemption under FFDCA section 408(d)(4), or any regulation that is the subject of such an order. The underlying action here is Agency disposition of a petition seeking the establishment, modification, or revocation of a tolerance or exemption.

(4) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the denial of a petition under FFDCA section 408(d)(4).

(5) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the establishment, modification, suspension, or revocation of a tolerance or exemption under FFDCA section 408(e)(1)(A) or (e)(1)(B). The underlying action here is the establishment, modification, suspension, or revocation of a tolerance or exemption upon the initiative of EPA including EPA actions pursuant to FFDCA sections 408(b)(2)(B)(v), 408(b)(2)(E)(ii), 408(d)(4)(C)(ii), 408(l)(4), and 408(q)(1).

(6) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the revocation or modification of a tolerance or exemption under FFDCA section 408(f)(2) for noncompliance with requirements for the submission of data.

(7) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to rules issued under FFDCA sections 408(n)(3) and 408(d) or (e) regarding determinations pertaining to State authority to establish regulatory limits on pesticide chemical residues.

(8) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to orders issued under FFDCA section 408(n)(5)(C) authorizing States to establish regulatory limits not identical to certain tolerances or exemptions.

(b) Any issue as to which review is or was obtainable under paragraph (a) of this section shall not be the subject of judicial review under any other provi-

sion of law. In part, this means that, for the Agency actions subject to the objection procedure in FFDCA section 408(g)(2), judicial review is not available unless an adversely affected party exhausts these objection procedures, and any petition procedures preliminary thereto.

[70 FR 33362, June 8, 2005]

### § 180.31 Temporary tolerances.

(a) A temporary tolerance (or exemption from a tolerance) established under the authority of FFDCA section 408(r) shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of FFDCA section 408(a)(1) or (a)(2) and for the purposes of § 180.30.

(b) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained or is seeking an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by such data as are available on subjects outlined in § 180.7(b) and an advance deposit to cover fees as provided in § 180.33.

(c) To obtain a temporary tolerance, a requestor must comply with the petition procedures specified in FFDCA section 408(d) and § 180.7 except as provided in this section.

(d) A temporary tolerance or exemption from a tolerance may be issued for a period designed to allow the orderly marketing of the raw agricultural commodities produced while testing a pesticide chemical under an experimental permit issued under authority of the Federal Insecticide, Fungicide, and Rodenticide Act if the Administrator concludes that the safety standard in FFDCA section 408(b)(2) or (c), as applicable, is met. Subject to the requirements of FFDCA section 408(e), a temporary tolerance or exemption from a tolerance may be revoked if the experimental permit is revoked, or may be revoked at any time if it develops that the application for a temporary tolerance contains a misstatement of a material fact or that new scientific data or experience with the pesticide chemical indicates that it does not meet the safety standard in FFDCA section 408(b)(2) or (c), as applicable.