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U.S. GOVERNMENT
INFORMATION
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Title 40—Protection of Environment

(This book contains parts 150 to 189)

Part

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CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter I appear at 65 FR 47324, 47325, Aug. 2, 2000, and at 66 FR 34375, 34376, June 28, 2001.

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SUBCHAPTER E—PESTICIDE PROGRAMS

PART 150—GENERAL

AUTHORITY: Reorganization Plan No. 3 of 1970 (5 U.S.C. App.).

§ 150.17 Addresses for applications and correspondence.

The official addresses for all submissions directed to the Office of Pesticide Programs (OPP) of the Environmental Protection Agency are as follows:

(a) *United States Postal Service mailing address.* Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460–0001.

(b) *Hand/courier delivery address.* Office of Pesticide Programs, Environmental Protection Agency, 2777 S. Crystal Dr., Arlington, VA 22202–4501.

(c) *OPP Regulatory Public Docket address.* OPP Regulatory Public Docket is physically located in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202–4501. This is not a mailing address.

[71 FR 35545, June 21, 2006]

PART 151 [RESERVED]

PART 152—PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

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AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Subpart A—General Provisions

SOURCE: 53 FR 15975, May 4, 1988, unless otherwise noted.

§ 152.1 Scope.

(a) Part 152 sets forth procedures, requirements and criteria concerning the registration of pesticide products under FIFRA section 3, including plant-incorporated protectants (PIPs). Unless specifically superseded by part 174, the regulations in part 152 apply to PIPs.

(b) Part 152 also describes associated regulatory activities affecting registration, as described in this paragraph.

(1) *Data compensation and exclusive use of data in support of registration.* Refer to subpart E of this part.

(2) *Rights and obligations of registrants.* Refer to subpart G of this part.

(3) *Classification of pesticide uses.* Refer to subpart I of this part.

(4) *Fees.* Refer to subpart U of this part.

(5) *Requirements pertaining to pesticide devices.* Refer to subpart Z of this part.

[73 FR 75594, Dec. 12, 2008]

§ 152.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, the following terms have the meanings set forth in this section.

Act or *FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in § 174.3 of this chapter.

Acute dermal LD_{50} means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC_{50} means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD_{50} means a statistically derived estimate of the single oral dose

of a substance that would cause 50 percent mortality to the test population under specified conditions.

Administrator means the Administrator of the United States Environmental Protection Agency or his delegate.

Agency means the United States Environmental Protection Agency (EPA), unless otherwise specified.

Applicant means a person who applies for a registration or amended registration under FIFRA sec. 3.

Biological control agent means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

Distribute or sell and other grammatical variations of the term such as ''distributed or sold'' and ''distribution or sale,'' means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

End use product means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

Final printed labeling means the label or labeling of the product when distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by § 174.3 of this chapter.

Institutional use means any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

(1) Hospitals and nursing homes.

(2) Schools other than preschools and day care facilities.

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Manufacturing use product means any pesticide product that is not an end-use product.

New use, when used with respect to a product containing a particular active ingredient, means:

(1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation under section 408 of the Federal Food, Drug and Cosmetic Act;

(2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

(3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Operated by the same producer, when used with respect to two establishments, means that each such establishment is either owned by, or leased for operation by and under the control of, the same person. The term does not include establishments owned or operated by different persons, regardless of contractural agreement between such persons.

Package or *packaging* means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use, or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(1) Is a new animal drug under FFDCA sec. 201(w), or

(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or

(3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s)(1) or (2) of this section.

Pesticide product means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Released for shipment. A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where finished products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment unless subsequent activities, such as relabeling or repackaging, constitute production.

Residential use means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

[53 FR 15975, May 4, 1988, as amended at 66 FR 37814, July 19, 2001; 73 FR 64224, Oct. 29, 2008; 73 FR 75594, Dec. 12, 2008]

§ 152.5 Pests.

An organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is:

(a) Any vertebrate animal other than man;

(b) Any invertebrate animal, including but not limited to, any insect, other arthropod, nematode, or mollusk such as a slug and snail, but excluding any internal parasite of living man or other living animals;

(c) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher order, and any plant part such as a root; or

(d) Any fungus, bacterium, virus, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA sec. 201(g)(1)) and cosmetics (as defined in FFDCA sec. 201(i)).

§ 152.6 Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) *Liquid chemical sterilants.* A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

(1) *Composition*. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

(2) *Claims.* The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than ''sterilant'' are not excluded and are jointly regulated by EPA and FDA.

(3) *Use site.* (i) The product must be intended and labeled only for use on ''critical or semi-critical devices.'' A ''critical device'' is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A *semi-critical device* is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(ii) Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA.

(iii) Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

(b) *Nitrogen stabilizers.* A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria:

(1) The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of this section, living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

(2) The substance was in ''commercial agronomic use'' in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

(3) The substance was not registered under FIFRA before January 1, 1992.

(4) Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. EPA considers any of the following claims (or their equivalents) to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production:

(i) Improves crop utilization of applied nitrogen.

(ii) Reduces leaching of applied nitrogen or reduces groundwater nitrogen contamination.

(iii) Prevents nitrogen loss.

(iv) Prolongs availability of nitrogen.

(v) Increases nitrogen uptake, availability, usage, or efficiency.

(5) A product will be considered to have met the criterion of paragraph (b)(4) of this section that no nitrogen stabilization claim has been made if:

(i) The nitrogen stabilization claim, in whatever terms expressed, is made solely in compliance with a State requirement to include the claim in materials required to be submitted to a State legislative or regulatory authority, or in the labeling or other literature accompanying the product; and

(ii) The State requirement to include the claim was in effect both before the product bearing the claim was introduced into commercial agronomic use, and before the effective date of this rule.

(6) A product that meets all of the criteria of this paragraph with respect to one State is not thereby excluded from FIFRA regulation if distributed and sold in another State whose nitrogen stabilization statement requirement does not meet the requirements of paragraph (b)(5)(ii) of this section.

(c) *Human drugs.* Fungi, bacteria, viruses or other microorganisms in or on living man are not ''pests'' as defined in section 2(t) of FIFRA. Products intended and labeled for use against such organisms are human drugs subject to regulation by the FDA under the FFDCA.

(d) *Animal drugs.* (1) Fungi, viruses, bacteria or other microorganisms on or in living animals are not ''pests'' under section 2(t) of FIFRA. Products intended for use against such organisms

are ''animal drugs'' regulated by the FDA under the FFDCA.

(2) A ''new animal drug'' as defined in section 201(w) of the FFDCA, or an animal drug that FDA has determined is not a ''new animal drug'' is not a pesticide under section 2(u) of FIFRA. Animal drugs are regulated by the FDA under the FFDCA.

(e) *Animal feeds.* An animal feed containing a new animal drug is not a pesticide under section 2(u) of FIFRA. An animal feed containing a new animal drug is subject to regulation by the FDA under the FFDCA.

(f) *Vitamin hormone products.* A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a ''plant regulator'' under section 2(v) of FIFRA, provided it meets the following criteria:

(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of §156.62 of this chapter for Toxicity Category III or IV; and

(2) The product is not intended for use on food crop sites, and is labeled accordingly.

(g) *Products intended to aid the growth of desirable plants.* A product of any of the following types, intended only to aid the growth of desirable plants, is not a ''plant regulator'' under section 2(v) of FIFRA, and therefore is not a pesticide:

(1) A plant nutrient product, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

(2) A plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.

(3) A soil amendment product containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth.

[66 FR 64763, Dec. 14, 2001, as amended at 73 FR 75594, Dec. 12, 2008]

§152.8 Products that are not pesticides because they are not for use against pests.

A substance or article is not a pesticide, because it is not intended for use against ''pests'' as defined in §152.5, if it is:

(a) A fertilizer product not containing a pesticide.

(b) A product intended to force bees from hives for the collection of honey crops.

[53 FR 15975, May 4, 1988, as amended at 66 FR 64764, Dec. 14, 2001]

§152.10 Products that are not pesticides because they are not intended for a pesticidal purpose.

A product that is not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate or regulate the growth of plants, is not considered to be a pesticide. The following types of products or articles are not considered to be pesticides unless a pesticidal claim is made on their labeling or in connection with their sale and distribution:

(a) Deodorizers, bleaches, and cleaning agents;

(b) Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly;

(c) Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.

§152.15 Pesticide products required to be registered.

No person may distribute or sell any pesticide product that is not registered under the Act, except as provided in §§152.20, 152.25, and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, *i.e.*, use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

Subpart B—Exemptions

SOURCE: 53 FR 15977, May 4, 1988, unless otherwise noted.

§ 152.20 Exemptions for pesticides adequately regulated by another Federal agency.

The pesticides or classes of pesticide listed in this section are exempt from all requirements of FIFRA. The Agency has determined, in accordance with FIFRA sec. 25(b)(1), that they are adequately regulated by another Federal agency.

(a) *Certain biological control agents.* (1) Except as provided by paragraphs (a)(3) and (a)(4) of this section, all biological control agents are exempt from FIFRA requirements.

(2) If the Agency determines that an individual biological control agent or class of biological control agents is no longer adequately regulated by another Federal agency, and that it should not otherwise be exempted from the requirements of FIFRA, the Agency will revoke this exemption by amending paragraph (a)(3) of this section.

(3) The following biological control agents are not exempt from FIFRA requirements:

(i) A eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(ii) A procaryotic microorganism including, but not limited to, Eubacteria and Archaebacteria; or

(iii) A parasitically-replicating microscopic element, including, but not limited to, viruses.

(4) All living plants intended for use as biological control agents are exempt from the requirements of FIFRA. However, plant-incorporated protectants are not exempt pursuant to this section. Regulations, including exemptions, for plant-incorporated protectants are addressed in part 174 of this chapter.

(b) *Non-liquid chemical sterilants.* A non-liquid chemical sterilant, except ethylene oxide, that meets the criteria of § 152.6(a)(2) with respect to its claims and § 152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.

[53 FR 15977, May 4, 1988, as amended at 66 FR 37814, July 19, 2001; 66 FR 64764, Dec. 14, 2001; 72 FR 61027, Oct. 26, 2007]

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

(a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

(b) *Pheromones and pheromone traps.* Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient(s).

(1) For the purposes of this paragraph, a pheromone is a compound produced by an arthropod which, alone or

in combination with other such compounds, modifies the behavior of other individuals of the same species.

(2) For the purposes of this paragraph, a synthetically produced compound is identical to a pheromone only when their molecular structures are identical, or when the only differences between the molecular structures are between the stereochemical isomer ratios of the two compounds, except that a synthetic compound found to have toxicological properties significantly different from a pheromone is not identical.

(3) When a compound possesses many characteristics of a pheromone but does not meet the criteria in paragraph (a)(2) of this section, it may, after review by the Agency, be deemed a substantially similar compound.

(4) For the purposes of this paragraph, a pheromone trap is a device containing a pheromone or an identical or substantially similar compound used for the sole purpose of attracting, and trapping or killing, target arthropods. Pheromone traps are intended to achieve pest control by removal of target organisms from their natural environment and do not result in increased levels of pheromones or identical or substantially similar compounds over a significant fraction of the treated area.

(c) *Preservatives for biological specimens.* (1) Embalming fluids.

(2) Products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning.

(3) Products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis.

(d) *Foods.* Products consisting of foods and containing no active ingredients, which are used to attract pests.

(e) *Natural cedar.* (1) Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:

(i) The product consists totally of cedarwood or natural cedar.

(ii) The product is not treated, combined, or impregnated with any additional substance(s).

(iii) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as ''arthropods,'' ''insects,'' ''bugs,'' or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks.

(2) The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture.

(f) *Minimum risk pesticides*—(1) *Exempted products.* Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

Castor oil (U.S.P. or equivalent)
Cedar oil
Cinnamon and cinnamon oil
Citric acid
Citronella and citronella oil
Cloves and clove oil
Corn gluten meal
Corn oil
Cottonseed oil
Dried blood
Eugenol
Garlic and garlic oil
Geraniol
Geranium oil
Lauryl sulfate
Lemongrass oil
Linseed oil
Malic acid
Mint and mint oil
Peppermint and peppermint oil
2-Phenethyl propionate (2-phenylethyl propionate)
Potassium sorbate
Putrescent whole egg solids
Rosemary and rosemary oil
Sesame (includes ground sesame plant) and sesame oil
Sodium chloride (common salt)
Sodium lauryl sulfate
Soybean oil
Thyme and thyme oil
White pepper
Zinc metal strips (consisting solely of zinc metal and impurities)

(2) *Permitted inerts.* A pesticide product exempt under paragraph (f)(1) of this section may only include inert ingredients listed in the most current List 4A. This list is updated periodically. The most current list may be obtained by contacting the Registration

Division at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

[53 FR 15977, May 4, 1988, as amended at 59 FR 2751, Jan. 19, 1994; 61 FR 8878, Mar. 6, 1996; 66 FR 64764, Dec. 14, 2001; 71 FR 35545, June 21, 2006]

§ 152.30 Pesticides that may be transferred, sold, or distributed without registration.

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended, may be distributed or sold, or otherwise transferred, to the extent described by this section.

(a) *A pesticide transferred between registered establishments operated by the same producer.* An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide as transferred must be labeled in accordance with part 156 of this chapter.

(b) *A pesticide transferred between registered establishments not operated by the same producer.* An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:

(1) The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered;

(2) Each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either:

(i) A registered product; or

(ii) A pesticide that is produced by the registrant of the final product; and

(3) The product as transferred is labeled in accordance with part 156 of this chapter.

(c) *A pesticide distributed or sold under an experimental use permit.* (1) An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA sec. 5, if the product is labeled in accordance with § 172.6 of this chapter.

(2) An unregistered pesticide may be distributed or sold in accordance with the provisions of § 172.3 of this chapter, pertaining to use of a pesticide for which an experimental use permit is not required, provided the product is labeled in accordance with part 156 of this chapter.

(d) *A pesticide transferred solely for export.* An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions:

(1) The product is prepared and packaged according to the specifications of the foreign purchaser; and

(2) The product is labeled in accordance with part 156 of this chapter.

(e) *A pesticide distributed or sold under an emergency exemption.* An unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA sec. 18, if the product is labeled in accordance with part 156 of this chapter.

(f) *A pesticide transferred for purposes of disposal.* An unregistered, suspended, or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA sec. 19 or an applicable Administrator's order. The product must be labeled in accordance with part 156 of this chapter.

(g) *Existing stocks of a formerly registered product.* A cancelled or suspended pesticide may be distributed or sold to the extent and in the manner specified in an order issued by the Administrator concerning existing stocks of the pecticide.

Subpart C—Registration Procedures

SOURCE: 53 FR 15978, May 4, 1988, unless otherwise noted.

§ 152.40 Who may apply.

Any person may apply for new registration of a pesticide product. Any registrant may apply for amendment of the registration of his product.

§ 152.42 Application for new registration.

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in § 152.50. An application for new registration must be approved by the Agency before the product may legally be distributed or sold, except as provided by § 152.30.

§ 152.43 Alternate formulations.

(a) A product proposed for registration must have a single, defined composition, except that EPA may approve a basic formulation and one or more alternate formulations for a single product.

(b) An alternate formulation must meet the criteria listed in paragraph (b) (1) through (4) of this section. The Agency may require the submission of data to determine whether the criteria have been met.

(1) The alternate formulation must have the same certified limits for each active ingredient as the basic formulation.

(2) If the alternate formulation contains an inert ingredient or impurity of toxicological signficance, the formulation must have the same upper certified limit for that substance as the basic formulation;

(3) The label text of the alternate formulation product must be identical to that of the basic formulation.

(4) The analytical method required under § 158.355 of this chapter must be suitable for use on both the basic formulation and the alternate formulation.

(c) Notwithstanding the criteria in this section, the Agency may determine that an alternate formulation must be separately registered. If EPA makes this determination, the Agency will notify the applicant of its determination and its reasons. Thereafter the application for an alternate formulation will be treated as an application for new registration, and the alternate formulation will be assigned a new registration number.

[53 FR 15978, May 4, 1988, as amended at 72 FR 61027, Oct. 26, 2007]

§ 152.44 Application for amended registration.

(a) Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration;

(2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or

(3) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.46.

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

[53 FR 15978, May 4, 1988, as amended at 61 FR 33041, June 26, 1996; 66 FR 64764, Dec. 14, 2001]

§ 152.46 Notification and non-notification changes to registrations.

(a) *Changes permitted by notification.* (1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.

(2) A registrant may modify a registration consistent with paragraph (a)(1) of this section and any procedures issued thereunder and distribute or sell the modified product as soon as the Agency has received the notification. Based upon the notification, the Agency may require that the registrant submit an application for amended registration. If it does so, the Agency will notify the registrant and state its reasons for requiring an application for amended registration. Thereafter, if the registrant fails to submit an application the Agency may determine that the product is not in compliance with the requirements of the Act. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA section 12(a)(2)(M).

(b) *Changes permitted without notification.* EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of amendments permitted without notification (also known as non-notification). A registrant may distribute or sell a product changed in a manner consistent with such procedures without notification to or approval by the Agency.

(c) *Effect of non-compliance.* Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with paragraphs (a) or (b) of this section and any procedures issued thereunder, the Agency may initiate regulatory and/or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration.

[61 FR 33041, June 26, 1996]

§ 152.50 Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant*—(1) *Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the

results of the studies. The list of data submitted may be the same as the list required by § 158.32 or § 161.32, as applicable, of this chapter. The summary must state that it is releasable to the public after registration in accordance with § 152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

(1) The product name;

(2) The trade name(s) (if different); and

(3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(F) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 or part 161 of this chapter, as applicable, of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.32 of this chapter, with respect to format of data submission.

(ii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made.

(iii) Section 158.34 of this chapter, with respect to flagging for potential adverse effects.

(iv) Section 160.12 of this chapter, with respect to a statement whether studies were conducted in accordance with Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* (1) If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide chemical residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance or exemption from the requirement of a tolerance issued under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA).

(2) If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance, in accordance with part 180 of this chapter.

(j) *Fees.* (1) The applicant shall identify the appropriate fee category in the schedule provided for by FIFRA sec. 33,

and shall submit the fee for that category as prescribed by the latest EPA notice of section 33 fees.

(2) If FIFRA sec. 33 is not in effect, the applicant shall submit any fees required by subpart U of this part, if applicable.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995; 72 FR 61027, Oct, 26 2007; 73 FR 75594, Dec. 12, 2008]

§ 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be sent to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[71 FR 35545, June 21, 2006]

Subpart D [Reserved]

Subpart E—Procedures To Ensure Protection of Data Submitters' Rights

SOURCE: 49 FR 30903, Aug. 1, 1984, unless otherwise noted.

§ 152.80 General.

This subpart E describes the information that an applicant must submit with his application for registration or amended registration to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(1)(F). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

[73 FR 75594, Dec. 12, 2008]

§ 152.81 Applicability.

(a) Except as provided in paragraph (b) of this section, §§ 152.83 through 152.119 apply to:

(1) Each application for registration of a new product;

(2) Each application for an amendment of a registration; and

(3) Each application for reregistration under FIFRA section 3(g).

