

Environmental Protection Agency

§ 180.29

with the committee. Except for discussions with authorized persons the committee shall not disclose data originating with a petitioner prior to publication of a regulation.

ADOPTION OF TOLERANCE ON INITIATIVE OF ADMINISTRATOR OR ON REQUEST OF INTERESTED PERSONS; JUDICIAL REVIEW; TEMPORARY TOLERANCES; AMENDMENT AND REPEAL OF TOLERANCES; FEES

§ 180.29 Adoption of tolerance on initiative of Administrator or on request of an interested person.

(a) Upon the Administrator's own initiative, or at the written request of any interested person furnishing reasonable grounds therefor and such fees or deposits as are prescribed by § 180.33, the Administrator may propose, under sec. 408(e) of the Federal Food, Drug, and Cosmetic Act, 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. As used in the preceding sentence, "reasonable grounds" shall include a statement describing the nature of the requestor's interest in issuance of such a tolerance or exemption, and adequate data on subjects outlined in sec. 408(d)(1) (A) through (F) of the Federal Food, Drug, and Cosmetic Act. Any petition received by the Agency which requests establishment of a tolerance or exemption for pesticide residues in or on a raw agricultural commodity that result from any pesticide use not directly associated with producing, storing, or transporting that commodity, will be treated by the Agency as a request for issuance of the tolerance or exemption under sec. 408(e) of that Act. (As the Agency interprets that Act, the certification of usefulness which is a prerequisite of issuing a regulation under sec. 408(d) can only be made with respect to pesticides used to help produce, store, or transport the commodity for which the tolerance or exemption is sought.) Requests shall be submitted in duplicate to: Registration Division (TS-767), Environmental Protection Agency, Washington, DC 20460. If any part of the request or supporting data is in a language other than

English, it must be accompanied by a complete and accurate English translation. If the Administrator decides that a request does not warrant a proposal for the issuance of a regulation, he shall so inform the requestor and state the reasons for his decision.

(b) The notice of the proposal shall show whether it is made on the initiative of the Administrator or at the request of an interested person, naming such person.

(c) If within 30 days after publication of the proposal a person who has registered, or who has submitted an application for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests in writing that the proposal be referred to an advisory committee and makes advance deposit as provided by § 180.33, the Administrator shall appoint a committee as provided in § 180.11 and refer the proposal and relevant data to such committee. The Agency and the committee shall proceed as prescribed in section 408 and this part.

(d) If further advance deposits are not made upon request of the Administrator, as provided in § 180.33, the request for referral of the petition to an advisory committee shall be considered withdrawn, and a tolerance shall be established within 90 days from the date on which the Administrator requested the further advance deposit.

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

(f) 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.

(g) 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.

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(h) In ruling on a request under paragraph (a) of this section, the Administrator may publish a FEDERAL REGISTER notice requesting information and views on the request, or provide other procedures as a matter of discretion.

(i) When a request is denied under this section, the administrative record consists of:

(1) The request, including all data and information submitted in support of the request.

(2) Any FEDERAL REGISTER notice requesting information and views.

(3) Any comments submitted by members of the public in response to the FEDERAL REGISTER notice requesting information and views.

(4) If the request resulted in any other procedures, the order of the Administrator providing the procedures and the administrative record of the procedure provided.

(5) All other documents or information submitted to the record.

(6) The Administrator's order and decision on the request, including all information identified by the Administrator as part of the record.

[36 FR 22540, Nov. 25, 1971, as amended at 46 FR 3020, Jan. 13, 1981; 55 FR 21200, May 23, 1990; 55 FR 50300, Dec. 5, 1990]

§ 180.30 Judicial review.

(a) It is the Agency's view that the Act does not allow a person to obtain direct judicial review of a regulation issued under this part that establishes, amends, or revokes a tolerance regulation or a regulation exempting a pesticide chemical from the need for a tolerance. 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 objections (see sections 408(d)(5) and 408(i) of the Act).

(b) A decision under §§ 180.29 and 180.32 that a request does not warrant the issuance of a proposed regulation is final agency action. Although the Act makes no special provision for review of such final agency action, the action may be reviewable under other provi-

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sions of the United States Code (see e.g., 5 U.S.C. 701-706, 28 U.S.C. 1331).

[55 FR 50300, Dec. 5, 1990]

§ 180.31 Temporary tolerances.

(a) A temporary tolerance (or exemption from a tolerance) established under authority of section 408(j) of the act shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of section 408(a) (1) or (2) of the act.

(b)(1) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by a copy of such experimental permit, such data as are available on subjects outlined in clauses (A), (B), (C), (D), (E), (F), and (G) of section 408(d)(1), and an advance deposit to cover fees as provided in § 180.33(d).

(2) Before an experimental permit has been obtained, the Pesticides Tolerance Division upon request of the Environmental Protection Agency or a person who proposes to apply for an experimental permit will consider available data and discuss its adequacy for the purpose of justifying a tolerance or exemption from a tolerance.

(c) A notice of the issuance of a temporary tolerance outlining any restrictions as to use of the chemical imposed under the experimental permit under the Federal Insecticide, Fungicide, and Rodenticide Act may be published in the FEDERAL REGISTER if the Administrator deems such publication desirable.

(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 when the Administrator concludes that the public health can be adequately protected during such marketing. A temporary tolerance or exemption from a tolerance may be revoked if the experimental permit is revoked, or may be revoked