Environmental Protection Agency

Subpart B—Procedural Regulations

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

(a) Petitions to be filed with the Agency under the provisions of FFDCA section 408(d) shall be submitted in duplicate. 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 the petitioner’s mail address to which notice of objection under FFDCA section 408(g)(2) may be sent. The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(b) Petitions shall include the following information:

(1) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition. Both a paper and electronic copy of the summary should be submitted. The electronic copy should be formatted according to the Office of Pesticide Programs’ current standard for electronic data submission as specified at http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.

(2) A statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under FFDCA section 408(q)(2) may be sent. The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(c) The data specified under paragraphs (b)(1) through (b)(16) of this section should be on separate sheets or sets of sheets, suitably identified. If such data have already been submitted.

(6) Full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used. (See §180.34 for further information about residue tests.)

(7) Proposed tolerances for the pesticide chemical residue if tolerances are proposed.

(8) Practicable methods for removing any amount of the residue that would exceed any proposed tolerance.

(9) A practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed.

(10) If the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food.

(11) Such information as the Administrator may require to make the determination under FFDCA section 408(b)(2)(C).

(12) Such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(13) Information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue.

(14) Information concerning any maximum residue level established by the Codex Alimentarius Commission for the pesticide chemical residue addressed in the petition. If a Codex maximum residue level has been established for the pesticide chemical residue and the petitioner does not propose that this level be adopted, a statement explaining the reasons for this departure from the Codex level.

(15) Such other data and information as the Administrator requires by regulation to support the petition.

(16) Reasonable grounds in support of the petition.
§ 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 the 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. A deposit for fees as specified in §180.33

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]