(b) This subpart E does not apply to:

(1) Applications for registration submitted to States under FIFRA section 24(c);

(2) Applications for experimental use permits under FIFRA section 5;

(3) Applications for emergency exemptions under FIFRA section 18;

(4) Applications to make only one or more of the following types of amendments to existing registrations, unless the Administrator or his designee finds that Agency consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5):

(i) An increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;

(ii) A revision of the identity or amount of impurities present in the product;

(iii) The addition or deletion of one or more deliberately added inert ingredients;

(iv) The deletion of one or more active ingredients;

(v) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;

(vi) Deletion of approved uses of claims;

(vii) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;

(viii) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;

(ix) Clarification of directions for use;

(x) Correction of typographical errors;

(xi) Changes in the registrant's name or address;

(xii) Adding or deleting supplemental registrants;

(xiii) Changes in the package or container size;

(xiv) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;

(xv) ''Splitting'' a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;

(xvi) Any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and

(xvii) Compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

§ 152.83 Definitions.

As used in this subpart, the following terms shall have the meanings set forth in this section:

Data gap means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

Data Submitters List means the current Agency list, entitled ''Pesticide Data Submitters by Chemical,'' of persons who have submitted data to the Agency.

Exclusive use study means a study that meets each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

Original data submitter means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(F) have been transferred, or the authorized representative of a group of joint data developers.

Valid study means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.84 When materials must be submitted to the Agency.

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.

§ 152.85 Formulators' exemption.

(a) *Statutory provision*. FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption*. (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption*. EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption*. (1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

(e) *Approval of registration*. Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

[72 FR 61027, Oct. 26, 2007]

§ 152.86 The cite-all method.

An applicant may comply with this subpart by citing all data in Agency files that are pertinent to its consideration of the requested registration

under FIFRA section 3(c)(5), in accordance with the procedures in this section, as applicable.

(a) *Exclusive use studies.* The applicant must certify to the Agency that he has obtained, from each person listed on the Data Submitters List as an exclusive use data submitter for the chemical in question, a written authorization that contains at least the following information:

(1) Identification of the applicant to whom the authorization is granted;

(2) Authorization to the applicant to use all pertinent studies in satisfaction of data requirements for the application in question; and

(3) The signature and title of the original data submitter or his authorized representative and date of the authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List, the applicant will be required prior to registration to obtain the necessary written authorization from such person.

(b) *Other studies.* The applicant must certify to the Agency that, with respect to each other person on the Data Submitters List for the chemical in question:

(1) He has obtained from that person a written authorization that contains the information required by paragraphs (a) (1) through (3) of this section; or

(2) He has furnished to that person:

(i) A notification of his intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F) for any data on which the application relies;

(iii) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study; and

(iv) His name, address and telephone number.

(c) *General offer to pay statement.* The applicant must submit to the Agency the following general offer to pay statement:

[*Name of applicant*] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA section 3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act.

(d) *Acknowledgement of reliance on data.* Each application filed under this section shall include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F) the application relies on the following data:

(1) All data submitted with or specifically cited in the application; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of the applicant's product, of any product which is identical or substantially similar to the applicant's product, or of one or more of the active ingredients in the applicant's product; and

(ii) Is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.90 The selective method.

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has previously been submitted to the Agency. This section summarizes the procedures that an applicant must follow if he chooses the selective method of demonstrating compliance. Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or demonstrating a data gap.

(a) *List of data requirements.* Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under FIFRA section 3(c)(5) for the first time. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulator's exemption.

(1) If a Registration Standard has been issued for any active ingredient, the applicant must list the applicable data requirements enumerated in that Standard for the active ingredient and, if end use products are covered by the Registration Standard, for such products containing that active ingredient.

(2) If a Registration Standard has not been issued, or if an issued Registration Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158 or part 161, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in § 152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

(b) *Methods of demonstrating compliance.* The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to § 152.91.

(2) Submission of a new valid study. Refer to § 152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with any necessary written authorizations or offers to pay. Refer to § 152.93.

(4) Citation of a public literature study. Refer to § 152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to § 152.95.

(6) Documentation of a data gap. Refer to § 152.96.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007]

§ 152.91 Waiver of a data requirement.

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) *Request for extension of an existing waiver.* An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for his product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Registration Standard, and must explain why that waiver should apply to his product.

(b) *Request for a new waiver.* An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45 or 40 CFR 161.45.

(c) *Effect of denial of waiver request.* If the request for a new waiver or extension of an existing waiver is denied by the Agency, the applicant must choose another method of satisfying the data requirement.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007]

§ 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the Agency should not be resubmitted but should be cited in accordance with § 152.93.

§ 152.93 Citation of a previously submitted valid study.

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) *Study originally submitted by the applicant.* If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) *Study previously submitted by another person.* If the applicant is not the original data submitter, the applicant may cite the study only in accordance

with paragraphs (b) (1) through (3) of this section.

(1) *Citation with authorization of original data submitter.* The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

(i) Identification of the applicant to whom the authorization is granted;

(ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;

(iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and

(iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) *Citation with offer to pay compensation to the original data submitter.* The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(F)(i) without written authorization from the original data submitter if the applicant certifies to the Agency that he has furnished to the original data submitter:

(i) A notification of the applicant's intent to apply for registration, including the proposed product name and a list of the product's active ingredients;

(ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study; and

(v) The applicant's name, address and telephone number.

(3) *Citation without authorization or offer to pay.* The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in § 152.83(c).

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.94 Citation of a public literature study or study generated at government expense.

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

(1) A valid study from the public literature.

(2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(F).

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent of that data requirement. The applicant who selects this cite-all option must submit to the Agency:

(a) A general offer to pay statement having the same wording as that specified in § 152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;

(b) A certification that:

(1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the

information required by § 152.86(a) for the use the any exclusive use study that would be pertinent to the applicant's product; and

(2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:

(i) A notification of the applicant's intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made;

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and

(v) The applicant's name, address and telephone number; and

(c) An acknowledgment having the same wording as that specified in § 152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.96 Documentation of a data gap.

Except as provided in paragraph (a) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requests the data if he can demonstrate, by the procedure in this section, that no other person has previously submitted to the Agency a study that would satisfy the data requirement in question.

(a) *When data gap procedures may not be used.* (1) An applicant for registration of a product containing a new chemical may not defer his obligation by the procedure in this section, unless he can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to FIFRA section 3(c)(7)(C).

(2) An applicant for registration of a product under FIFRA section 3(c)(7) (A) or (B) may not defer his obligation by the procedure in this section if the Agency requires the data to determine:

(i) Whether the product is identical or substantially similar to another currently registered product or differs only in ways that would not substantially increase the risk of unreasonable adverse effects on the environment;

(ii) If efficacy data are required, whether the product is efficacious; or

(iii) Whether the new use would substantially increase the risk of unreasonable adverse effects on the environment, usually required when the application involves a new use of a product which is identical or substantially similar to a currently registered product.

(b) *Data gap listed in a Registration Standard.* The applicant may rely on a data gap that is documented by a Registration Standard without submitting the certification required by paragraph (c) of this section. If the data gap listed in the Registration Standard has been filled since the issuance of the Standard, the Agency will notify the applicant and require him to choose another method of demonstrating compliance.

(c) *Certification of a data gap.* Except as provided by paragraph (b) of this section, an applicant who wishes to claim that a data gap exists must certify to the Agency that:

(1) The applicant has furnished, by certified mail, to each original data submitter on the current Data Submitters List for the active ingredient in question, a notice containing the following information:

(i) The name and address of the applicant;

(ii) The name of the product, and a statement that the applicant intends to apply for registration of that product;

(iii) The name(s) of the active ingredient(s) in the procuct;

(iv) A list of the data requirements for which the applicant intends to claim under this section that a data gap exists; and

(v) A request that the data submitter identify, within 60 days of receipt of the notice, any valid study which he has submitted to the Agency that would fulfill any of the data requirement(s) listed.

(2) The applicant has, within that 60-day period, received no response, or has received a negative response, from each person notified; and

(3) The applicant has no basis to believe that any data have been submitted to the Agency that would fulfill the data requirement, and is entitled to claim that a data gap exists.

(d) *Requirement to obtain permission or make offer to pay.* In responding to a data gap letter, the original data submitter is not deemed to have given his authorization for the applicant to cite any study which the data submitter identifies in his response. The applicant must seek and obtain specific written authorization from, or make an offer to pay to, the original data submitter to cite the identified study in order to demonstrate compliance for the data requirement. Nothing, however, precludes the applicant from requesting written authorization or making an offer to pay at the same time that he requests confirmation of a data gap.

§ 152.97 Rights and obligations of data submitters.

(a) *Right to be listed on Data Submitters List.* (1) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(2) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(i) Name and current address;

(ii) Chemical name and common name (if any) of the active ingredient(s), with respect to which he is an original data submitter;

(iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158 or part 161, as applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(3) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

(b) *Obligation to respond to data gap letters.* An applicant who chooses to defer his obligation by demonstrating the existence of a data gap must write to each original data submitter for confirmation that the data submitter has not submitted a valid study that would satisfy the requirement. The original data submitter is not required to respond to such letters. However, if he fails to respond, the applicant is entitled to assume (and the Agency will act on the assumption) that the original data submitter has not submitted a study to satisfy the requirement. The data submitter may thereby limit his right to later challenge the applicant's claim if he fails respond in writing delivered to the applicant within 60 days of receipt of the applicant's data gap letter.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007]

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

(vii) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

(2) No court order prohibits the transfer, and any required court approvals have been obtained; and

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(F), unless a new transfer agreement is submitted to the Agency.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.99 Petitions to cancel registration.

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) *Grounds for petition.* (1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant's failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on compensation. The petitioner shall submit a copy of the agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure.

(iv) The applicant has failed to comply with the terms of an arbitration decision. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures of this subpart has deprived him of the rights accorded him under FIFRA section 3(c)(1)(F). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has failed to comply with the procedure for showing that a data gap exists.

(v) The applicant has improperly certified that a data gap exists. An original data submitter who has failed without good cause to respond to an applicant's request for confirmation of a data gap may not petition the Agency for review on this basis.

(vi) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) *Procedure for petition to the Agency*—(1) *Time for filing.* A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, he shall send a copy by certified mail to the affected applicant or registrant. The applicant or registrant shall have 60 days from the date of his receipt of the petition to submit written comments to the Agency.

(c) *Disposition of petitions.* The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or registrant that it intends to deny or cancel the registration of the product in support of which the data were cited. The affected applicant or registrant will have 15 days from the date of delivery of this notice to respond. If the Agency determines, after considering any response, that the affected applicant or registrant has acted in the ways described by paragraph (a)(1) of this section, the Agency will deny or cancel the registration without further hearing. Refer to FIFRA section 3(c)(1)(F)(ii). Denial or cancellation of a registration is a final Agency action.

(3) Except as provided in paragraph (c)(2) of this section, if the Agency determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(F), the Agency will take steps to deny the application or cancel the registration, as appropriate. The procedures in FIFRA section 3(c)(6) or section 6(b) shall be followed. Denial or cancellation is a final Agency action.

(d) *Hearing.* Any hearing will be conducted in accordance with the procedures in 40 CFR part 164. The only matter for resolution at the hearing shall be whether the registrant failed to comply with the requirements and procedures of FIFRA section 3(c)(1)(F) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

Subpart F—Agency Review of Applications

SOURCE: 53 FR 15980, May 4, 1988, unless otherwise noted.

§ 152.100 Scope.

(a) The Agency will follow the procedures in this subpart for all applications for registration, except an application for registration of a pesticide that has been the subject of a previous Agency cancellation or suspension notice under FIFRA sec. 6.

(b) The Agency will follow the procedures of subpart D of part 164 of this chapter in evaluating any application for registration of a pesticide involving use of the pesticide in a manner that is prohibited by a suspension or cancellation order, to the extent required by subpart D of part 164.

§ 152.102 Publication.

The Agency will issue in the FEDERAL REGISTER a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the FEDERAL REGISTER a

notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

§ 152.104 Completeness of applications.

The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in § 152.50 has not been submitted, or has been incorrectly submitted (for example, data required by part 158, or part 161 of this chapter, as applicable, and not submitted in accordance with the requirements for format, claims of confidential business information, or flagging).

[72 FR 61028, Oct. 26, 2007

§ 152.105 Incomplete applications.

The Agency will not begin or continue the review of an application that is incomplete. If the Agency determines that an application is incomplete or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the application. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, the Agency will terminate any action on such application, and will treat the application as if it had been withdrawn by the applicant. Any subsequent submission relating to the same product must be submitted as a new application.

§ 152.107 Review of data.

(a) The Agency normally will review data submitted with an application that have not previously been submitted to the Agency.

(b) The Agency normally will review other data submitted or cited by an applicant only:

(1) As part of the process of reregistering currently registered products;

(2) When acting on an application for registration of a product containing a new active ingredient;

(3) If such data have been flagged in accordance with § 158.34 or 161.34 of this chapter; or

(4) When the Agency determines that it would otherwise serve the public interest.

(c) If the Agency finds that it needs additional data in order to determine whether the product may be registered, it will notify the applicant as early as possible in the review process.

[53 FR 15980, May 4, 1988, as amended at 72 FR 61028, Oct. 26, 2007]

§ 152.108 Review of labeling.

The Agency will review all draft labeling submitted with the application. If an applicant for amended registration submits only that portion of the labeling proposed for amendment, the Agency may review the entire label, as revised by the proposed changes, in deciding whether to approve the amendment. The Agency will not approve final printed labeling, but will selectively review it for compliance.

§ 152.110 Time for agency review.

The Agency will complete its review of applications as expeditiously as possible. Applications subject to specific timeframes under the fee schedule established by FIFRA section 33 will be reviewed within the timeframes established for the application or action type.

[73 FR 75595, Dec. 12, 2008]

§ 152.111 Choice of standards for review of applications.

The Agency has discretion to review applications under either the unconditional registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7). The type of review chosen depends primarily on the extent to which the relevant data base has been reviewed for

completeness and scientific validity. EPA conducts data reviews needed to support unconditional registrations on a chemical-by-chemical basis, according to an established priority list. Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration. Instead the Agency will review the application using the criteria for conditional registration in FIFRA sec. 3(c)(7) (A) and (B).

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

[53 FR 15980, May 4, 1988, as amended at 72 FR 61028, Oct. 26, 2007; 73 FR 75595, Dec. 12, 2008]

§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered peticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA

sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

§ 152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.

An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA sec. 3(c)(5) if the Agency determines that:

(a) Insufficient time has elapsed since the imposition of the data requirement for those data to have been developed;

(b) All other required test data and materials have been submitted to the Agency;

(c) The criteria in § 152.112(a), (b), (d), and (f) through (h) have been satisfied;

(d) The use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment; and

(e) The registration of the pesticide product and its subsequent use during the period of the conditional registration are in the public interest.

§ 152.115 Conditions of registration.

(a) *Substantially similar products and new uses.* Each registration issued under § 152.113 shall be conditioned upon the submission or citation by the registrant of all data which are required for unconditional registration of his product under FIFRA sec. 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered. If a notice requiring submission of such data has been issued under FIFRA sec. 3(c)(2)(B) prior to the date of approval of the application, the applicant must submit or cite the data described by that notice at the time specified by that notice. The applicant must agree to these conditions before the application may be approved.

(b) *New active ingredients.* Each registration issued under § 152.114 shall be conditioned upon the applicant's agreement to each of the following conditions:

(1) The applicant will submit remaining required data (and interim reports if required) in accordance with a schedule approved by the Agency.

(2) The registration will expire upon a date established by the Agency, if the registrant fails to submit data as required by the Agency. The expiration date will be established based upon the length of time necessary to generate and submit the required data. If the studies are submitted in a timely manner, the registration will be cancelled if the Agency determines, based on the data (alone, or in conjuction with other data), that the product or one or more of its uses meets or exceeds any of the risk criteria established by the Agency to initiate a special review. If the Agency so determines, it will issue to the registrant a Notice of Intent to Cancel under FIFRA sec. 6(e), and will specify any provisions for sale and distribution of existing stocks of the pesticide product.

(3) The applicant will submit an annual report of the production of the product.

(c) *Other conditions.* The Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7).

(d) *Cancellation if condition is not satisfied.* If any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action towards fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA sec. 6(e).

[53 FR 15980, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 152.116 Notice of intent to register to original submitters of exclusive use data.

(a) Except as provided in paragraph (c) of this section, at least 30 days before registration of a product containing an active ingredient for which a previously submitted study is eligible for exclusive use under FIFRA sec. 3(c)(1)(F)(i), the Agency will notify the original submitter of the exclusive use study of the intended registration of the product. If requested by the exclusive use data submitter within 30 days, the Agency will also provide the applicant's list of data requirements and method of demonstrating compliance with each data requirement.

(b) Within 30 days after receipt of the Agency's notice, or of the applicant's list of data requirements, whichever is later, the exclusive use data submitter may challenge the issuance of the registration in accordance with the procedures in § 152.99 (b) and (c). If the Agency finds that the challenge has merit, it will issue a notice of denial of the application. The applicant may then avail himself of the hearing procedures provided by FIFRA sec. 3(c)(6). If the Agency finds that the challenge is without merit, it will deny the petition and register the applicant's product. Denial of the petition is a final Agency action.

(c) If an applicant has submitted to the Agency a certification from an exclusive use data submitter that he is aware of the applicant's application for registration, and does not object to the issuance of the registration, the Agency will not provide the 30-day notification described in paragraph (a) of this section to that exclusive use data submitter.

[53 FR 15980, May 4, 1988, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.117 Notification to applicant.

The Agency will notify the applicant of the approval of his application by a Notice of Registration for new registration, or by a letter in the case of an amended registration.

§ 152.118 Denial of application.

(a) *Basis for denial.* The Agency may deny an application for registration if the Agency determines that the pesticide product does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7), as specified in §§ 152.112 through 152.114.

(b) *Notification of applicant.* If the Agency determines that an application should be denied, it will notify the applicant by certified letter. The letter will set forth the reasons and factual basis for the determination with conditions, if any, which must be fulfilled in order for the registration to be approved.

(c) *Opportunity for remedy by the applicant.* The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action. During this time the applicant may request that his application be withdrawn.

(d) *Notice of denial.* If the applicant fails to correct the deficiencies within the 30-day period, the Agency may issue a notice of denial, which will be published in the FEDERAL REGISTER, and which will set forth the reasons and the factual basis for the denial.

(e) *Hearing rights.* Within 30 days following the publication of the notice of denial, an applicant, or any interested person with written authorization of the applicant, may request a hearing in accordance with FIFRA sec. 6(b). Hearings will be conducted in accordance with part 164 of this chapter.

§ 152.119 Availability of material in support of registration.

(a) The information submitted to support a registration application shall be part of the official Agency file for that registration.

(b) Within 30 days after registration, the Agency will make available for public inspection, upon request, the materials required by subpart E to be submitted with an application. Materials that will be publicly available include an applicant's list of data requirements, the method used by the applicant to demonstrate compliance for each data requirement, and the applicant's citations of specific studies in the Agency's possession if applicable.

(c) Except as provided by FIFRA sec. 10, within 30 days after registration, the data on which the Agency based its decision to register the product will be made available for public inspection, upon request, in accordance with the procedures in 40 CFR part 2.

