

§ 180.4

Phorate (*O,O*-diethyl *S*-(ethylthio)methyl phosphorodithioate) and its cholinesterase-inhibiting metabolites.
Phosalone (*S*-(6-chloro-3-mercaptomethyl)-2-benzoxazolinone) *O,O*-diethyl phosphorodithioate).
Phosphamidon (2-chloro-2-diethylcarbomoyl-1-methylvinyl dimethyl phosphate) including all of its related cholinesterase-inhibiting compounds.
Pirimiphos-methyl *O*-[2-diethylamino-6-methyl-pyrimidinyl] *O,O*-dimethyl phosphorothioate
Ronnel.
Schradan (octamethylpyrophosphoramide).
Tetraethyl pyrophosphate.
O,O,O',O'-Tetramethyl *O,O'*-sulfinyldi-*p*-phenylene phosphorothioate.
O,O,O',O'-Tetramethyl *O,O'*-thiodi-*p*-phenylene phosphorothioate.
Tributyl phosphorotritilioite.
S,S,S-Tributyl phosphorothrithioate.
3,4,5-Trimethylphenyl methylcarbamate and its isomer 2,3,5-trimethylphenyl methylcarbamate.

(6) The following pesticides are members of the class of dinitrophenols:

2,4-Dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate, mixture of.

4,6-Dinitro-*o*-cresol and its sodium salt.

Dinoseb (2-*sec*-butyl-4,6-dinitrophenol) and its alkanolamine, ammonium, and sodium salts.

[41 FR 8969, Mar. 2, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.3, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 180.4 Exceptions.

The substances listed in this section are excepted from the definitions of "pesticide chemical" and "pesticide chemical residue" under FFDCA section 201(q)(3) and are therefore exempt from regulation under FFDCA section 402(a)(2)(B) and 408. These substances are subject to regulation by the Food and Drug Administration as food additives under FFDCA section 409.

(a) Inert ingredients in food packaging treated with a pesticide, 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, as amended at 73 FR 54976, Sept. 24, 2008]

40 CFR Ch. I (7-1-20 Edition)

§ 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 animals 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 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

§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(d)(3) and as a part of a proposed or final regulation issued under FFDCA section 408.

(3) The name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue.