

chemical residue" under FFDC section 201(q)(3) and are therefore exempt from regulation under FFDC section 402(a)(2)(B) and 408. These substances are subject to regulation by the Food and Drug Administration as food additives under FFDC section 409.

(a) Inert ingredients in food packaging impregnated with an insect repellent when such inert ingredients are the components of the food packaging material (e.g., paper and paperboard, coatings, adhesives, and polymers).

(b) [Reserved]

[63 FR 10720, Mar. 4, 1998]

§ 180.5 Zero tolerances.

A zero tolerance means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

(c) The pesticide chemical is toxic, but is normally used at times when, or in such manner that, fruit, vegetables, or other raw agricultural commodities will not bear or contain it.

(d) All residue of the pesticide chemical is normally removed through good agricultural practice such as washing or brushing or through weathering or other changes in the chemical itself, prior to introduction of the raw agricultural commodity into interstate commerce.

§ 180.6 Pesticide tolerances regarding milk, eggs, meat, and/or poultry; statement of policy.

(a) When establishing tolerances for pesticide residues in or on raw agricultural commodities, consideration is always given to possible residues of those pesticide chemicals or their conversion products entering the diet of man through the ingestion of milk, eggs, meat, and/or poultry produced by ani-

mals fed agricultural products bearing such pesticide residues. In each instance an evaluation of all available data will result in a conclusion either:

(1) That finite residues will actually be incurred in these foods from feed use of the raw agricultural commodity including its byproducts; or

(2) That it is not possible to establish with certainty whether finite residues will be incurred, but there is a reasonable expectation of finite residues; or

(3) That it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

(b) When the data show that finite residues will actually be incurred in milk, eggs, meat, and/or poultry, a tolerance will be established on the raw agricultural commodity used as feed provided that tolerances can be established at the same time, on the basis of the toxicological and other data available, for the finite residues incurred in milk, eggs, meat, and/or poultry. 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 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

§ 180.7

40 CFR Ch. I (7-1-04 Edition)

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.

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,

Per _____ (Petitioner)

Mail address _____ (Indicate authority)

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