Subpart G—Obligations and Rights of Registrants

SOURCE: 53 FR 15983, May 4, 1988, unless otherwise noted.

§ 152.122 Currency of address of record and authorized agent.

(a) The registrant must keep the Agency informed of his current name and address of record. If the Agency's good faith attempts to contact the registrant are not successful, the Agency will issue in the FEDERAL REGISTER a notice of intent to cancel all products of the registrant under FIFRA sec. 6(b). The registrant must respond within 30 days requesting that the registrations be maintained in effect, and providing his name and address of record. If no response is received, the cancellations will become effective at the end of 30 days without further notice to the registrant. The Agency may make provision for the sale and distribution of existing stocks of such products after the effective date of cancellation.

(b) The registrant must also notify the Agency if he changes his authorized agent.

§ 152.125 Submission of information pertaining to adverse effects.

If at any time the registrant receives or becomes aware of any factual information regarding unreasonable adverse effects of the pesticide on the environment that has not previously been submitted to the Agency, the registrant shall, in accordance with FIFRA section 6(a)(2) and the requirements of part 159, subpart D of this chapter, provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

[73 FR 75595, Dec. 12, 2008]

§ 152.130 Distribution under approved labeling.

(a) A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency.

(b) A registrant may distribute or sell a product under labeling bearing any subset of the approved directions for use, provided that in limiting the uses listed on the label, no changes would be necessary in precautionary statements, use classification, or packaging of the product.

(c) Normally, if the product labeling is amended on the initiative of the registrant, by submission of an application for amended registration, the registrant may distribute or sell under the previously approved labeling for a period of 18 months after approval of the revision, unless an order subsequently issued by the Agency under FIFRA sec. 6 or 13 provides otherwise. However, if paragraph (d) of this section applies to the registrant's product, the time frames established by the Agency in accordance with that paragraph shall take precedence.

(d) If a product's labeling is required to be revised as a result of the issuance of a Registration Standard, a Label Improvement Program notice, or a notice concluding a special review process, the Agency will specify in the notice to the registrant the period of time that previously approved labeling may be used. In all cases, supplemental or sticker labeling may be used as an interim compliance measure for a reasonable period of time. The Agency may establish dates as follows governing when label changes must appear on labels:

(1) The Agency may establish a date after which all product distributed or sold by the registrant must bear revised labeling.

(2) The Agency may also establish a date after which no product may be

distributed or sold by any person unless it bears revised labeling. This date will provide sufficient time for product in channels of trade to be distributed or sold to users or otherwise disposed of.

§ 152.132 Supplemental distribution.

The registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed ''supplemental distribution'' and the product is referred to as a ''distributor product.'' The distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to the Agency if all the following conditions are met:

(a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product.

(b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with § 152.30) who produces, packages, and labels the registered product.

(c) The distributor product is not repackaged (remains in the producer's unopened container).

(d) The label of the distributor product is the same as that of the registered product, except that:

(1) The product name of the distributor product may be different (but may not be misleading);

(2) The name and address of the distributor may appear instead of that of the registrant;

(3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request);

(4) The establishment number must be that of the final establishment at which the product was produced; and

(5) Specific claims may be deleted, provided that no other changes are necessary.

(e) Voluntary cancellation of a product applies to the registered product and all distributor products distributed or sold under that registration number. The registrant is responsible for ensuring that distributors under his cancelled registration are notified and comply with the terms of the cancellation.

[53 FR 15975, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 152.135 Transfer of registration.

(a) A registrant may transfer the registration of a product to another person, and the registered product may be distributed and sold without the requirement of a new application for registration by that other person, if the parties submit to the Agency the documents listed in paragraphs (b) and (c) of this section, and receive Agency approval as described in paragraph (d) of this section.

(b) Persons seeking approval of a transfer of registration must provide a document signed by the authorized representative of the registrant (the transferor) and of the person to whom the registration is transferred (the transferee) that contains the following information:

(1) The name, address and State of incorporation (if any) of the transferor;

(2) The name, address and State of incorporation of the transferee;

(3) The name(s) and EPA registration number(s) of the product(s) being transferred;

(4) A statement that the transferor transfers irrevocably to the transferee all right, title, and interest in the EPA registration(s) listed in the document;

(5) A statement that the transferred registration(s) shall not serve as collateral or otherwise secure any loan or other payment arrangement or executory promise, and that the registration(s) shall not revert to the transferor unless a new transfer agreement is submitted to and approved by the Agency;

(6) A description of the general nature of the underlying transaction, e.g., merger, spinoff, bankruptcy transfer (no financial information need be disclosed);

(7) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(8) An acknowledgment by the transferee that his rights and duties concerning the registration under FIFRA and this chapter will be deemed by EPA to be the same as those of the transferor at the time the transfer is approved.

(c) In addition, the transferor must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the registrant to bind the transferor;

(2) No court order prohibits the transfer, and that any required court approvals have been obtained; and

(3) The transfer is authorized under all relevant Federal, State and local laws and all relevant corporate charters, bylaws, partnerships, or other agreements.

(d) If the required documents are submitted, and no information available to the Agency indicates that the information is incorrect, the Agency will approve the transfer without requiring that the transferee obtain a new registration. The Agency will notify the transferor and transferee of its approval.

(e) The transfer will be effective on the date of Agency approval. Thereafter the transferee will be regarded as the registrant for all purposes under FIFRA.

(f) Rights to exclusive use of data or compensation under FIFRA section 3(c)(1)(F) are separate from the registration itself and may be retained by the transferor, or may be transferred independently in accordance with the provisions of § 152.98. If the registrant as the original data submitter wishes to transfer data rights at the same time as he transfers the registration, he may submit a single transfer document containing the information required by this section for both the registration and the data.

[53 FR 15983, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 73 FR 75595, Dec. 12, 2008]

Subpart H [Reserved]

Subpart I—Classification of Pesticides

SOURCE: 53 FR 15986, May 4, 1988, unless otherwise noted.

§ 152.160 Scope.

(a) *Types of classification.* A pesticide product may be unclassified, or it may be classified for restricted use or for general use. The Agency does not normally classify products for general use; products that are not restricted remain unclassified.

(b) *Kinds of restrictions.* The Agency may restrict a product or its uses to use by a certified applicator, or by or under the direct supervision of a certified applicator, as described in FIFRA sec. 3(d)(1)(C). The Agency may also, by regulation, prescribe restrictions relating to the product's composition, labeling, packaging, uses, or distribution and sale, or to the status or qualifications of the user.

§ 152.161 Definitions.

In addition to the definitions in § 152.3, the following terms are defined for the purposes of this subpart:

(a) *Dietary* LC_{50} means a statistically derived estimate of the concentration of a test substance in the diet that would cause 50 percent mortality to the test population under specified conditions.

(b) *Outdoor use* means any pesticide application that occurs outside enclosed manmade structures or the consequences of which extend beyond enclosed manmade structures, including, but not limited to, pulp and paper mill water treatments and industrial cooling water treatments.

§ 152.164 Classification procedures.

(a) *Grouping of products for classification purposes.* In its discretion, the Agency may identify a group of products having common characteristics or

uses and may classify for restricted use same or all of the products or uses included in that group. Such a group may be comprised of, but is not limited to, products that:

(1) Contain the same active ingredients.

(2) Contain the same active ingredients in a particular concentration range, formulation type, or combination of concentration range and formulation type.

(3) Have uses in common.

(4) Have other characteristics, such as toxicity, flammability, or physical properties, in common.

(b) *Classification reviews.* The Agency may conduct classification reviews and classify products at any time, if it determines that a restriction on the use of a pesticide product is necessary to avoid unreasonable adverse effects on the environment. However, classification reviews normally will be conducted and products classified only in the following circumstances:

(1) As part of the review of an application for new registration of a product containing an active ingredient not contained in any currently registered product.

(2) As part of the review of an application for a new use of a product, if existing uses of that product previously have been classified for restricted use. Review of a restricted use product at this time is for the purpose of determining whether the new use should also be classified for restricted use. Normally the Agency will not conduct initial classification reviews for existing uses of individual products in conjunction with an application for amended registration.

(3) As part of the process of developing or amending a registration standard for a pesticide. The Agency normally will conduct classification reviews of all uses of a currently registered pesticide at this time.

(4) As part of any special review of a pesticide, in accordance with the procedures of 40 CFR part 154.

(c) *Classification procedures.* (1) If the Agency determines that a product or one or more of its uses should be classified for restricted use, the Agency initially may classify the product by regulation. In this case, within 60 days after the effective date of a final rule, each registrant of a product subject to the rule must submit to the Agency one of the following, as directed in the final rule:

(i) A copy of the amended label and any supplemental labeling to be used as an interim compliance measure.

(ii) A statement, which the Agency considers a report under the Act, that the registrant will comply with the labeling requirements prescribed by the Agency within the timeframes prescribed by the regulation.

(iii) An application for amended registration to delete the uses which have been restricted, or to ''split'' the registration into two registrations, one including only restricted or all uses, and the other including only uses that have not been classified.

(2) Alternatively, EPA may notify the applicant or registrant of the classification decision and require that he submit the information required by paragraph (c)(1) of this section. The Agency may deny registration or initiate cancellation proceedings if the registrant fails to comply within the timeframes established by the Agency in its notification.

§ 152.166 Labeling of restricted use products.

(a) *Products intended for end use.* A product whose labeling bears directions for end use and that has been classified for restricted use must be labeled in accordance with the requirements of § 156.10 of this chapter or other Agency instructions. The Agency will permit the use of stickers or supplemental labeling as an interim alternative to the use of an approved amended label, in accordance with § 152.167.

(b) *Products intended only for formulation.* A product whose labeling does not bear directions for end use (a product that is intended and labeled solely for further formulation into other pesticide products) is not subject to the labeling requirements of this subpart.

§ 152.167 Distribution and sale of restricted use products.

Unless modified by the Agency, the compliance dates in this section shall apply to restricted use products.

(a) *Sale by registrant or producer.* (1) No product with a use classified for restricted use may be distributed or sold by the registrant or producer after the 120th day after the effective date of such classification unless the product:

(i) Bears an approved amended label which contains the terms of restricted use imposed by the Agency and otherwise complies with part 156 of this chapter;

(ii) Bears a sticker containing the product name, EPA registration number, and any terms of restricted use imposed by the Agency; or

(iii) Is accompanied by supplemental labeling bearing the information listed in paragraph (a)(1)(ii) of this section.

(2) If the registrant chooses to delete the restricted uses from his product label, that product may not be distributed or sold after the 180th day after the effective date of classification unless the product bears amended labeling with the restricted uses deleted.

(3) Notwithstanding paragraphs (a)(1) and (2) of this section, after the 270th day after the effective date of classification, no registrant or producer may distribute or sell a product that does not bear the approved amended label. After that date, stickers and supplemental labeling described in paragraph (a)(1) (ii) and (iii) are no longer acceptable.

(b) *Sale by retailer.* No product with a use classified for restricted use by a regulation may be distributed or sold by a retailer or other person after the 270th day after the effective date of the final rule unless the product bears a label or labeling which complies with paragraph (a)(1) of this section.

§ 152.168 Advertising of restricted use products.

(a) Any product classified for restricted use shall not be advertised unless the advertisement contains a statement of its restricted use classification.

(b) The requirement in paragraph (a) of this section applies to all advertisements of the product, including, but not limited, to:

(1) Brochures, pamphlets, circulars and similar material offered to purchasers at the point of sale or by direct mail.

(2) Newspapers, magazines, newsletters and other material in circulation or available to the public.

(3) Broadcast media such as radio and television.

(4) Telephone advertising.

(5) Billboards and posters.

(c) The requirement may be satisfied for printed material by inclusion of the statement ''Restricted Use Pesticide,'' or the terms of restriction, prominently in the advertisement. The requirement may be satisfied with respect to broadcast or telephone advertising by inclusion in the broadcast of the spoken words ''Restricted use pesticide,'' or a statement of the terms of restriction.

(d) The requirements of this section shall be effective:

(1) After 270 days after the effective date of restriction of a product that is currently registered, unless the Agency specifies a shorter time period;

(2) Upon the effective date of registration of a product not currently registered.

§ 152.170 Criteria for restriction to use by certified applicators.

(a) *General criteria.* An end-use product will be restricted to use by certified applicators (or persons under their direct supervision) if the Agency determines that:

(1) Its toxicity exceeds one or more of the specific hazard criteria in paragraph (b) or (c) of this section, or evidence described in paragraph (d) of this section substantiates that the product or use poses a serious hazard that may be mitigated by restricting its use;

(2) Its labeling, when considered according to the factors in paragraph (e)(2) of this section, is not adequate to mitigate these hazard(s);

(3) Restriction of the product would decrease the risk of adverse effects; and

(4) The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

(b) *Criteria for human hazard*—(1) *Residential and institutional uses.* A pesticide product intended for residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as diluted for use, has an acute oral LD_{50} of 1.5 g/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 2000 mg/kg or less;

(iii) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.5 mg/liter or less, based upon a 4-hour exposure period;

(iv) The pesticide, as formulated, is corrosive to the eye (causes irreversible destruction of ocular tissue) or results in corneal involvement or irritation persisting for more than 7 days;

(v) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe irritation (severe erythema or edema) at 72 hours; or

(vi) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic, chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues.

(2) *All other uses.* A pesticide product intended for uses other than residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as formulated, has an acute oral LD_{50} of 50 mg/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 200 mg/kg or less;

(iii) The pesticide, as diluted for use, has an acute dermal LD_{50} of 16 g/kg or less;

(iv) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.05 mg/liter or less, based upon a 4-hour exposure period;

(v) The pesticide, as formulated, is corrosive to the eye or causes corneal involvement or irritation persisting for more than 21 days;

(vi) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring); or

(vii) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic toxicity, chronic toxicity, or delayed toxic effects on man, as a result of single or multiple exposures to the product ingredients or residues.

(c) *Criteria for hazard to non-target species*—(1) *All products.* A pesticide product intended for outdoor use will be considered for restricted use classification if:

(i) When used according to label directions, application results in residues of the pesticide, its metabolites, or its degradation products, in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of such residues equals or exceeds one-fifth of the acute dietary LC_{50}; or

(B) The amount of pesticide consumed in one feeding day (mg/kg/day) equals or exceeds one-fifth of the mammalian acute oral LD_{50};

(ii) When used according to label directions, application results, immediately after application, in residues of the pesticide, its metabolites or its degradation products, in the diet of exposed birds at levels that equal or exceed one-fifth of the avian subacute dietary LC_{50};

(iii) When used according to label directions, application results in residues of the pesticide, its metabolites or its degradation products, in water that equal or exceed one-tenth of the acute LC_{50} for non-target aquatic organisms likely to be exposed; or

(iv) Under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the pesticide, its metabolites or its degradation products.

(2) *Granular products.* In addition to the criteria of paragraph (c)(1) of this section, a pesticide intended for outdoor use and formulated as a granular product will be considered for restricted use classification if:

(i) The formulated product has an acute avian or mammalian oral LD_{50} of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

(ii) It is intended to be applied in such a manner that significant exposure to birds or mammals may occur.

(d) *Other evidence.* The Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restricted use classification.

(e) *Alternative labeling language.* (1) If the Agency determines that a product meets one or more of the criteria of paragraphs (b) or (c) of this section, or if other evidence identified in paragraph (d) of this section leads the Agency to conclude that the product should be considered for restricted use classification, the Agency will then determine if additional labeling language would be adequate to mitigate the identified hazard(s) without restricted use classification. If the labeling language meets all the criteria specified in paragraph (e)(2) of this section, the product will not be classified for restricted use.

(2) The labeling will be judged adequate if it meets all the following criteria:

(i) The user, in order to follow label directions, would not be required to perform complex operations or procedures requiring specialized training and/or experience.

(ii) The label directions do not call for specialized apparatus, protective equipment, or materials that reasonably would not be available to the general public.

(iii) Failure to follow label directions in a minor way would result in few or no significant adverse effects.

(iv) Following directions for use would result in few or no significant adverse effects of a delayed or indirect nature through bioaccumulation, persistence, or pesticide movement from the original application site.

(v) Widespread and commonly recognized practices of use would not nullify or detract from label directions such that unreasonable adverse effects on the environment might occur.

§ 152.171 Restrictions other than those relating to use by certified applicators.

The Agency may by regulation impose restrictions on a product or class of products if it determines that:

(a) Without such restrictions, the product when used in accordance with warnings, cautions and directions for use or in accordance with widespread and commonly recognized practices of use may cause unreasonable adverse effects on the environment; and

(b) The decrease in risks as a result of restricted use would exceed the decrease in benefits as a result of restricted use.

§ 152.175 Pesticides classified for restricted use.

The following uses of pesticide products containing the active ingredients specified below have been classified for restricted use and are limited to use by or under the direct supervision of a certified applicator.

Active ingredient	Formulation	Use pattern	Classification [1]	Criteria influencing restriction
Acrolein	As sole active ingredient. No mixtures registered.	All uses	Restricted	Inhalation hazard to humans. Residue effects on avian species and aquatic organisms.
Aldicarb	As sole active ingredient	Ornamental uses (indoor and outdoor).	do	Other hazards—accident history.
	No mixtures registered	Agricultural crop uses.	Under further evaluation.	
Aluminum phosphide.	As sole active ingredient. No mixtures registered.	do	do	Inhalation hazard to humans.
Azinphos methyl	All liquids with a concentration greater than 13.5 pct.	do	do	Do.
	All other formulations	do	Under futher evaluation..	

Active ingredient	Formulation	Use pattern	Classification [1]	Criteria influencing restriction
Carbofuran	All concentrate suspensions and wettable powders 40% and greater.	do	do	Acute inhalation toxicity.
	All granular formulations	Rice	Under evaluation.	
	All granular and fertilizer formulations.	All uses except rice	do.	
Chloropicrin	All formulations greater than 2%	All uses	do	Acute inhalation toxicity.
	All formulations	Rodent control	do	Hazard to non-target organisms.
	All formulations 2% and less	Outdoor uses (other than rodent control).	Unclassified.	
Clonitralid	All wettable powders 70% and greater.	All uses	Restricted	Acute inhalation toxicity.
	All granulars and wettable powders	Molluscide uses	Restricted	Effects on aquatic organisms.
	Pressurized sprays 0.55% and less	Hospital antiseptics	Unclassified.	
Dicrotophos	All liquid formulations 8% and greater.	All uses	Restricted	Acute dermal toxicity; residue effects on avian species (except for tree injections).
Disulfoton	All emulsifiable concentrates 65% and greater, all emulsifiable concentrates and concentrate solutions 21% and greater with fensulfothion 43% and greater, all emulsifiable concentrates 32% and greater in combination with 32% fensulfothion and greater.	do	Restricted	Do. Acute inhalation toxicity.
	Non-aqueous solution 95% and greater.	Commercial seed treatment.	Restricted	Acute dermal toxicity.
	Granular formulations 10% and greater.	Indoor uses (greenhouse).	do	Acute inhalation toxicity.
Ethoprop	Emulsifiable concentrates 40% and greater.	Aquatic uses	do	Acute dermal toxicity.
	All granular and fertilizer formulations.	All uses	Under evaluation.	
Ethyl parathion	All granular and dust formulations greater than 2 pct, fertilizer formulations, wettable powders, emulsifiable concentrates, concentrated suspensions, concentrated solutions.	do	Restricted	Inhalation hazard to humans. Acute dermal toxicity. Residue effects on mammalian, aquatic, avian species.
	Smoke fumigants	do	do	Inhalation hazard to humans.
	Dust and granular formulations 2 pct and below.	do	do	Other hazards—accident history.
Fenamiphos	Emulsifiable concentrates 35% and greater.	do	do	Acute dermal toxicity.
Fonofos	Emulsifiable concentrates 44% and greater.	do	do	Acute dermal toxicity.
	Emulsifiable concentrates 12.6% and less with pebulate 50.3% and less.	Tobacco	Unclassified.	
Methamidophos	Liquid formulations 40% and greater	do	Restricted	Acute dermal toxicity; residue effects on avian species.
	Dust formulations 2.5% and greater	do	do	Residue effects on avian species.
Methidathion	All formulations	All uses except nursery stock, safflower and sunflower.	do	Do.
	All formulations	Nursery stock, safflower and sunflower.	Unclassified.	
Methomyl	As sole active ingredient in 1 pct to 2.5 baits (except 1 pct fly bait).	Nondomestic outdoors-agricultural crops, ornamental and turf. All other registered uses.	Restricted	Residue effects on mammalian species.

