

## Environmental Protection Agency

## § 180.30

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 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 provision of law. In part, this means that, for the Agency actions subject to the

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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.

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### § 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.

(e) Conditions under which a temporary tolerance is established shall include:

(1) A limitation on the amount of the chemical to be used on the designated crops permitted under the experimental permit.

(2) A limitation for the use of the chemical on the designated crops to bona fide experimental use by qualified persons as indicated in the experimental permit.

(3) A requirement that the person or firm which obtains the experimental permit for which the temporary tolerance is established will immediately inform the Environmental Protection Agency of any reports on findings from the experimental use that have a bearing on safety.

(4) A requirement that the person or firm which obtained the experimental permit for which the temporary tolerance is established will keep records of production, distribution, and performance for a period of 2 years and, on request, at any reasonable time, make these records available to any authorized officer or employee of the Environmental Protection Agency.

[70 FR 33362, June 8, 2005]

### § 180.32 Procedure for modifying and revoking tolerances or exemptions from tolerances.

(a) The Administrator on his/her own initiative may propose the issuance of a regulation modifying or revoking a tolerance for a pesticide chemical residue on raw agricultural commodities or processed foods or modifying or revoking an exemption from tolerance for such residue.

(b) Any person may file with the Administrator a petition proposing the issuance of a regulation modifying or revoking a tolerance or exemption from a tolerance for a pesticide chemical residue. The petition shall furnish reasonable grounds for the action sought. Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such tolerance or exemption from tolerance and an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available