

it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is a reasonable expectation of finite residues in light of data reflecting exaggerated pesticides levels in feeding studies, a tolerance will be established on the raw agricultural commodity provided that appropriate tolerances can be established at the same time, on the basis of the toxicological and other data available, for the finite residues likely to be incurred in these foods through the feed use of the raw agricultural commodity or its byproducts. When it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is no reasonable expectation of finite residues in light of data such as those reflecting exaggerated pesticide levels in feeding studies and those elucidating the biochemistry of the pesticide chemical in the animal, a tolerance may be established on the raw agricultural commodity without the necessity of a tolerance on food products derived from the animal.

(c) The principles outlined in paragraphs (a) and (b) of this section will also be followed with respect to tolerances for residues which will actually be incurred or are reasonably to be expected in milk, eggs, meat, and/or poultry by the use of pesticides directly on the animal or administered purposely in the feed or drinking water.

(d) Tolerances contemplated by paragraphs (a) and (b) of this section will in addition to toxicological considerations be conditioned on the availability of a practicable analytical method to determine the pesticide residue; that is, the method must be sensitive and reliable at the tolerance level or in special cases at a higher level where such level is deemed satisfactory and safe in light of the toxicity of the pesticide residue and of the unlikelihood of such residue exceeding the tolerance. The analytical methods to be used for enforcement purposes will be those set forth in the "Pesticide Analytical Manual" (see §180.101(c)). The sensitivities of these methods are expressed in that manual.

Subpart B—Procedural Regulations

PROCEDURE FOR FILING PETITIONS

§ 180.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities.

(a) Petitions to be filed with the Agency under the provisions of section 408(d) shall be submitted in duplicate to the Registration Division. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall be accompanied by an advance deposit for fees described in §180.33. The petition shall state petitioner's mail address to which notice of objection under section 408(d)(5) may be sent.

(b) Petitions shall include the following data and be submitted in the following form:

(Date) _____

Registration Division,
Environmental Protection Agency,
Washington, DC 20460

Dear Sirs:

The undersigned, _____, submits this petition pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical _____.

Attached hereto, in duplicate and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical. (If the pesticide chemical is an ingredient of an economic poison, the complete quantitative formula of the resulting economic poison should be submitted. The submission of this information does not restrict the application of any tolerance or exemption granted to the specific formula(s) submitted.)

B. The amount, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical. (These reports should include, where necessary, detailed data derived from appropriate animal or other biological experiments in which the methods used and the results obtained are clearly set forth.)

D. The results of tests on the amount of residue remaining, including a description of the analytical method used. (See §180.34 for further information about residue tests.)

E. Practicable methods for removing residue that exceeds any proposed tolerance.

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F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

Enclosed is (money order, bank draft, or certified check) for \$_____, payable to the Environmental Protection Agency to cover clerical operations, initial administrative review, and the cost incurred in considering the petition after it has been filed.

Very truly yours,

(Petitioner)
Per _____
(Indicate authority)
Mail address _____

This petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

The data specified under the several lettered headings should be on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by reference to the earlier one.

The petition shall be submitted in duplicate. The petitioner shall show that he has registered or has submitted an application for the registration of an economic poison containing the pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act.

(c) Except as noted in paragraph (d) of this section, a petition shall not be accepted for filing if any of the data prescribed by section 408(d) are lacking or are not set forth so as to be readily understood. The availability to the public of information provided to, or otherwise obtained by, the Agency under this part shall be governed by part 2 of this chapter.

(d) The Registration Division shall notify the petitioner within 15 days after its receipt of acceptance or non-acceptance of a petition, and if not accepted the reasons therefor. Copy of the notice shall be sent to the Registration Division, Environmental Protection Agency. If accepted, the date of notification becomes the date of filing for the purposes of section 408(d)(1). If petitioner desires, he may supplement a deficient petition after notification as to deficiencies. If the supplementary material or explanation of petition is deemed acceptable, petitioner shall be notified, and date of such notification becomes the date of filing. If the petitioner does not wish to supplement or

explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. The Administrator shall publish in the FEDERAL REGISTER within 30 days a notice of filing, name of petitioner, and a brief outline of the petition, including description of analytical method or reference to a publication in which it appears, if such publication is generally available.

(e) The Registration Division may request a sample of the pesticide chemical at any time while a petition is under consideration. The Registration Division 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. The date used for computing the 90-day limit for the purposes of section 408(d)(2) shall be moved forward 1 day for each day in excess of 15 from the mailing date of the request taken by the petitioner to submit the sample. If the sample is not submitted within 180 days after mailing date of the request, the petition will be considered withdrawn without prejudice.

(f) The date of receipt from the Administration of certification as to usefulness shall be the date used for computing the 90-day limit for the purposes of section 408(d)(2).

(g) If the petition is not referred to an advisory committee, or upon receipt of the report of an advisory committee under §180.12(c) if such a referral occurred, 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), or whether to publish a proposed tolerance regulation and request public comment thereon under §180.29. 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

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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.

[36 FR 22540, Nov. 25, 1971, as amended at 41 FR 36918, Sept. 1, 1976; 46 FR 34345, July 1, 1981; 55 FR 21200, May 23, 1990; 55 FR 50299, Dec. 5, 1990]

§ 180.8 Withdrawal of petitions without prejudice.

In some cases the Registration Division or an advisory committee to which the petition has been referred 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 additional data. This withdrawal may be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling or the date of receipt of certification from the Administrator, whichever is later. A deposit for fees as specified in § 180.33 shall accompany the resubmission of the petition.

[46 FR 22450, Nov. 25, 1971, as amended at 46 FR 34345, July 1, 1981; 55 FR 21200, May 23, 1990]

§ 180.9 Substantive amendments to petitions.

After a petition has been filed or referred to an advisory committee, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date or a new initial date of consideration by the advisory committee, and the time limitation will begin to run anew.

[41 FR 4537, Jan. 30, 1976, as amended at 55 FR 21200, May 23, 1990]

ADVISORY COMMITTEES

§ 180.10 Referral of petition to advisory committee.

(a) If within the prescribed period a person filing a petition requests that the petition be referred to an advisory committee, he shall make such request in writing to the Administrator and forward with such request an advance deposit for fees prescribed by § 180.33.

(b) If further advance deposits are not made upon request of the Administrator, as provided for 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 of the date on which the Administrator requested the further advance deposit.

(c) In case the Administrator on his own initiative deems it necessary to refer a petition to an advisory committee, he shall, in writing, so inform the person filing the petition.

[41 FR 4537, Jan. 30, 1976, as amended at 55 FR 21200, May 23, 1990]

§ 180.11 Appointment of advisory committee.

(a) Whenever the referral of a petition or proposal to an advisory committee is requested or the Administrator otherwise deems such referral necessary, the Administrator will request the National Academy of Sciences, National Research Council, to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in biology, medicine, physiology, toxicology, pharmacology, veterinary medicine, or other appropriate science to evaluate the safety of pesticide chemicals. The Administrator will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(b) Each advisory committee shall consist of not less than three experts,