Active ingredient	Formulation	Use pattern	Classification [1]	Criteria influencing restriction
	All concentrated solution formulations.	.....do	.....do	Other hazards-accident history.
	90 pct wettable powder formulations (not in water soluble bags).	.....do	.....do	Do.
	90 pct wettable powder formulation in water soluble bags.	.....do	Unclassified.	
	All granular formulations	.....do	.....do.	
	25 pct wettable powder formulations	.....do	.....do.	
	In 1.24 pct to 2.5 pct dusts as sole active ingredient and in mixtures with fungicides and chlorinated hydrocarbon, inorganic phosphate and biological insecticides.	.....do	.....do.	
Methyl bromide	All formulations in containers greater than 1.5 lb.	All uses	Restricted	Do.
	Containers with not more than 1.5 lb of methyl bromide with 0.25 pct to 2.0 pct chloropicrin as an indicator.	Single applications (nondomestic use) for soil treatment in closed systems.	Unclassified.	
	Container with not more than 1.5 lb having no indicator.	All uses	Restricted	Do.
Methyl parathion	All dust and granular formulations less than 5 pct.	.....do	.....do	Other hazards-accident history. All foliar applications restricted based on residue effects on mammalian and avian species.
	Microencapsulated	.....do	.....do	Residue effects on avian species. Hazard to bees.
	All dust and granular formulations 5 pct and greater and all wettable powders and liquids.	.....do	.....do	Acute dermal toxicity. Residue effects on mammalian and avian species.
Nicotine (alkaloid).	Liquid and dry formulations 14% and above.	Indoor (greenhouse)	.....do	Acute inhalation toxicity.
	All formulations	Applications to cranberries.	.....do	Effects on aquatic organisms.
	Liquid and dry formulations 1.5% and less.	All uses (domestic and nondomestic).	Unclassified.	
Paraquat (dichloride) and paraquat bis(methyl sulfate).	All formulations and concentrations except those listed below.	All uses	Restricted	Other hazards. Use and accident history, human toxicological data.
	Pressurized spray formulations containing 0.44 pct Paraquat bis(methyl sulfate) and 15 pct petroleum distillates as active ingredients.	Spot weed and grass control.	.....do.	
	Liquid fertilizers containing concentrations of 0.025 pct paraquat dichloride and 0.03 percent atrazine; 0.03 pct paraquat dichloride and 0.37 pct atrazine, 0.04 pct paraquat dichloride and 0.49 pct atrazine.	All uses	Unclassified.	
Phorate	Liquid formulations 65% and greater	.....do	Restricted	Acute dermal toxicity. Residue effects on avian species (applies to foliar applications only). Residue effects on mammalian species (applies to foliar application only).
	All granular formulations	Rice	.....do	Effects on aquatic organisms.
Phosphamidon ..	Liquid formulations 75% and greater	.....do	.....do	Acute dermal toxicity. Residue effects on mammalian species. Residue effects on avian species.
	Dust formulations 1.5% and greater	.....do	.....do	Do. Residue effects on mammalian species.

Active ingredient	Formulation	Use pattern	Classification [1]	Criteria influencing restriction
Picloram	All formulations and concentrations except tordon 101 R.	do	do	Hazard to nontarget organisms (specifically nontarget plants both crop and noncrop).
	Tordon 101 R forestry herbicide containing 5.4 pct picloram and 20.9 pct 2.4–D.	Control of unwanted trees by cut surface treatment.	Unclassified.	
Sodium cyanide [3].	All capsules and ball formulations	All uses	Restricted	Inhalation hazard to humans.
Sodium fluoroacetate.	All solutions and dry baits	do	do	Acute oral toxicity. Hazard to nontarget organisms. Use and accident history.
Strychnine	All dry baits, pellets and powder formulations greater than 0.5 pct.	do	do	Acute oral toxicity. Hazard to nontarget avain species. Use and accident history.
	All dry baits, pellets and powder formulations.	All uses calling for burrow builders.	do	Hazard to nontarget organisms.
	All dry baits, pellets and powder formulations 0.5 pct and below.	All uses except subsoil.	do	Do.
	do	All subsoil uses	Unclassified.	
Sulfotepp	Sprays and smoke generators	All uses	Restricted	Inhalation hazard to humans.
Zinc Phosphide	All formulations 2% and less	All domestic uses and non-domestic uses in and around buildings.	Unclassified.	
	All dry formulations 60% and greater..			
	All bait formulations	Non-domestic outdoor uses (other than around buildings).	do	Hazard to non-target organisms.
	All dry formulations 10% and greater	Domestic uses	do	Acute oral toxicity.

[1] "Under evaluation" means no classification decision has been made and the use/formulation in question is still under active review within EPA.
[2] Percentages given are the total of dioxathion plus related compounds.
[3] (NOTE—M–44 sodium cyanide capsules may only be used by certified applicators who have also taken the required additional training.)

[43 FR 5790, Feb. 9, 1978, as amended at 44 FR 45132, Aug. 1, 1979; 46 FR 5698, Jan. 19, 1981. Redesignated and amended at 53 FR 15988, May 4, 1988; 60 FR 32096, June 19, 1995]

Subparts J–T [Reserved]

Subpart U—Registration Fees

SOURCE: 53 FR 19114, May 26, 1988, unless otherwise noted.

§ 152.400 Purpose.

Subpart U prescribes fees to be charged for the pesticide regulatory activities set forth in § 152.403 as performed by the Environmental Protection Agency (as authorized by 31 U.S.C. 9701 and Pub. L. 100–202) and provisions regarding their payment.

§ 152.401 Inapplicability of fee provisions to applications filed prior to October 1, 1997.

No fee required by this subpart U shall be levied with respect to any application filed during the period beginning on October 25, 1988, and ending on September 30, 1997. See FIFRA section 4(i)(7) (added to FIFRA by Pub. L. 100–532, October 25, 1988, 102 Stat. 2654).

[53 FR 11923, Mar. 22, 1989]

§ 152.403 Definitions of fee categories.

(a) *New chemical registration review* means review of an application for registration of a pesticide product containing a chemical active ingredient which is not contained as an active ingredient in any other pesticide product

that is registered under FIFRA at the time the application is made.

(b) *New biochemical and microbial registration review* means review of an application for registration of a biochemical or microbial pesticide product containing a biochemical or microbial active ingredient not contained in any other pesticide product that is registered under FIFRA at the time the application is made. For purposes of this subpart, the definitions of biochemical and microbial pesticides contained in § 158.2000 and § 158.2100, respectively, shall apply.

(c) *New use pattern registration review* means review of an application for registration, or for amendment of a registration entailing a major change to the use pattern of an active ingredient contained in a product registered under FIFRA or pending Agency decision on a prior application at the time of application. For purposes of this paragraph, examples of major changes include but are not limited to, changes from non-food to food use, outdoor to indoor use, ground to aerial application, terrestrial to aquatic use, and non-residential to residential use.

(d) *Old chemical registration review* means review of an application for registration of a new product containing active ingredients and uses which are substantially similar or identical to those currently registered or for which an application is pending Agency decision.

(e) *Amendment review* means review of any application requiring Agency approval to amend the registration of a currently registered product, or for which an application is pending Agency decision, not entailing a major change to the use pattern of an active ingredient.

(f) *Experimental use permit review* means review of an application for a permit pursuant to section 5 of FIFRA to apply a limited quantity of a pesticide in order to accumulate information necessary to register the pesticide. The application may be for a new chemical or for a new use of an old chemical. The fee applies to such experimental uses of a single unregistered active ingredient (no limit on the number of other active ingredients, in a tank mix, already registered for the crops involved) and no more than three crops. This fee does not apply to experimental use permits required for small-scale field testing of microbial pest control agents (40 CFR 172.3).

[53 FR 19114, May 26, 1988, as amended at 72 FR 61028, Oct. 26, 2007]

§ 152.404 Fee amounts.

The fee prescribed by the following table must be submitted with each application for registration, amended registration or experimental use permit. Fees will be adjusted annually in accordance with § 152.410. The Agency may waive or refund fees in accordance with § 152.412.

TABLE—REGISTRATION FEES

Type of review	Fee
New chemical	$184,500
New biochemical or microbial	64,000
New use pattern	33,800
Experimental use permit	4,500
Old chemical	4,000
Amendment	700

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 152.406 Submission of supplementary data.

Applicants may submit data to supplement pending applications without incurring additional charges if the proper fee was paid with submission of the original application and subsequent submissions of supplementary data do not constitute a change in the type of registration action requested.

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 152.408 Special considerations.

(a) If two or more applicants apply for a new chemical registration for products having the same active ingredient and each applicant provides a set of data in support of the registration developed independently of the other applicants' data, then each applicant submitting an independent set of data shall be charged the full new chemical registration review fee.

(b) If two or more applicants apply for a new chemical registration for products having the same active ingredient and the applicants have jointly

developed or paid for the joint development of a common set of data to support their applications for registration, then each applicant shall be charged an equal share of the total fee for review of the applications for all of the subject products. The total fee will include the sum of the new chemical registration review fee for one product and one old chemical registration review fee for each additional product.

(c) If an application is received for registration of a product that contains two or more new chemical active ingredients and a different set of generic data is required by the Agency for each new chemical for the purpose of registration, the applicant will be required to pay the full new chemical registration review fee for each active ingredient.

§ 152.410 Adjustment of fees.

(a) The fee schedule will be adjusted annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale. Such adjustments will be published in the FEDERAL REGISTER as a final rule and will be effective 30 days or more after promulgation.

(b) Processing costs and fees will be reviewed periodically and changes will be made to the schedule as necessary. Such adjustments will be published for notice and comment in the FEDERAL REGISTER.

§ 152.412 Waivers and refunds.

(a) *Refunds.* If an application is not accepted for processing because it is incomplete, the fee, less $1,200 for handling and initial review (or the amount of the fee, whichever is less), shall be returned. If an application is withdrawn by the applicant before significant Agency scientific review has begun, the fee, less $1,200, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were submitted for the first time.

(b) *Waiver of fees for activities initiated by the Agency.* The Agency may waive fees for amended registrations where the amendment has been initiated solely by the Agency. The Agency retains sole discretion in determining when this fee will be waived. The announcement of the fee waiver will accompany the EPA request for an amendment. The Agency will not approve any individual requests for waivers of EPA-initiated activity fees.

(c) *Waiver of fees for activities initiated by applicants.* Upon request by an applicant, together with the supporting documentation or justification described in this paragraph, the Agency may waive or refund fees in whole or in part. A request for waiver must be submitted in accordance with § 152.414(a). An application for which a waiver of fees has been requested will not be accepted for review until the waiver has been granted, or until the waiver has been denied and thereafter the proper fee has been submitted.

(1) *Minor use.* Fees may be waived for applications limited to minor uses that lack commercial feasibility for the pesticide applicant. An applicant requesting a waiver on this basis must provide supporting information that demonstrates that anticipated revenues from the uses that are the subject of the application would be insufficient to pay back the cost of the fee. The burden of proof of the reasonableness of this estimate rests with the applicant.

(2) *IR–4.* Fees will be waived for registration actions that are determined to be specifically associated with tolerance petitions submitted by the Inter-Regional Research Project Number 4 (IR–4 program) when such waiver is deemed by the Agency to be in the public interest.

(3) *Severe economic impact.* The Agency may waive two-thirds of any cumulative registration fee payment in a 12-month period following completion of the applicant's most recent fiscal year that exceeds 3 percent of the applicant's pesticide sales in its most recently completed fiscal year. An applicant requesting a waiver on this basis must provide documentation (e.g. copy of an annual report, or income tax forms filed with the Internal Revenue Service, or if needed, a notarized statement signed by a corporate officer regarding annual pesticide sales) demonstrating that:

(i) The company applying had less than $40 million in gross revenue (including all revenue sources) in the

most recently concluded fiscal year of operation, and a single fee would constitute more than 3 percent of the applicant's gross revenue from pesticide sales in the most recently completed fiscal year of operation, or

(ii) The company applying had less than $40 million in gross revenue (including all revenue sources) in the most recently concluded fiscal year of operation, and the cumulative registration fees paid during the 12 months following the applicant's most recently completed fiscal year, including any registration fees paid for the applicant for which a waiver is requested, constitute more than 3 percent of the applicant's gross revenue from pesticide sales in the most recently concluded fiscal year of operation.

(iii) The Agency will not grant such a waiver if it determines that the entity submitting the application has been formed or manipulated to qualify for such a waiver.

(4) *Public interest.* The Agency, in its discretion, may waive in whole or in part any of the fees established herein in the public interest. Examples include, but are not limited to, pesticides offering unique advantages for reducing public health risks, those that significantly reduce a current environmental risk, or a product with extraordinary utility for use in Integrated Pest Management (IPM).

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 152.414 Procedures.

(a) *Procedures for requesting a waiver.* (1) A request for a waiver must be submitted in writing at the time the application is submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(2) A payment of $1,200 for processing the waiver or the amount of the actual fee, whichever is less, must be submitted simultaneously to the address set forth in paragraph (b) of this section. This fee will be refunded (or applied to any resulting partial fee) if the waiver is granted. Payment of fees for the registration activities, in contrast to the waiver fee, shall not be required until the Agency makes a determination on the waiver request. Since the actual fee is submitted to an address different than the one to which the waiver request is submitted, a copy of the payment document must be submitted with the waiver request that is submitted to the Office of Pesticide Programs' Document Processing Desk as described in paragraph (a)(1) of this section. No fee is required from a person who has no financial interest in the application.

(b) *Procedures for payment of fees.* All fees required by this section must be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All payment of fees must be forwarded to the Environmental Protection Agency, Headquarters Accounting Operations Branch, Office of Pesticide Programs (Registration Fees), P.O. Box 360277M, Pittsburgh, PA 15251. The payments should be specifically labeled ''Registration Fees'' and should be accompanied only by a copy of the registration application form or the experimental use permit application form, as appropriate. An application will not be accepted for processing until the required fees have been submitted.

(c) *Procedures for submitting application and supporting data.* The application, along with supporting data, shall be forwarded within 30 days of payment to the Washington DC address set forth in paragraph (a)(1) of this section.

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993; 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

Subparts V–Y [Reserved]

Subpart Z—Devices

§ 152.500 Requirements for devices.

(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

(b) A device is not required to be registered under FIFRA sec. 3. The Agency has issued a policy statement concerning its authority and activities with respect to devices, which was published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51065). A device is subject to the requirements set forth in:

(1) FIFRA sec. 2(q)(1) and part 156 of this chapter, with respect to labeling;

(2) FIFRA sec. 7 and part 167 of this chapter, with respect to establishment registration and reporting;

(3) FIFRA sec. 8 and part 169 of this chapter, with respect to books and records;

(4) FIFRA sec. 9, with respect to inspection of establishments;

(5) FIFRA sec. 12, 13, and 14, with respect to violations, enforcement activities, and penalties;

(6) FIFRA sec. 17, with respect to import and export of devices;

(7) FIFRA sec. 25(c)(3), with respect to child-resistant packaging; and

(8) FIFRA sec. 25(c)(4), with respect to the Agency's authority to declare devices subject to certain provisions of the Act.

[53 FR 15990, May 4, 1988. Redesignated at 60 FR 32096, June 19, 1995]

PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

Subparts A–F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

Sec.
153.125 Criteria for determination of pesticidal activity.

Subpart H—Coloration and Discoloration of Pesticides

153.140 General.
153.155 Seed treatment products.

Subparts I–M [Reserved]

AUTHORITY: 7 U.S.C. 136w.

Subparts A–F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

SOURCE: 53 FR 15989, May 4, 1988, unless otherwise noted.

§ 153.125 Criteria for determination of pesticidal activity.

(a) An ingredient will be considered an active ingredient if it is contained in a pesticide product and:

(1) The ingredient has the capability by itself, and when used as directed at the proposed use dilution, to function as a pesticide; or

(2) The ingredient has the ability to elicit or enhance a pesticidal effect in another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Compounds which function simply to enhance or prolong the activity of an active ingredient by physical action, such as stickers and other adjuvants, are not generally considered to be active ingredients.

(b) Normally the applicant will determine and state in his application whether an ingredient is active or inert with respect to pesticidal activity. The Agency, as part of its review of an application for registration, or in conjunction with the Registration Standard or Special Review process, may require any ingredient, to be designated as an active ingredient if the Agency finds that it meets the criteria in paragraph (a) of this section. Conversely, the Agency may determine that any ingredient designated as active by an applicant is an inert ingredient if it fails to meet those criteria.

(c) If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement. If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.

(d) Designation of a substance as a pesticidally inert ingredient does not relieve the applicant or registrant of other requirements of FIFRA with respect to labeling of inert ingredients or submission of data, or from the requirements of the Federal Food, Drug,

and Cosmetic Act with respect to tolerances or other clearance of ingredients.

[53 FR 15989, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

Subpart H—Coloration and Discoloration of Pesticides

SOURCE: 53 FR 15990, May 4, 1988, unless otherwise noted.

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if the Administrator determines that such requirements are feasible and necessary for the protection of health and the environment. This subpart describes those pesticide products which must be colored or discolored.

[60 FR 32096, June 19, 1995]

§ 153.155 Seed treatment products.

(a) Pesticide products intended for use in treating seeds must contain an EPA-approved dye to impart an unnatural color to the seed, unless appropriate tolerances or other clearances have been established under the Federal Food, Drug and Cosmetic Act for residues of the pesticide.

(b) The following products are exempt from the requirement of paragraph (a) of this section:

(1) Products intended and labeled for use solely by commercial seed treaters, provided that the label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process.

(2) Products intended and labeled for use solely as at-planting or hopper box treatments.

(3) Products which are gaseous in form or are used as fumigants.

(c) EPA-approved dyes for seed treatment are listed in:

(1) Sections 180.910, 180.920, and 180.950 if an exemption from the requirement of a tolerance has been established.

(2) Section 180.2010 if EPA has determined that residues of the dye will be present, if at all, at levels that are below the threshold of regulation.

(3) Section 180.2020 if it has been determined that no tolerance or exemption from the requirement of a tolerance is needed as a result of a determination by EPA that the use is unlikely to result in residues in food/feed.

[53 FR 15990, May 4, 1988, as amended at 66 FR 66772, Dec. 27, 2001; 69 FR 23117, Apr. 28, 2004]

Subparts I–M [Reserved]

PART 154—SPECIAL REVIEW PROCEDURES

Subpart A—General Provisions

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AUTHORITY: 7 U.S.C. 136a, d, and w.

SOURCE: 50 FR 49015, Nov. 27, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 154.1 Purpose and scope.

(a) *Purpose.* The purpose of the Special Review process is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA). The process is intended to ensure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that, following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, reclassify, or require modifications to the registration of the product(s) in question unless it has been shown during the Special Review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks. Following completion of the Special Review process, a pesticide in question may be returned to the registration process.

(b) *Scope.* This part sets forth the substantive standards for initiating a Special Review of a pesticide product and the procedures for initiating and conducting the Special Review.

§ 154.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

Act or FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Administrator means the Administrator of the Environmental Protection Agency or any officer or employee thereof to whom authority has been delegated to act for the Administrator.

Confidential business information means trade secrets or confidential commercial or financial information under FIFRA section 10(b) or 5 U.S.C. 552(b)(3) or (4).

Other significant evidence means factually significant information that relates to the uses of the pesticide and its adverse risk to man or to the environment but does not include evidence based only on misuse of the pesticide unless such misuse is widespread and commonly recognized practice.

Person means an applicant, registrant, manufacturer, pesticide user, environmental group, labor union, or other individual or group of individuals interested in pesticide regulation.

Pesticide use means a use of a pesticide (described in terms of the application site and other applicable identifying factors) that is included in the labeling of a pesticide product which is registered, or for which an application for registration is pending, and the terms and conditions (or proposed terms and conditions) of registration for the use.

Terms and conditions of registration means the terms and conditions governing lawful sale, distribution, and use approved in conjunction with registration, including labeling, use classification, composition, and packaging.

Validated test means a test determined by the Agency to have been conducted and evaluated in a manner consistent with accepted scientific procedures.

[73 FR 75595, Dec. 12, 2008]

§ 154.5 Burden of persuasion in determinations under this part.

In making determinations under this part the Administrator shall be guided by the principle that the burden of persuasion that a pesticide product is entitled to registration or continued registration for any particular use or under any particular set of terms and conditions of registration is always on the proponent(s) of registration.

§ 154.7 Criteria for initiation of Special Review.

(a) The Administrator may conduct a Special Review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):

(1) May pose a risk of serious acute injury to humans or domestic animals.

(2) May pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms

of either the degree of risk to individual humans or the number of humans at some risk, based upon:

(i) Effects demonstrated in humans or experimental animals.

(ii) Known or predicted levels of exposure of various groups of humans.

(iii) The use of appropriate methods of evaluating data and relating such data to human risk.

(3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

(4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.

(5) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species.

(6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

(b) In making any determination that a pesticide use satisfies one of the criteria for issuance of a Special Review specified by paragraph (a) of this section, the Administrator shall consider available evidence concerning both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide.

§ 154.10 Petitions to begin the Special Review process.

The Administrator may evaluate a pesticide use under the criteria of § 154.7 either on his own initiative, or at the suggestion of any interested person.

§ 154.15 Docket for the Special Review.

(a) *Establishment of the docket.* When the Agency first notifies registrants privately that it is considering issuance of a Notice of Special Review for a pesticide, it shall establish a docket concerning that particular pesticide.

(b) *Contents of the docket.* For each pre-Special Review or Special Review, the docket shall contain:

(1) The Notice of Special Review, any Notice of Preliminary Determination, and any Notice of Final Determination.

(2) Any notice issued under § 154.21 or § 154.23.

(3) Any documents (other than information claimed to be confidential business information) referred to by the Agency in those notices as relied upon by the Agency in reaching its determination.

(4) Copies of all written comments or materials (other than information claimed to be confidential business information) responding to any notice furnished under § 154.21 or § 154.23 or submitted at any time during the Special Review process by any person outside of government.

(5) Any written response to the Notice of Preliminary Determination from the Secretary of Agriculture or the Scientific Advisory Panel.

(6) A transcript of all public meetings held by the Scientific Advisory Panel or conducted by the Agency for the purpose of gathering information.

(7) A memorandum describing each meeting between Agency personnel and any person or party outside of government which concerns a pending pre-Special Review or Special Review decision. Each such memorandum shall be based on notes taken at the meeting and shall specify the date and time of the meeting, the participants and their affiliations, who requested the meeting, the subject matter of the meeting, and the person who prepared the memorandum. Except for information claimed to be confidential business information, each memorandum shall describe fully and accurately all significant positions taken, arguments made, and facts presented by each participant in the meeting, and shall identify all documents, proposals, or other materials distributed or exchanged at the

meeting. Any discussion of claimed confidential business information shall be identified in meeting notes and referenced in the memorandum.

(8) All comments, correspondence, or other materials concerning a pending pre-Special Review or Special Review decision provided to the Agency by a person or party outside of government (other than information claimed to be confidential business information).

(9) All documents, proposals, or other materials concerning a pending pre-Special Review or Special Review decision, provided by the Agency to any person or party outside of government (other than information claimed to be confidential business information).

(c) *Assertion of confidential business information claims.* (1) Information, comments, data, or other written material submitted to the Agency concerning a Special Review may be claimed by the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter, or, in meetings, with the participants who wish to assert a claim of confidentiality.

(2) To assert a claim of confidentiality for all or any part of a written submission concerning a Special Review, the submitter must furnish three copies of the material. Two copies must be complete, with claimed confidential business information clearly marked in the text. Items in the document that are claimed confidential should be numbered consecutively throughout the text. The third copy must have the claimed confidential business information excised from the text without closing up or paraphrasing the remaining text. The deletions should be consecutively numbered to correspond to the numbering of the complete copies. Each copy must be marked on the cover as to whether it contains claimed confidential business information.

(3) Any written material concerning a Special Review received by the Agency that is not marked as confidential will be deemed to be nonconfidential, and may be made available through the public docket or otherwise disclosed without prior notice to the submitter.

(d) *Placement of materials in the docket.* Any memorandum identified under paragraph (b)(7) of this section shall be placed in the docket within 10 working days of the subject meeting. Materials identified under paragraph (b)(8) of this section shall be placed in the docket within 10 working days of receipt by the Office of Pesticide Programs, or within 15 working days of receipt by the Office of Pesticide Programs if the submitter has asserted a confidential business information claim concerning the submittal. Materials identified under paragraph (b)(9) of this section shall be placed in the docket within 15 working days of transmittal to such person or party outside of government.

(e) *Index.* The Agency shall prepare and maintain a current index of all materials included in the docket. The index will include a list identifying, for each meeting between Agency personnel and a person or party outside of government for which a memorandum has been prepared, the date, the subject, participants, and person who requested the meeting. The index will also list any document included in the docket by its title, its source, its recipient, and the date it was received or provided by the Agency.

(f) *Access to the docket.* (1)(i) For each chemical in Special Review, the docket shall be available for public inspection and copying and its index kept current and made available to the public on request. The docket and index for any pesticide for which the Agency has issued a pre-Special Review notification under § 154.21 will only be made available for public inspection and copying following issuance of a proposed decision not to start a Special Review under § 154.23, a Notice of Special Review under § 154.25(c), or as otherwise specified in § 154.34.

(ii) The docket and index will be available at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).

(2) Information contained in the docket shall not be disclosed to the public to the extent that FIFRA or any other statute or regulation (including, but not limited to, 5 U.S.C. 552(b)(3) or (4)) prohibits its disclosure.

(3) The Agency will distribute a compendium of indices for new materials in

the public docket by mail, on a monthly basis, to those members of the public who have specifically requested such material. The Agency will announce the availability of docket indices both annually in the FEDERAL REGISTER and in each FEDERAL REGISTER Notice concerning pre-Special Review or Special Review for specific pesticides. The Agency may also periodically require parties on the mailing list to renew their previous request for such materials.

[50 FR 49015, Nov. 27, 1985, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

Subpart B—Procedures

§ 154.21 Preliminary notification to registrants and applicants for registration.

(a) *Preliminary notification.* If the Administrator decides that he may initiate a Special Review of a pesticide use, he shall send written notice by certified mail to the affected registrant(s) and applicant(s) setting forth his decision and a general description of the information which supports it.

(b) *Comment opportunity.* Registrant(s) and applicant(s) will be allowed 30 days from the receipt of notification to respond in writing to dispute the validity of the Agency's conclusions or to present information in response to the notification.

§ 154.23 Proposed decision not to initiate a Special Review.

If the Administrator proposes not to initiate a Special Review after having given notice under § 154.21, he shall issue a proposed decision for publication in the FEDERAL REGISTER. The proposal shall include a description of the concerns which were the original basis for placement of the pesticide in pre-Special Review status and the Agency's rationale for its proposed decision, announce the availability of a public docket, and provide a period generally not less than 30 days for submission of comments. A notice under § 154.25(b) may not be published unless it has been preceded by a notice under this section. A proposal under this section shall not be based on the benefits of use of a pesticide product.

§ 154.25 Public announcement of final decision whether to initiate a Special Review.

(a) The Administrator shall evaluate the available information and the comments received in response to the notice under § 154.21 and any notice issued under § 154.23, and shall issue for publication in the FEDERAL REGISTER a notice under paragraph (b) or (c) of this section.

(b) If the Administrator determines after having given notice under § 154.21 not to initiate a Special Review, he shall issue his decision for publication in the FEDERAL REGISTER with a statement of reasons.

(c) If the Administrator determines after having given notice under § 154.21 that one or more of the risk criteria set forth in § 154.7 have been satisfied, the Agency shall issue a notice for publication in the FEDERAL REGISTER which shall include:

(1) Identification of the pesticide uses for which a Special Review has been initiated and an identification of the criteria which have been satisfied.

(2) A brief discussion of the Agency's reasons for determining that the criteria have been satisfied.

(3) A statement indicating that EPA has established a docket for the Special Review, the contents of the docket, the location of the docket, and the times during which the docket will be available for inspection and copying.

(4) An invitation to all interested persons to submit further information concerning the risks and benefits associated with each use of the pesticide subject to the Special Review.

(5) A brief description of the Special Review process and a statement that registrants and applicants bear an affirmative burden of supporting registration of a pesticide product.

(6) A date by which information in response to the Agency's request for further information must be submitted.

(d) In his discretion, the Administrator may request that the Scientific Advisory Panel hold a public meeting to review the scientific issues related to the Special Review.

§ 154.26 Comment opportunity.

After issuance of a Notice of Special Review that applies to a use of a pesticide product (or category of products), any person may submit to the Agency any information, argument, or both, pertinent to:

(a) Whether the use of a pesticide product satisfies any of the § 154.7 risk criteria, with respect to the composition, labeling, packaging, and restrictions on use of the product as currently registered.

(b) Whether the use of a pesticide product would satisfy any of the § 154.7 risk criteria if its composition, labeling, packaging, and restrictions on use were approved in accordance with an application for registration or amended registration pending before the Agency. For further information see § 154.27(b).

(c) Whether any risks posed by the use or proposed use of the product that satisfy the § 154.7 risk criteria are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product.

(d) What regulatory action, if any, the Agency should take with respect to the use of the product.

§ 154.27 Meetings with interested persons.

(a) In the Special Review process, to assure openness and responsiveness, no person or party outside of government will be afforded special or preferential access to Agency Special Review decisionmakers or to the Agency's Special Review process. At the same time, however, Agency personnel are free to meet and otherwise communicate with persons or parties outside of government, including registrants and manufacturers, users, trade unions, environmental groups and other interested persons, to obtain information, exchange views, explore factual and substantive positions, or discuss regulatory options concerning Special Review decisions.

(b) Meetings between EPA and any person or party outside of government will not result in undue delay in reaching Special Review decisions. During such meetings, the Agency will not commit to take any particular action concerning a pending decision. The Agency may receive and consider information and recommendations from persons or parties outside of government; however, the Agency will make the final administrative decision on a wholly independent basis and in accordance with law.

(c) Any interested person may ask to meet with Agency officials to discuss factual information available to the Agency, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding a pesticide which is or may be the subject of a Special Review. If, at its discretion, the Agency holds such meetings with any person outside of government concerning a use of a pesticide product, the Agency will prepare and file in the docket a memorandum of such meeting, meeting the requirements specified in § 154.15(b)(7).

(d) Meetings described in this section may include meetings held after issuance of a Notice of Special Review with any registrant who proposes to change voluntarily the composition, packaging, and labeling, or other terms and conditions of registration of his pesticide product in a way which he believes would reduce the risks of use of the product so that it would no longer meet or exceed the risk criteria of § 154.7. Meetings for this purpose will be most helpful and productive for both registrants and the Agency if they are requested by registrants shortly after the issuance of the Notice of Special Review.

(e) If the Agency meets with any person or party outside of government concerning a pending Special Review decision, the Agency will not issue a final Special Review decision until 30 days after inclusion of a memorandum concerning that meeting in the public docket. During those 30 days, any person or party may submit written comments to the Agency regarding the subject matter of the meeting in question. The Agency may issue a final Special Review decision without allowing this 30-day period if expedited action is necessary to protect public health or the environment, or if the Agency has invited other parties with potentially opposing viewpoints to the meeting in

question (e.g., registrants, users, labor, and environmental groups).

(f) The Agency may decline to meet subsequently with any person or party who asserts unreasonable confidential business information claims pursuant to § 154.15(c) for the purpose of circumventing the docketing procedures described in § 154.15(b).

§ 154.29 Informal public hearings.

(a) *Timing.* At any time after issuance of a Notice of Special Review and prior to issuance of a Notice of Final Determination, the Administrator may conduct an informal public hearing to gather relevant information or otherwise assist Agency decisionmaking.

(b) FEDERAL REGISTER notice. The Administrator shall issue a notice for publication in the FEDERAL REGISTER of any informal public hearing to be held under this section. The notice shall contain the following information:

(1) The time, date, and place of the hearing.

(2) A brief description of the procedures governing participation in the hearing by interested persons.

(3) The issues to be considered at the hearing.

(c) *Transcript.* A verbatim transcript of the hearing shall be prepared and filed in the public docket.

§ 154.31 Notices of Preliminary Determination.

The Administrator shall prepare a Notice of Preliminary Determination after the close of the comment period on a Notice of Special Review.

(a) *Contents of notice.* The Notice of Preliminary Determination shall respond to all significant comments submitted in response to the Notice of Special Review. For each use of a pesticide product that was the subject of the Notice of Special Review, the Notice of Preliminary Determination shall also include, as appropriate:

(1) A determination whether the use satisfies any of the risk criteria set forth in § 154.7, and a discussion of the reasons for the determination.

(2) A determination of whether any changes in the composition, packaging, labeling, or restrictions on use of a pesticide product that were proposed in an application for new or amended registration submitted after issuance of the Notice of Special Review would reduce the risk so that the use no longer would satisfy any of the risk criteria in § 154.7.

(3) If the use satisfies any of the risk criteria set forth in § 154.7, a determination of whether the adverse effects posed by the use are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product, and a discussion of reasons for the determination.

(4) If the use is determined to pose an unreasonable adverse effect, a statement of the regulatory action, if any, which the Agency intends to initiate with respect to the use, and a discussion of the reasons for initiating that regulatory action.

(5) A statement that the Administrator is requesting comments from the Secretary of Agriculture and the Scientific Advisory Panel on the notices and analysis specified in paragraph (b) of this section, and that the notices and analysis are available on request.

(6) Instructions to interested persons on how to submit comments (including the deadline for submission of comments).

(7) The location of the docket under § 154.15 and the times during which the docket will be available for inspection and copying.

(b) *Referral to Secretary of Agriculture and Scientific Advisory Panel.* If the Administrator proposes to cancel, deny, or change the classification of the registration of a pesticide product which is the subject of a Special Review, or to hold a hearing under FIFRA section 6(b)(2) on whether to take any of those actions, he shall:

(1) Prepare a proposed form of a Notice of Intent to Cancel, a Notice of Intent to Deny Registration, a Notice of Intent to Hold a Hearing, and/or a Notice of Intent to Change Classification, as appropriate.

(2) Prepare an Agricultural Impact Analysis, analyzing the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

(3) Send the proposed notices and analysis to the Secretary of Agriculture and the Scientific Advisory Panel for comment, as provided by the Act.

(4) Send the Notice of Preliminary Determination and the other notices and analysis prepared under this section to all registrants and applicants for registration of products that are subject to the Special Review.

(c) *Publication.* The Agency shall issue the Notice of Preliminary Determination for publication in the FEDERAL REGISTER.

§ 154.33 Notice of Final Determination.

(a) *Publication and notice to registrants and applicants.* The Administrator shall prepare a Notice of Final Determination after the close of the comment period on a Notice of Preliminary Determination. As necessary, the Administrator shall also prepare Notices of Intent to Cancel, Notices of Denial, Notices of Intent to Hold a Hearing under FIFRA section 6(b)(2), or Notices of Intent to Change Classification.

(b) *Contents.* The Notice of Final Determination shall include:

(1) For each pesticide use subject to the Notice of Preliminary Determination, the Agency's final determination with respect to each use, along with a discussion of the reasons for the determination.

(2) Any comments submitted by the Secretary of Agriculture or the Scientific Advisory Panel, and the responses of the Administrator to these comments.

(3) The response of the Administrator to any significant public comments submitted on the Notice of Preliminary Determination.

(4) Instructions to registrants, applicants for registration, and other interested persons concerning the procedures which will be used to implement any regulatory action which the Administrator has decided upon, including instructions concerning how to request hearings, if hearings are available as of right under the Act or have been made available by the Administrator under the Act.

(5) The location of the docket under § 154.15 and the times during which the docket will be available for inspection and copying.

(c) *Publication and notification of registrants and applicants.* The Notice of Final Determination and any Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification shall be published in the FEDERAL REGISTER. If the Administrator issues a Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification, such notice, along with the Notice of Final Determination, also shall be sent by certified mail to all affected registrants and applicants.

§ 154.34 Expedited procedures.

(a) The Agency may elect to issue a Notice of Special Review and a Notice of Preliminary Determination simultaneously; or, to initiate cancellation, suspension, or denial proceedings concerning a pesticide or any of its uses without first conducting a Special Review or issuing a Notice of Preliminary Determination.

(b) If the Agency elects to issue a simultaneous Notice of Special Review and Notice of Preliminary Determination, the Agency will make the docket for that decision available for public inspection no more than 3 months after the Agency privately notifies the registrant of its risk concerns pursuant to § 154.21(a).

§ 154.35 Finality of determinations.

(a) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in paragraph (c) of this section, if:

(1) The application proposes registration of a product for a use which earlier had been the subject of a notice under § 154.21(a);

(2) After the Administrator issued the notice, he determined not to initiate a Special Review, because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for a Special Review; and

(3) The application for registration or amended registration now proposes that the terms and conditions which served as the basis of the earlier determination be eliminated, or be modified in a way which might increase the risk which was the subject of the notice under § 154.21(a).

