

Environmental Protection Agency

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such other relevant, reliable information as may be available. When the Administrator submits a proposal to an advisory committee, he shall inform the petitioner and furnish him with copies of material other than the petition and certification that is furnished the committee. The chairman of the committee shall acknowledge receipt of the information and readiness of the committee to act. The date of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. Copy of this acknowledgement shall be forwarded to the petitioner by the chairman of the committee.

(b) A secretariat to advisory committees will be established by the Administrator. The secretariat shall furnish members of the committee with copies of the proposal or petition, certification from the Administrator, and any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so advise the Administrator. Such meetings shall be held in Washington, DC, or such other place as the Administrator may designate. The Administrator shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(c) As soon as practicable, but not later than 60 days after receipt of proposal or petition (unless the time has been extended as provided in paragraph (d) of this section), the chairman shall certify to the Administrator the report of the committee, including any minority report, and shall return the petition for tolerances and the certification. The report will include copies of all relevant material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. The report of the advisory committee shall be available for inspection by any interested person after a tolerance or exemption resulting from the petition is published.

(d) If at any time within 60 days, the chairman believes that the advisory

committee needs more time, he shall so inform the Administrator in writing, in which case he shall make the certification contemplated by section 408(d)(3) of the act within the additional 30 days.

(e) The date of receipt of the committee report will be the date for computing time for the Administrator to act for the purposes of both sections 408 (d)(3) and (e).

(f) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion as to the member who may best represent the committee at a hearing, if one occurs.

(g) More than one petition or proposal may be handled by a committee concurrently.

(h) Persons authorized under section 408(h) to discuss proposals or petitions with the committee shall notify the chairman and if practicable make appointments through him. The report of the committee shall show the names of persons other than committee members discussing proposals or petitions 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.

(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.

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(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 provisions 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 En-

vironmental 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 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 may be hazardous to the public health.

(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