(b) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in paragraph (c) of this section, if:

(1) The application proposed registration of a product for a use which earlier had been the subject of a Notice of Special Review issued under § 154.25;

(2) After the Administrator issued that Notice, he determined not to issue a notice under FIFRA section 3(c)(6) or 6(b) because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for issuance of a notice under FIFRA section 3(c)(6) or 6(b); and

(3) The application for registration or amended registration now proposes that the terms and conditions of registration which served as the basis for the earlier determination now be eliminated or be modified in a way which might increase the risk which was the subject of the Notice of Special Review.

(c) An application to which paragraph (a) or (b) of this section applies may not be approved until:

(1) The Administrator issues a notice for publication in the FEDERAL REGISTER which describes why the application is subject to the provisions of this section, states that the Administrator proposes to approve the application and his reasons, solicits public comment on whether the application should be approved, and provides a period not less than 30 days for comments to be submitted; and

(2) If any substantive comments are submitted in response to the notice, the Administrator issues a second notice for publication in the FEDERAL REGISTER responding to the comments.

PART 155—REGISTRATION STANDARDS AND REGISTRATION REVIEW

Subpart A [Reserved]

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AUTHORITY: 7 U.S.C. 136a and 136w.

SOURCE: 50 FR 49001, Nov. 27, 1985, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Docketing and Public Participation Procedures

§ 155.23 Definitions.

For the purposes of this part, *confidential business information* means trade secrets or confidential commercial or financial information under FIFRA sec. 10(b) or 5 U.S.C. 552(b) (3) or (4).

§ 155.25 Schedule.

EPA will issue annually in the FEDERAL REGISTER a notice listing the pesticides (or groups of pesticides) for

which Registration Standards are currently being developed. The list will include pesticides for which a Registration Standard is scheduled for issuance within the next year, and the approximate sequence of issuance. The list may also include pesticides for which a Registration Standard will be under development during the upcoming year, but which are not scheduled for issuance until the succeeding year. The notice will invite comment and submission of information on the individual pesticides on the list.

§ 155.27 Agency review of data.

EPA will independently (or using the services of disinterested contractors or consultants) review available data in preparation for the development of a Registration Standard, and will be responsible for the drafting of the Registration Standard based on such data reviews. The Agency will not permit registrants to prepare, or assist in the preparation of, data reviews or other Registration Standard documents. The Agency may, however, meet with registrants to discuss its pending reviews, decisions, or documents, in accordance with the meeting procedures in § 155.30, and the docketing procedures in § 155.32.

§ 155.30 Meetings and communications.

EPA personnel may, upon their own initiative or upon request of any interested person or party, meet or communicate with persons or parties outside of government concerning a Registration Standard under development. Such meetings or communications will conform to the following policies and procedures:

(a) *Purpose.* Meetings and communications may be for the purpose of receiving and considering information, exchanging views, exploring factual and substantive positions, discussing regulatory options or for any other purpose deemed appropriate by the Agency in its deliberations concerning development of a Registration Standard. The Agency will not commit to take any particular action concerning a Registration Standard under development during discussions with any person or party outside of government. The Agency will make its final administrative decision on a wholly independent basis, and in accordance with law.

(b) *Meetings with persons or parties outside of government.* Requests by responsible persons or parties outside of government to meet with Agency personnel concerning a Registration Standard under development should be directed in writing to the Registration Division. Reasonable requests will ordinarily be granted on a timely basis. EPA will decide the time and place of such meetings, and the Agency personnel who will attend. EPA may decline to meet with persons or parties who assert unreasonable claims of confidential business information for the purpose of circumventing the docketing procedures in § 155.32. EPA may also decline to meet if the number or frequency of meetings would delay unduly the issuance of the Registration Standard. Further, no person or party outside government will be accorded special or preferential access to Agency pesticide decisionmaking or to the Agency's decisional process.

(c) *Information submitted to the Agency concerning a Registration Standard under development.* (1) Information, comments, data, or other written material submitted to the Agency at any time concerning a Registration Standard under development may be claimed by the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter, or, in meetings, with the participants from outside of government who wish to assert a claim of confidentiality.

(2) To assert a claim of confidentiality for all or any part of a written submission concerning a Registration Standard under development, the submitter must furnish three copies of the material. Two copies must be complete, with claimed confidential business information clearly marked in the text. Items in the document that are claimed confidential should be numbered consecutively throughout the document. The third copy must have the claimed confidential business information excised from the text without

closing up or paraphrasing the remaining text. The deletions should be consecutively numbered to correspond to the numbering of the complete copies. Each copy must be marked on the cover as to whether it contains claimed confidential business information.

(3) Any written material received by the Agency that is not marked as confidential will be deemed to be nonconfidential, and may be made available through the public docket or otherwise disclosed without prior notice to the submitter.

(d) *Memorandum of meeting.* For each meeting with a person or party outside of government, the Agency will prepare, based on notes taken at the meeting, a memorandum of the meeting. The memorandum will be prepared within 10 working days of the meeting and will include all of the following information:

(1) The date and time of the meeting.

(2) The name of the person who requested the meeting.

(3) The names and affiliations of the participants.

(4) The subject matter of the meeting.

(5) A full and accurate description of all significant positions taken, facts presented, and arguments made by each participant (except that any discussion of claimed confidential business information will be identified in meeting notes, and referenced in the memorandum).

(6) Identification of all documents, proposals, or other materials (other than information claimed to be confidential business information) distributed or exchanged at the meeting.

(7) The name of the person who prepared the memorandum.

[50 FR 49001, Nov. 27, 1985, as amended at 58 FR 34203, June 23, 1993]

§ 155.32 Public docket.

(a) *When created.* (1) A docket will be created for each Registration Standard under development when the Agency begins review of data for the Registration Standard or upon publication of the notice described in § 155.25 setting out the list and sequence of Registration Standards, whichever is earlier. The Agency will announce in its annual schedule notice the dockets that are available for Registration Standards under development.

(2) If the Agency notifies registrants privately in accordance with 40 CFR 154.21 that one or more risk criteria set forth in 40 CFR 154.7 (leading to a special review) may have been exceeded, that notification and any subsequent communications concerning that notification will be placed in a separate docket pertaining to possible special review in accordance with the provisions of § 154.15.

(b) *Contents of docket.* The docket will contain, within the time frames indicated, all of the following documents and information (except that information claimed to be confidential business information will not be included):

(1) An index of its contents (refer to paragraph (c) of this section).

(2) A copy of each comment received in response to the notice described in § 155.25 that pertains to a pesticide for which the notice indicated a Registration Standard was under development (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(3) A copy of each memorandum of a meeting between the Agency and persons or parties outside of government, prepared in accordance with § 155.30(d) (within 10 working days after the meeting).

(4) A copy of each document, comment, item of correspondence or other written material concerning the Registration Standard submitted to the Agency by any person or party outside of government, whether in a meeting or separately (within 10 working days after receipt, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

Subpart C—Registration Review Procedures

SOURCE: 71 FR 45732, Aug. 9, 2006, unless otherwise noted.

§ 155.40 General.

(a) *Purpose.* These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

(1) Among other things, FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment. Registration review is intended to ensure that each

pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.

(2) If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA.

(b) *Applicability*. This subpart applies to every pesticide product registered under FIFRA section 3 as well as all pesticide products registered under FIFRA section 24(c). It does not apply to products whose sale or distribution is authorized under FIFRA section 5 or section 18.

(c) *Limitations*. (1) At any time, the Agency may undertake any other review of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing, scheduled, or not yet scheduled registration review.

(2) When the Agency determines that new data or information are necessary for a pesticide's registration review, it will require such data under FIFRA section 3(c)(2)(B).

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75595, Dec. 12, 2008]

§ 155.42 Registration review cases.

(a) *Establishing registration review cases*. A registration review case will be composed of one or more active ingredients and all the products containing such ingredient(s). The Agency may group related active ingredients into a registration review case when the active ingredients are so closely related in chemical structure and toxicological profile as to allow common use of some or all required data for hazard assessment.

(1) *Existing pesticides*. The Agency will assign each pesticide registered on or before the effective date of this regulation to a registration review case.

(2) New pesticides. The Agency will assign each pesticide registered after the effective date of this regulation to an existing registration review case or to a new registration review case.

(3) A pesticide product that contains multiple active ingredients will belong to the registration review cases for each of its active ingredients.

(b) *Modifying registration review cases*. New data or information may suggest that a registration review case should be modified. The Agency may modify a registration review case in the following ways:

(1) Add a new active ingredient to a registration review case. The Agency may determine that a new active ingredient is chemically and toxicologically similar to active ingredients in an existing registration review case and should be grouped with the ingredients in the existing registration review case.

(2) Split a registration review case into two or more registration review cases. For example, new data or information may suggest that active ingredients in a registration review case are not as similar as previously believed and that they belong in two or more separate registration review cases.

(3) Move an ingredient from one registration review case to another. For example, new data or information might suggest that an ingredient should not be grouped with the other ingredients in the registration review case and that it belongs in a different registration review case.

(4) Merge two or more registration review cases into a single registration review case. For example, new data or information might suggest that the active ingredients in two or more registration review cases should be grouped together for registration review.

(5) Delete an active ingredient from a registration review case. For example, the Agency will remove the ingredient from the case if the registrations of all products containing an active ingredient in a registration review case are canceled.

(c) *Closing a registration review case*. The Agency will close a registration review case if all products in the case are canceled.

(d) *Establishing a baseline date for a registration review case*. For the purpose of scheduling registration reviews, the Agency will establish a baseline date for each registration review case. In general, the baseline date will be the date of initial registration of the oldest pesticide product in the case or the date of reregistration, whichever is

later. For the purpose of these procedures, the date of reregistration is the date on which the Reregistration Eligibility Decision or Interim Reregistration Decision was signed, whichever date the Agency determines to be more appropriate based on the comprehensiveness of the review.

(1) The Agency generally will not change the baseline date for a registration review case when it modifies a case by adding or deleting ingredients or products.

(2) When the Agency splits a registration review case into two or more cases, the new case(s) generally will have the baseline date of the original registration review case.

(3) When the Agency merges two or more registration review cases into a single case, the Agency generally will use the earliest baseline date as the baseline date for the new case.

(e) *Announcing registration review cases and baseline dates.* The Agency will maintain a list of registration review cases, including baseline dates, on its website.

§ 155.44 Establish schedules for registration review.

The Agency will develop schedules for registration review that are generally based on the baseline date of the registration review case or on the date of the latest registration review of the registration review case. The Agency may also take into account other factors, such as achieving process efficiencies by reviewing related cases together, when developing schedules for registration review. The Agency will maintain schedules for the current year and at least two subsequent years on its website.

§ 155.46 Deciding that a registration review is complete and additional review is not needed.

The Agency may determine that there is no need to reconsider a previous decision that a pesticide satisfies the standard of registration in FIFRA. In such cases, instead of establishing a pesticide registration review case docket as described in § 155.50, the Agency may propose that, based on its determination that a pesticide meets the FIFRA standard for registration, no further review will be necessary. In such circumstances, the Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the proposed decision and provide a comment period of at least 60 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a final version of the decision, an explanation of any changes to the proposed decision and its response to any comments. The date of the final notice of availability would be used as the date of the latest registration review for the purpose of scheduling subsequent registration reviews.

§ 155.48 Data Call-In.

The Agency may issue a Data Call-In notice under FIFRA section 3(c)(2)(B) at any time if the Agency believes that the data are needed to conduct the registration review. The provisions in FIFRA section 3(c)(1), (c)(2)(B), and (c)(2)(D) apply to the submission, compensation, and exemption of data required to conduct a registration review.

§ 155.50 Initiate a pesticide's registration review.

The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under § 155.46, and opening it for public review.

(a) *Contents of the registration review case docket.* The Agency will place in this docket information that will assist the public in understanding the types of information and issues that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any FEDERAL REGISTER notices regarding pending registration actions, and current or pending tolerances;

(3) Risk assessment documents;

(4) Bibliographies concerning current registrations;

(5) Summaries of incident data; and

(6) Any other pertinent data or information.

(b) *Public review of the registration review case docket.* The Agency will publish a notice in the FEDERAL REGISTER announcing the availability for public review of the information described in paragraph (a) of this section and establishing a comment period of at least 60 days. During this comment period, interested persons may identify any additional information they believe the Agency should consider in the course of the registration review.

(c) *Submission of data and other information during the comment period.* The Agency may identify, either in the notice published under paragraph (b) of this section, or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review. Any person may submit data or information in response to such identification. In order to be considered during a pesticide's registration review, the submitted data or information must meet the requirements listed below.

(1) In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section. The Agency may, at its discretion, consider data or information submitted at a later date.

(2) The data or information must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

§ 155.52 Stakeholder engagement.

In addition to the public participation opportunities described in § 155.50 and § 155.53(c), the Agency may meet with stakeholders regarding a forthcoming or ongoing registration review. For example, before conducting a pesticide's registration review, the Agency may consult with registrants or pesticide users regarding the use and usage of the pesticide. The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review with regard to developing risk management options for a pesticide. The Agency may informally consult with officials of Federal, State or Tribal agencies regarding a forthcoming or ongoing registration review.

(a) *Minutes of meetings with persons outside of government.* Subject to paragraph (c) of this section, if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting, not later than the earlier of:

(1) 45 days after the meeting; or

(2) The date of issuance of the registration review decision.

(b) *Exchange of documents or other written material.* In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged.

(c) *Confidential business information.* The Agency will identify, but not include in the docket, any confidential business information whose disclosure is prohibited by FIFRA section 10.

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75596, Dec. 12, 2008]

§ 155.53 Conduct of a pesticide's registration review.

The Agency will review data and information described in § 155.50(a), (b), and (c) or submitted in response to a Data Call-In notice that it believes should be considered in the pesticide's registration review.

(a) *Assess changes since a pesticide's last review*. The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted under § 155.50 or in response to a Data Call-In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under § 155.50 or in response to a Data Call-In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) *Conduct new assessments as needed*. (1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it can base the new assessment on available data or information, including data or information submitted under § 155.50 or in response to a Data Call-In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(c) *Public participation during a pesticide's registration review*. The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment.

(1) The Agency might not request comments on a draft risk assessment in cases where the Agency's initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, poses low risk, and/or requires little or no risk mitigation. In such cases, the Agency will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case.

(2) If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in § 155.58.

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

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Subpart H—Container Labeling

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156.144 Residue removal instructions—general.
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AUTHORITY: 7 U.S.C. 136–136y.

Subpart A—General Provisions

§ 156.3 Definitions.

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this part, the following terms shall have the meanings set forth below.

Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

[73 FR 64224, Oct. 29, 2008]

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, ''securely attached''

shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation*. While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage*. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements*. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as ''safe,'' ''nonpoisonous,'' ''noninjurious,'' ''harmless'' or ''nontoxic to humans and pets'' with or without such a qualifying phrase as ''when used as directed''; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) ''Contains all natural ingredients'';

(B) ''Among the least toxic chemicals known''

(C) ''Pollution approved''

(6) *Final printed labeling*. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark*. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as ''Packed for * * *,'' ''Distributed by * * *,'' or ''Sold by * * *'' to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 °F (20 °C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, *i.e.*, ''1 pound 10 ounces'' rather than ''26 ounces.''

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(7) For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank to allow the net weight or measure of content to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide. As required in paragraph (a)(1)(iii) of this section, the net contents must be shown clearly and prominently on the label.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase ''EPA Registration No.,'' or the phrase ''EPA Reg. No.'' The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishment's registration number.* The producing establishment registration number preceded by the phrase ''EPA Est.'', of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank after the phrase ''EPA Est.'' to allow the EPA establishment registration number to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term ''active ingredients'' and the inert ingredients by the term ''inert ingredients,'' or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The

statement ''Inert Ingredients, none'' is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term ''analysis'' shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as ''22–25%.'' If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: ''Not for sale or use after [date].''

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) [Reserved]

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as ''See directions in the enclosed circular:'' and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use.* (A) Detailed directions for use may be omitted from labeling of

pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings ''Directions for Use'':

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading ''Directions for Use.''

(ii) Immediately below the statement of use classification, the statement ''It is a violation of Federal law to use this product in a manner inconsistent with its labeling.''

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, ''Storage and Disposal.'' This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in § 156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in § 156.78(d)(1), the following

statements must be included in the ''Directions for Use.''

DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. Do not use in a room 5 ft.×5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames, or running electrical appliances that cycle off and on (*i.e.*, refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights.''

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of use classification.* Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words ''General Classification'' immediately below the heading ''Directions for Use.'' And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement ''Restricted Use Pesticide'' shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: ''For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.'' If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988; 57 FR 38146, Aug. 21, 1992; 60 FR 32096, June 19, 1995; 63 FR 9082, Feb. 23, 1998; 66 FR 64764, Dec. 14, 2001; 71 FR 47420, Aug. 16, 2006; 73 FR 75596, Dec. 12, 2008]

Subparts B–C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

SOURCE: 66 FR 64764, Dec. 14, 2001, unless otherwise noted.

§ 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either

direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*—(1) *Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*—(1) *Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

Size of Label Front Panel (Square Inches)	Point Size	
	Signal Word (All Capital Letters)	Child Hazard Warning
5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

§ 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

§ 156.64 Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word

must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word ''DANGER.'' In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word ''Poison'' must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word ''Poison.''

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word ''WARNING.''

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word ''CAUTION.''

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be ''CAUTION.''

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

§ 156.66 Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement ''Keep Out of Reach of Children.'' That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

§ 156.68 First aid statement.

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be ''First Aid'' or ''Statement of Practical Treatment.''

(d) *Location of first aid statement.* The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as ''See first aid statement on back panel'' appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

§ 156.70 Precautionary statements for human hazards.

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading ''Precautionary Statements'' and under appropriate subheadings similar to ''Humans and Domestic Animals,'' ''Environmental Hazards'' (see subpart E of this part) and ''Physical or Chemical Hazards.'' The phrase ''and Domestic Animals'' may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing.	
IV	No precautionary statements required	No precautionary statements required.	

§ 156.78 Precautionary statements for physical or chemical hazards.

(a) *Requirement.* Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical

hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

Flash point/flame extension of product	Required labeling statement
—Flash point at or below 20 °F OR —Flashback at any valve opening	*Extremely flammable.* Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
—Flash point >20 °F to 80 °F OR —Flame extension more than 18 in. long at a distance of 6 in from the flame	*Flammable.* Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
All other pressurized products	*Contents under pressure.* Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

Flash point	Required labeling statement
At or below 20 °F	*Extremely flammable.* Keep away from fire, sparks and heated surfaces.
Greater than 20 °F to 80 °F	*Flammable.* Keep away from heat and open flame.
Greater than 80 °F to 150 °F	*Combustible.* Do not use or store near heat or open flame.

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20 °F, then the following special instructions must be added to the ''Physical and Chemical Hazards'' warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the ''Physical and Chemical Hazards'' warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.

Highly Flammable Ingredient

Ingrediente Altamente Inflamable

Subpart E—Environmental Hazard and Precautionary Statements

SOURCE: 66 FR 64767, Dec. 14, 2001, unless otherwise noted.

§ 156.80 General.

(a) *Requirement.* Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) *Location of statements.* Environmental hazard and precautionary

statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading ''Environmental Hazards.'' Typically the statements are grouped as a sub-category within the ''Precautionary Statements'' section of the labeling.

(c) *Type size.* All environmental hazard and precautionary statements must be at least 6 point type.

§ 156.85 Non-target organisms.

(a) *Requirement.* Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage.

(b) *Examples.* The statements in this paragraph illustrate the types of hazard statements that EPA may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 mg/kg or less, the statement, ''This pesticide is toxic to wildlife'' is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement, ''This pesticide is toxic to fish'' is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement, ''This pesticide is toxic to wildlife'' is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, ''This pesticide is extremely toxic to wildlife (fish)'' is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to pollinating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, ''Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.''

Subparts F–G [Reserved]

Subpart H—Container Labeling

SOURCE: 71 FR 47420, Aug. 16, 2006, unless otherwise noted.

§ 156.140 Identification of container types.

For products other than plant-incorporated protectants, the following statements, as applicable, must be placed on the label or container. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

(a) *Nonrefillable container.* For nonrefillable containers, the statements in paragraphs (a)(1) through (a)(4) of this section are required except as provided in paragraphs (a)(5), (c), (d), and (e) of this section. If placed on the label, the statements in paragraphs (a)(1) through (a)(3) of this section must be under an appropriate heading under the heading ''Storage and Disposal.'' If any of the statements in paragraphs (a)(1) through (a)(3) of this section are placed on the container, an appropriate referral statement such as ''See container for recycling [or other descriptive word] information.'' must be placed on the label under the heading ''Storage and Disposal.''

(1) *Statement identifying a nonrefillable container.* The following phrase is required: ''Nonrefillable container.''

(2) *Reuse statement.* One of the following statements is required. Products with labels that allow household/residential use must use the statement in paragraph (a)(2)(i) or (a)(2)(iii) of this section. All other products must

use the statement in paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section.

(i) ''Do not reuse or refill this container.''

(ii) ''Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.''

(iii) The following statement may be used if a product is ''ready-to-use'' and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: ''Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container.''

(3) *Recycling or reconditioning statement.* One of the following statements is required:

(i) ''Offer for recycling if available.''

(ii) ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]. For example, this statement could be ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1–877–952–2272 (toll-free) or *www.acrecycle.org.*''

(iii) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(iv) An alternative recycling statement that has been reviewed and approved by EPA.

(v) ''Offer for reconditioning if appropriate.''

(4) *Batch code.* A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product which is distributed and sold is required.

(5) *Exemptions.* Pesticide products in the following types of nonrefillable containers, and their packaging, are exempt from the requirements in paragraphs (a)(1) and (a)(2) of this section:

(i) Aerosol cans.

(ii) Devices as defined in §152.500 of this chapter.

(iii) One-time use caulking tubes and other one-time use squeezable tube containers for paste, gel, or other similar substances.

(iv) Foil packets for water soluble packaging, repellent wipes, and other one-time use products.

(v) One-time use portion control packets, such as polyethylene sleeve packages, or rodenticide placepacks.

(vi) One-time use bait stations.

(vii) One-time use cages for repellent or trapping strips.

(viii) Pet collars or animal ear tags, such as cattle ear tags.

(ix) One-time use semiochemical dispersion devices.

(x) Any container that is destroyed by the use of the product contained.

(xi) Any container that would be destroyed if reuse of the container were attempted.

(b) *Refillable container.* For refillable containers, one of the following statements is required, except as provided in paragraphs (c), (d), and (e) of this section. If placed on the label, the statement must be under the heading ''Storage and Disposal.'' If the statement is placed on the container, an appropriate referral statement, such as ''Refilling limitations are on the container.'' must be placed under the heading ''Storage and Disposal.''

(1) ''Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose.''

(2) ''Refillable Container. Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose.''

(c) *Modification.* EPA may, on its own initiative or based on data or information submitted by any person, modify or waive the requirements of this section or permit or require alternative labeling statements.

(d) *Exemption for articles.* Pesticidal articles that are not exempted from FIFRA regulation by §152.25(a) of this

chapter are exempt from the requirements of this section.

(e) *Exemption for transport vehicles.* Transport vehicles are exempt from the requirements of this section.

[71 FR 47420, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

§ 156.144 Residue removal instructions—general.

(a) *General.* Except as provided by paragraphs (c) through (g) of this section, the label of each pesticide product must include the applicable instructions for removing pesticide residues from the container prior to container disposal that are specified in § 156.146 and § 156.156. The residue removal instructions are required for both nonrefillable and refillable containers.

(b) *Placement of residue removal statements.* All residue removal instructions must be placed under the heading ''Storage and Disposal.''

(c) *Exemption for residential/household use products.* Residential/household use pesticide products are exempt from the residue removal instruction requirements in this section through § 156.156.

(d) *Modification.* EPA may, on its own initiative or based on data submitted by any person, modify or waive the requirements of this section through § 156.156, or permit or require alternative labeling statements.

(e) *Exemption for gases.* Pesticide products that are gaseous at atmospheric temperature and pressure are exempt from the residue removal instruction requirements in this section through § 156.156.

(f) *Exemption for articles.* Pesticidal articles that are not exempted from FIFRA regulation by § 152.25(a) of this chapter are exempt from the residue removal instruction requirements in this section through § 156.156.

(g) *Exemption for transport vehicles.* Transport vehicles are exempt from the requirements in this section through § 156.156.

[71 FR 47420, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

§ 156.146 Residue removal instructions for nonrefillable containers—rigid containers with dilutable pesticides.

The label of each dilutable (liquid or solid) pesticide product packaged in a rigid nonrefillable container must include the following residue removal instructions as appropriate.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraphs (b) and (c) of this section:

(1) ''Clean container promptly after emptying.''

(2) ''Triple rinse or pressure rinse container (or equivalent) promptly after emptying.''

(3) ''Triple rinse container (or equivalent) promptly after emptying.''

(b) *Triple rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers must include one of the following sets of instructions.

(1) For liquid dilutable pesticide products in containers small enough to shake, use the following instructions: ''Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.''

(2) For solid dilutable pesticide products in containers small enough to shake, use the following instructions: ''Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.''

(3) For containers that are too large to shake, use the following instructions: ''Triple rinse as follows: Empty remaining contents into application

equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.''

(c) *Pressure rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers may include one of the following sets of instructions, and one of them must be used if the statement in paragraph (a)(2) of this section is used. If one of these statements is included on the label, it must immediately follow the triple rinse instructions specified in paragraph (b) of this section.

(1) For liquid dilutable pesticide products, use the following label instruction: ''Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.''

(2) For solid dilutable pesticide products, use the following label instruction: ''Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.''

(d) *Non-water diluent.* (1) A registrant who wishes to require users to clean a container with a diluent other than water (e.g., solvents) must submit to EPA a written request to modify the residue removal instructions of this section. The registrant may not distribute or sell the pesticide with the modified residue removal instructions until EPA approves the request in writing.

(2) The registrant must indicate why a non-water diluent is necessary for efficient residue removal, and must propose residue removal instructions and disposal instructions that are appropriate for the characteristics and formulation of the pesticide product and non-water diluent. The proposed residue removal instructions must identify the diluent. If the Directions for Use permit the application of a mixture of the pesticide and the non-water diluent, the instructions may allow the rinsate to be added to the application equipment or mix tank. If the Directions for Use do not identify the non-water diluent as an allowable addition to the pesticide, the instructions must require collection and storage of the rinsate in a rinsate collection system.

(3) EPA may approve the request if EPA finds that the proposed instructions are necessary and appropriate.

§ 156.156 Residue removal instructions for refillable containers.

The label of each pesticide product packaged in a refillable container must include the residue removal instructions in this section. Instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraph (b) of this section:

(1) ''Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.''

(2) ''Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.''

(b) *Residue removal instructions prior to container disposal.* (1) Instructions for cleaning each refillable container prior to disposal are required. The residue

removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.

(2) Subject to meeting the standard in paragraph (b)(1) of this section, the statement on residue removal instructions could include any one of the following:

(i) The refilling residue removal procedure developed by the registrant for the pesticide product.

(ii) Standard industry practices for cleaning refillable containers.

(iii) For pesticides that require dilution prior to application, the following statement: ''To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.''

(iv) Any other statement the registrant considers appropriate.

§ 156.159 Compliance date.

Any pesticide product released for shipment by a registrant after August 16, 2010 must bear a label that complies with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146, and 156.156.

[73 FR 64224, Oct. 29, 2008]

Subparts I–J [Reserved]

Subpart K—Worker Protection Statements

SOURCE: 57 FR 38146, Aug. 21, 1992, unless otherwise noted.

§ 156.200 Scope and applicability.

(a) *Scope.* (1) This subpart prescribes statements that must be placed on the pesticide label and in pesticide labeling. These statements incorporate by reference the Worker Protection Standard, part 170 of this chapter. The requirements addressed in these statements are designed to reduce the risk of illness or injury resulting from workers' and pesticide handlers' occupational exposures to pesticides used in the production of agricultural plants on agricultural establishments as defined in § 170.3 of this chapter. These statements refer to specific workplace practices designed to reduce or eliminate exposure and to respond to emergencies that may arise from the exposures that may occur.

(2) This subpart prescribes interim requirements that must be placed on the pesticide label and in pesticide labeling. These interim requirements pertain to restricted-entry intervals, personal protective equipment, and notification. On a case-by-case basis, these interim requirements will be reviewed and may be revised during reregistration or other agency review processes.

(b) *Applicability.* (1) The requirements of this subpart apply to each pesticide product that bears directions for use in the production of any agricultural plant on any agricultural establishment as defined in § 170.3 of this chapter, or whose labeling reasonably permits such use.

(2) The requirements of this subpart do not apply to a product that bears directions solely for uses excepted by § 170.202(b) of this chapter.

(c) *Effective dates.* No product to which this subpart applies shall be distributed or sold without amended labeling by any registrant after April 21, 1994, or by any person after October 23, 1995.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.203 Definitions.

Terms in this subpart have the same meanings as they do in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, the following terms, as used in this subpart, shall have the meanings stated below:

Fumigant means any pesticide product that is a vapor or gas or forms a vapor or gas on application and whose method of pesticidal action is through the gaseous state.

Restricted-entry interval or REI means the time after the end of a pesticide application during which entry to the treated area is restricted.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.204 Modification and waiver of requirements.

(a) *Modification on Special Review.* If the Agency concludes in accordance with § 154.25(c) of this chapter that a pesticide should be placed in Special Review because the pesticide meets or exceeds the criteria for human health effects of § 154.7(a)(1)(2) or (6) of this chapter, the Agency may modify the personal protective equipment required for handlers or early-entry workers or both, the restricted-entry intervals, or the notification to workers requirements.

(b) *Other modifications.* The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data conducted according to Subdivisions U or K of the Pesticide Assessments guidelines or data from medical, epidemiological, or health effects studies. A registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

[57 FR 38146, Aug. 21, 1992, as amended at 73 FR 75596, Dec. 12, 2008]

§ 156.206 General statements.

(a) *Application restrictions.* Each product shall bear the statement: ''Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.'' This statement shall be near the beginning of the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *40 CFR part 170 reference statement.* (1) Each product shall bear the reference statement: ''Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170.'' This statement shall be placed on the product label under the heading AGRICULTURAL USE REQUIREMENTS.

(2) Each product shall bear the statement: ''This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling] about [use any of the following that are applicable] personal protective equipment, restricted-entry interval, and notification to workers.'' These statements shall be placed immediately following the reference statement required by paragraph (b)(1) of this section, or they shall be placed in the supplemental product labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(3) If the statements in paragraph (b)(2) of this section are included in supplemental labeling rather than on the label of the pesticide container, the container label must contain this statement immediately following the statement required in paragraph (b)(1) of this section: ''Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard.''

(4) If the statements in paragraph (b)(2) of this section are included in supplemental labeling, they must be preceded immediately by the statement in paragraph (b)(1) of this section under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(c) *Product-type identification.* (1) If the product contains an organophosphate (*i.e.*, an organophosphorus ester that inhibits cholinesterase) or an *N*-methyl carbamate (*i.e.*, an *N*-methyl carbamic acid ester that inhibits cholinesterase), the label shall so state. The statement shall be associated with the product name or product-type identification or

shall be in the STATEMENT OF PRACTICAL TREATMENT or FIRST AID section of the label.

(2) If the product is a fumigant, the label shall so state. The identification shall appear:

(i) As part of the product name; or

(ii) Close to the product name, as part of the product-type identification or as a separate phrase or sentence.

(d) *State restrictions.* Each product shall bear the statement: ''For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation.'' This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(e) *Spanish warning statements.* If the product is classified as toxicity category I or toxicity category II according to the criteria in § 156.62, the signal word shall appear in Spanish in addition to English followed by the statement, ''Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find some one to explain it to you in detail.)'' The Spanish signal word ''PELIGRO'' shall be used for products in toxicity category I, and the Spanish signal word ''AVISO'' shall be used for products in toxicity category II. These statements shall appear on the label close to the English signal word.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 73 FR 75596, Dec. 12, 2008]

§ 156.208 Restricted-entry statements.

(a) *Requirement.* Each product with a restricted-entry interval shall bear the following statement: ''Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI).'' This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(b) *Location of specific restricted-entry interval statements.* (1) If a product has one specific restricted-entry interval applicable to all registered uses of the product on agricultural plants, the restricted-entry interval for the product shall appear as a continuation of the statement required in paragraph (a) of this section and shall appear as follows: ''of X hours'' or ''of X days'' or ''until the acceptable exposure level of X ppm or mg/m^3 is reached.''

(2) If different restricted-entry intervals have been established for some crops or some uses of a product, the restricted-entry statement in paragraph (b)(1) of this section shall be associated on the labeling of the product with the directions for use for each crop each use to which it applies, immediately preceded or immediately followed by the words ''Restricted-entry interval'' (or the letters ''REI'').

(c) *Restricted-entry interval based on toxicity of active ingredient*—(1) *Determination of toxicity category.* A restricted-entry interval shall be established based on the acute toxicity of the active ingredients in the product. For the purpose of setting the restricted-entry interval, the toxicity category of each active ingredient in the product shall be determined by comparing the obtainable data on the acute dermal toxicity, eye irritation effects, and skin irritation effects of the ingredient to the criteria of § 156.62. The most toxic of the applicable toxicity categories that are obtainable for each active ingredient shall be used to determine the restricted-entry interval for that product. If no acute dermal toxicity data are obtainable, data on acute oral toxicity also shall be considered in this comparison. If no applicable acute toxicity data are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If no acute toxicity data are obtainable on the active ingredients and no toxicity category of a registered manufacturing-use product is obtainable, the toxicity category of the end-use product (corresponding to the signal word on its labeling) shall be used.

(2) *Restricted-entry interval for sole active ingredient products.* (i) If the product contains only one active ingredient and it is in toxicity category I by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 48 hours. If, in addition, the active ingredient is an organophosphorus ester that inhibits cholinesterase and that may be applied outdoors in an

area where the average annual rainfall for the application site is less than 25 inches per year, the following statement shall be added to the restricted-entry interval statement: ''(72 hours in outdoor areas where average annual rainfall is less than 25 inches a year).''

(ii) If the product contains only one active ingredient and it is in toxicity category II by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 24 hours.

(iii) If the product contains only active ingredients that are in toxicity category III or IV by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 12 hours.

(3) *Restricted-entry interval for multiple active ingredient products.* If the product contains more than one active ingredient, the restricted-entry interval (including any associated statement concerning use in arid areas under paragraph (c)(2)(i) of this section) shall be based on the active ingredient that requires the longest restricted-entry interval as determined by the criteria in this section.

(d) *Exception for fumigants.* The criteria for determining restricted-entry intervals in paragraph (c) of this section shall not apply to any product that is a fumigant. For fumigants, any existing restricted-entry interval (hours, days, or acceptable exposure level) shall be retained. Entry restrictions for fumigants have been or shall be established on a case-by-case basis at the time of registration, reregistration, or other Agency review process.

(e) *Existing product-specific restricted-entry intervals.* (1) A product-specific restricted-entry interval, based on data collected in accordance with § 158.1070 or § 161.390 of this chapter and Subdivision K of the Pesticide Assessment Guidelines, shall supersede any restricted-entry interval applicable to the product under paragraph (c) of this section.

(2) Product-specific restricted-entry intervals established for pesticide products or pesticide uses that are not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(f) *Existing interim restricted-entry intervals.* (1) An interim restricted-entry interval established by the Agency before the effective date of this subpart will continue to apply unless a longer restricted-entry interval is required by paragraph (c) of this section.

(2) Existing interim restricted-entry intervals established by the Agency for pesticide products or pesticide uses not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 72 FR 61028, Oct. 26, 2007; 73 FR 75596, Dec. 12, 2008]

§ 156.210 Notification-to-workers statements.

(a) *Requirement.* Each product that meets the requirements of paragraph (b) of this section shall bear the posting and oral notification statements prescribed below. The statements shall be in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *Notification to workers of pesticide application.* (1) Each product that contains any active ingredient classified as toxicity category I for either acute dermal toxicity or skin irritation potential under the criteria in § 156.62 shall bear the statement: ''Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.'' If no acute dermal toxicity data are obtainable, data on acute oral toxicity of the active ingredient shall be considered instead. If no data on acute dermal toxicity, skin irritation potential, or acute oral toxicity are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If none of the applicable acute toxicity data are obtainable on the active ingredient and no toxicity category of the registered manufacturing-use product is obtainable, the toxicity category of the end-use product corresponding to the product's signal word shall be used.

(2) Each product that is a fumigant and is registered for use in a greenhouse (or whose labeling allows use in a greenhouse) shall bear the statement: ''For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse.''

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 73 FR 75596, Dec. 12, 2008]

§ 156.212 Personal protective equipment statements.

(a) *Requirement.* Each product shall bear the personal protective equipment statements prescribed in paragraphs (d) through (j) of this section.

(b) *Exceptions.* (1) If personal protective equipment were required for a product before the effective date of this subpart, the existing requirements shall be retained on the labeling wherever they are more specific or more protective (as specified in EPA guidance materials) than the requirements in the table in paragraph (e) of this section.

(2) Any existing labeling statement that prohibits the use of gloves or boots overrides the corresponding requirement in paragraph (e) of this section and must be retained on the labeling.

(3) If the product labeling contains uses that are not covered by part 170 of this chapter, the registrant may adopt the personal protective equipment required in this section for those uses. However, if the personal protective equipment required in this section would not be sufficiently protective or would be onerously overprotective for uses not covered by part 170 of this chapter, the registrant must continue to apply the existing personal protective equipment requirements to those uses. The labeling must indicate which personal protective equipment requirements apply to uses covered by part 170 of this chapter and which personal protective equipment requirements apply to other uses.

(c) *Location of personal protective equipment statements*—(1) *Personal protective equipment statements for pesticide handlers.* Personal protective equipment statements for pesticide handlers shall be in the HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) section of the labeling. The required statements may be combined to avoid redundancy as long as the requirements and conditions under which they apply are identified.

(2) Personal protective equipment statements for early-entry workers. Personal protective equipment statements for early-entry workers shall be placed in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS and immediately after the restricted-entry statement required in § 156.208(a).

(d) *Personal protective equipment statements for pesticide handlers.* (1) The table in paragraph (e) of this section specifies minimum requirements for personal protective equipment (as defined in § 170.240 of this chapter) and work clothing for pesticide handlers. This personal protective equipment requirement applies to any product that presents a hazard through any route of exposure identified in the table (acute dermal toxicity, skin irritation potential, acute inhalation toxicity, and eye irritation potential).

(2) The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure as defined by § 156.62. If data to determine the acute dermal toxicity or the acute inhalation toxicity are not obtainable, the acute oral toxicity shall be used as a surrogate to determine the personal protective equipment requirements for that route of exposure. If data to determine the acute toxicity of the product by a specific route of exposure (including acute oral toxicity in lieu of acute dermal or acute inhalation toxicity) are not obtainable, the toxicity category corresponding to the signal word of the end-use product shall be used to determine personal protective equipment requirements for that route of exposure. If the signal word is ''CAUTION,'' toxicity category III will be used.

(3) The minimum personal protective equipment and work clothing requirements specified in this section shall be

included in a statement such as the following: ''Applicators and other handlers must wear: (body protection statement); (glove statement, if applicable); (footwear statement, if applicable); (protective eyewear statement, if applicable); (respirator statement, if applicable).'' The format of statements given in this paragraph is optional, but it is recommended for clarity.

(e) *Summary of personal protective equipment requirements.* The following table 1 summarizes the personal protective equipment requirements by route of exposure and toxicity category:

TABLE 1—MINIMUM PERSONAL PROTECTIVE EQUIPMENT (PPE) AND WORK CLOTHING FOR HANDLING ACTIVITIES

Route of Exposure	Toxicity Category of End-Use Product			
	I	II	III	IV
Dermal Toxicity or Skin Irritation Potential [1]	Coveralls worn over long-sleeved shirt and long pants Socks Chemical-resistant footwear Chemical-resistant gloves [2]	Coveralls worn over short-sleeved shirt and short pants Socks Chemical-resistant footwear Chemical-resistant gloves [2]	Long-sleeved shirt and long pants Socks Shoes Chemical-resistant gloves [2]	Long-sleeved shirt and long pants Socks Shoes No minimum [4]
Inhalation Toxicity	Respiratory protection device [3]	Respiratory protection device [3]	No minimum [4]	No minimum [4]
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum [4]	No minimum [4]

[1] If dermal toxicity and skin irritation potential are in different toxicity categories, protection shall be based on the more toxic (lower numbered) category.
[2] For labeling language for chemical-resistant gloves, see paragraph (f) of this section.
[3] For labeling language for respiratory protection device, see paragraphs (g) and (h) of this section.
[4] Although no minimum PPE is required by this section for this toxicity category and route of exposure, the Agency may require PPE on a product-specific basis.

(f) *Chemical-resistant gloves labeling statements for pesticide handlers.* If the table in paragraph (e) of this section indicates that chemical-resistant gloves are required, the glove statement shall be as specified in paragraph (f)(2), (3), (4), or (5) of this section.

(1) *Exception.* The registrant shall specify a glove type other than that selected through the criteria in paragraphs (f)(2) through (5) of this section if information available to the registrant indicates that such a glove type is more appropriate or more protective than the glove type specified in this section. The statement must specify the particular types of chemical-resistant glove (such as nitrile, butyl, neoprene, and/or barrier-laminate).

(2) *Solid formulations.* For products formulated and applied as solids or formulated as solids and diluted solely with water for application, the glove statement shall specify: ''waterproof gloves.''

(3) *Aqueous-based formulations.* For products formulated and applied as a water-based liquid or formulated as a water-based liquid and diluted solely with water for application, the glove statement may specify: ''waterproof gloves'' instead of the statement in paragraph (f)(4) of this section.

(4) *Other liquid formulations.* For products formulated or diluted with liquids other than water, the glove statement shall specify: ''chemical-resistant (such as nitrile or butyl) gloves.''

(5) *Gaseous formulations and applications.* For products formulated or applied as gases, any existing glove statement established before the effective date of this subpart, including any glove prohibition statement, will continue to apply. If no glove statement or glove prohibition now exists, the glove statement shall specify ''chemical-resistant (such as nitrile or butyl) gloves.''

(g) *Existing respirator requirement for pesticide handlers on product labeling*—(1) *General requirement.* If a statement placed on a product's labeling before the effective date of this subpart indicates that respiratory protection is required, that requirement for protection

shall be retained. The statement must specify, or be amended to specify, one of the following respirator types and the appropriate MSHA/NIOSH approval number prefix:

(i) Dust/mist filtering respirator with MSHA/NIOSH/ approval number prefix TC-21C; or

(ii) Respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides with MSHA/NIOSH approval number prefix TC-23C or with a canister approved for pesticides with MSHA/NIOSH approval number prefix TC-14G; or

(iii) Supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C or self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F.

(2) *Respirator type already specified on labeling.* If the existing respiratory protection requirement specifies a respirator type, it shall be retained. The respirator statement must be revised, if necessary, to conform to the wording in paragraph (g)(1) of this section.

(3) *Respirator type not already specified on labeling.* If the existing respiratory protection requirement on product labeling does not specify a respirator type as listed in paragraph (g)(1) of this section, the specific respirator type shall be that required in the criteria in paragraphs (g)(3)(ii) through (vi) of this section.

(i) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device selected through the criteria in paragraphs (g)(3)(ii) through (vi) of this section would not be adequately protective, or might increase risks to the user unnecessarily.

(ii) *Gases applied outdoors.* For products that are formulated or applied as a gas (space and soil fumigants) and that may be used outdoors, the respiratory protection statement shall be: ''For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).''

(iii) *Gases used in enclosed areas.* For products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas, the respiratory protection statement shall specify: ''For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F.''

(iv) *Solids.* For products that are formulated and applied as solids, the respiratory protection statement shall specify: ''dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).''

(v) *Liquids in toxicity category I.* For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category I, the respiratory protection statement shall specify: ''either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G).''

(vi) *Liquids in toxicity category II.* For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category II, the respiratory protection statement shall specify: ''For handling activities during (select uses applicable to the product: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead) exposures, wear either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).''

(h) *New respirator requirement established for pesticide handlers in this part*—

(1) *General requirement.* If the table in paragraph (e) of this section indicates a respiratory protection device is required, and existing product labeling has no respiratory protection requirement, the registrant shall add a respiratory protection statement that specifies a: ''dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).''

(2) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device required in paragraph (h)(1) of this section would not be adequately protective or might increase risks to the user unnecessarily.

(i) *Additional personal protective equipment requirements for pesticide handlers.* In addition to the minimum personal protective equipment and work clothing requirements given in the table in paragraph (e) of this section, the labeling statement for any product in toxicity category I or II on the basis of dermal toxicity or skin irritation potential (or their surrogate as specified in paragraph (d)(2) of this section), shall include the following personal protective equipment instructions, additions, or substitutions as applicable:

(1) If the product is not ready-to-use and there is no existing requirement for a chemical-resistant suit, the following statement shall be included: ''Mixers/Loaders: add a chemical-resistant apron.''

(2) If the application of the product may result in overhead exposure to any handler (for example, applicator exposure during airblast spraying of orchards or flagger exposure during aerial application), the following statement shall be included: ''Overhead Exposure: wear chemical-resistant headgear.''

(3) If any type of equipment other than the product container may be used to mix, load, or apply the product, and there is no requirement for a chemical-resistant protective suit, the following statement shall be included: ''For Cleaning Equipment: add a chemical-resistant apron.''

(j) *Personal protective equipment for early-entry workers.* This paragraph specifies minimum requirements for personal protective equipment (as defined in §170.240 of this chapter) and work clothing for early-entry workers.

(1) For all pesticide products, add the statement: ''For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (list the body protection, glove, footwear, protective eyewear, and protective headgear, if applicable, statements specified for applicators and other handlers, but omit any respiratory protection statement).''

(2) If the body protection statement in the personal protective equipment requirement for handlers specifies a long-sleeved shirt and long pants, ''coveralls'' must be specified in the statement of personal protective equipment for early-entry workers.

(3) If there is no statement requiring gloves and no prohibition against gloves for applicators and other handlers under the heading HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) in the labeling, add a requirement for ''waterproof gloves'' in the statement of personal protective equipment for early-entry workers.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993; 73 FR 75596, Dec. 12, 2008]

PART 157—PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

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AUTHORITY: 7 U.S.C. 136w.

SOURCE: 51 FR 21286, June 11, 1986; 51 FR 36692, Oct. 15, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

§ 157.20 General.

This subpart prescribes requirements for child-resistant packaging of pesticide products and devices. The requirements are established under the authority of FIFRA section 25(a)(1), which authorizes the Administrator to issue regulations to carry out the purposes of the Act, and FIFRA section 25(c)(3), which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under the Act.

§ 157.21 Definitions.

Terms used in this subpart shall have the following meanings:

Appropriate, when used with respect to child-resistant packaging, means that the packaging is chemically compatible with the pesticide contained therein.

Child-resistant packaging means packaging that is designed and constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

Package or *packaging* means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

Practicable, when used with respect to child-resistant packaging, means that the packaging can be mass produced and can be used in assembly line production.

Residential use means use of a pesticide or device:

(1) Directly on humans or pets;

(2) In, on, or around any structure, vehicle, article, surface or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles; or

(3) In or around any preschool or day care facility.

Technically feasible, when applied to child-resistant packaging, means that the technology exists to produce the child-resistant packaging for a particular pesticide.

Unit packaging means a package that is labeled with directions to use the entire contents of the package in a single application.

[51 FR 21286, June 11, 1986, as amended at 73 FR 75596, Dec. 12, 2008]

§ 157.22 When required.

Unless exempted under § 157.24, a pesticide product must be distributed and sold in child-resistant packaging complying with § 157.32 if it meets both of the following criteria:

(a) *Toxicity criterion.* Based upon testing with an appropriate test species, the product meets any of the following toxicity criteria:

(1) The pesticide has an acute oral LD_{50} of 1.5 g/kg or less;

(2) The pesticide has an acute dermal LD_{50} of 2000 mg/kg or less;

(3) The pesticide has an acute inhalation LC_{50} of 2 mg/liter or less;

(4) The pesticide is corrosive to the eye (causes irreversible destruction of ocular tissue) or causes corneal involvement or irritation persisting for 21 days or more;

(5) The pesticide is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe skin irritation (severe erythema or edema) at 72 hours; or

(6) The pesticide or device has such characteristics that, based upon human toxicological data, use history, accident data or such other evidence as is available, the Agency determines there is serious hazard of accidental injury or illness which child-resistant packaging could reduce; and

(b) *Use criterion.* The product's labeling either directly recommends residential use or reasonably can be interpreted to permit residential use.

§ 157.24 Exemptions.

(a) *General exemptions.* The Agency hereby exempts from the requirement for child-resistant packaging the following classes of products:

(1) *Products classified for restricted use.* (i) A product restricted to use by or under the supervision of a certified applicator is not required to be distributed and sold in child-resistant packaging.

(ii) Notwithstanding the exemption in paragraph (a)(1)(i) of this section, the Agency may require the use of child-resistant packaging for a product classified for restricted use by or under the direct supervision of a certified applicator if the Agency determines that the product poses a risk of serious accidental injury or illness which child-resistant packaging could reduce. If the Agency makes such a determination, it will notify the registrant in writing and provide a short statement of the basis of its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to require the product to be distributed only in child-resistant packaging and will notify the registrant of its decision.

(2) *Products packaged in large sizes.* (i) Except as provided by paragraph (a)(2)(ii) of this section, a product is not required to be in child-resistant packaging if distributed and sold in the following sizes:

(A) If the product is a solid product, regardless of pesticide type, a size of 50 pounds or greater;

(B) If the product is a liquid product intended for use in swimming pools, a size greater than 7.5 gallons by volume;

(C) If the product is a liquid product intended for any other pesticide use, a size of 5 gallons or greater by volume;

(D) If the product is packaged as an aerosol (measured by weight), regardless of pesticide type, a weight of 2 pounds or greater.

(ii) The Agency may require that a product packaged in a size exceeding that listed in paragraphs (a)(2)(i) (A) through (D) of this section be distributed and sold only in child-resistant packaging if the Agency determines that the product is, or is intended to be, distributed or sold to homeowners or other members of the general public. If the Agency makes such a determination, it will notify the registrant in writing and provide a short statement of the basis of its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to require the product to be distributed only in child-resistant packaging and will notify the registrant of its decision.

(b) *Exemptions requiring Agency approval.* The Agency may, in accordance with paragraphs (b) (1) through (3) of this section, grant an exemption from the requirements of this subpart. An exemption may be withdrawn in accordance with paragraph (b)(4) of this section.

(1) *Requesting an exemption.* A request for an exemption must be submitted to the Agency, and must be accompanied by two copies of the following information:

(i) The name, address, and telephone number of the requester;

(ii) The name and registration number (or file symbol) of the product(s) for which the exemption is requested;

(iii) A description of the package and the size(s) for which the exemption is requested; and

(iv) Documentation supporting the request for exemption, including the length of time for which the exemption is requested.

(2) *Exemption based upon lack of toxicity.* The Agency may grant an exemption from the requirements of this subpart if the registrant or applicant demonstrates to the Agency's satisfaction that the hazards indicated by the toxicity criteria in § 157.22(a) are not indicative of the hazards to man. If granted, an exemption shall apply to other products of substantially similar composition. A notice will be issued in the FEDERAL REGISTER stating the nature of and reasons for the exemption.

(3) *Exemption based upon technical factors.* The Agency may grant an exemption from the requirements of this subpart based upon technical considerations. If granted, the exemption will be for a specified length of time, and will apply to other products of substantially similar composition and intended uses. A notice of the granting of

an exemption will be issued in the FEDERAL REGISTER. In considering whether to grant an exemption, the Agency will consider, among other things, the following:

(i) Whether the toxicity of the product is such that it should not be allowed to be distributed or sold except in child-resistant packaging.

(ii) Whether child-resistant packaging is technically feasible, practicable, or appropriate. An exemption may be granted if the Agency determines that any one of these criteria has not been met.

(iii) Whether the composition or use pattern of the product necessitates a particular form of packaging for proper use.

(iv) Whether child-resistant packaging that is technically feasible, practicable, and appropriate is available for the product or can reasonably be made available to the registrant in sufficient quantities to meet his packaging needs. This determination does not include a consideration of whether the packaging would be adaptable to a registrant's existing package type or packaging equipment.

(v) Whether the registrant has made a timely and good faith effort to obtain child-resistant packaging for the product.

(vi) If child-resistant packaging which is technically feasible, practicable, and appropriate is not yet available, when such packaging is likely to be available.

(4) An exemption may be withdrawn by the Agency at any time if the lack of child-resistant packaging results in serious illnesses or injuries to children. If the Agency determines that an exemption should be withdrawn, it will notify the registrant, stating the basis for its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to withdraw the exemption, and will notify the registrant of its decision.

§ 157.27 Unit packaging.

Pesticide products distributed or sold as an aggregate of one or more unit packages and meeting the criteria of § 157.22 must be distributed or sold in child-resistant packaging either for each unit package or for the outer retail container which contains the unit packages. Child-resistant packaging is not required for both the outer package and the unit packages unless the Agency determines, on a case-by-case basis, that it is necessary for risk reduction.

§ 157.30 Voluntary use of child-resistant packaging.

A registrant whose product is not required to be in child-resistant packaging may distribute or sell his pesticide product in child-resistant packaging. If he does so, that packaging must meet the standards for child-resistant packaging stated in § 157.32. The registrant must certify to this effect in accordance with § 157.34, and must retain the records required by § 157.36.

§ 157.32 Standards.

(a) *Effectiveness standard.* The child-resistant packaging, when tested by the protocol specified in 16 CFR 1700.20, shall meet the effectiveness specifications in 16 CFR 1700.15(b).

(b) *Compatibility standard.* The child-resistant packaging must continue to meet the effectiveness specifications of paragraph (a) of this section when in actual use as a pesticide container. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the child-resistant packaging to determine that the chemical and physical characteristics of the pesticide will not compromise or interfere with the proper functioning of the child-resistant packaging and that the packaging will not be detrimental to the integrity of the product during storage and use.

(c) *Durability standard.* The child-resistant packaging must continue to meet the effectiveness and compatibility standards of paragraphs (a) and (b) of this section for the reasonably expected lifetime of the package, taking into account the number of times the package is customarily opened and closed. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors of packaging, the force required for activation, and other relevant factors.

§ 157.34 Certification.

(a) *General.* (1) The registrant of a pesticide product required to be in child-resistant packaging shall certify to the Agency that the package meets the standards of § 157.32.

(2) Certification must be submitted with each application for new registration, if applicable. If the Agency determines, in accordance with § 157.24(a)(1)(ii), (2)(ii), or (b)(4), that a currently registered product is required to be packaged in child-resistant packaging, a certification must be submitted within 6 months after the Agency finally notifies the registrant of the requirement.

(b) *Contents of certification.* The certification must contain the following information:

(1) The name and EPA registration number of the product to which the certification applies, the registrant's name and address, the date, and the name, title and signature of the company official making the certification.

(2) A statement that the packaging that is being used for the product will meet the standards of § 157.32. The statement, ''I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32,'' will suffice for this purpose.

§ 157.36 Recordkeeping.

For as long as the registration of a pesticide product required to be in child-resistant packaging is in effect, the registrant must retain the records listed in this section. The registrant must, upon request by the Agency, make them available to Agency representatives for inspection and copying, or must submit them to the Agency.

(a) A description of the package, including a description of:

(1) The container and its dimensions and composition.

(2) The closure or child-resistant mechanism, including the name of its manufacturer and the manufacturer's designation for the closure or the physical working of the child-resistant packaging mechanism.

(b) A copy of the certification statement required by § 157.34.

(c) One of the following types of records verifying that each package for the product is child-resistant:

(1) Test data on the package based on the Consumer Product Safety Commission protocol in 16 CFR 1700.20.

(2) Test data, not conforming to the protocol in 16 CFR 1700.20, or a set of measurements on the package, together with an explanation as to why such data or measurements demonstrate that the package is child-resistant.

(3) Test data, whether or not conforming to the protocol in 16 CFR 1700.20, on a different package, together with an explanation of why such data demonstrate that the package being used is child-resistant.

(4) Written evidence that verifies that testing on the package has been conducted according to the protocol in 16 CFR 1700.20. Written evidence may be one of the following:

(i) A letter or literature from the packaging supplier;

(ii) A letter from the facility that conducted the testing; or

(iii) A specification in the contract between the registrant or applicant and the packaging supplier;

(5) When the container and closure are purchased separately by the registrant:

(i) Information of the kinds described in paragraphs (c) (1) through (4) of this section showing that the closure is child-resistant; and

(ii) A written explanation of why the container is child-resistant; and

(iii) Information showing that the closure and container are compatible with each other, and a written explanation of why the resulting package is child-resistant.

(6) A combination of the records listed in paragraphs (c) (1) through (5).

(d) Records verifying that the package meets the compatibility and durability standards of § 157.32(b) and (c).

[51 FR 21286, June 11, 1986; 51 FR 36692, Oct. 15, 1986, as amended at 65 FR 39304, June 26, 2000]

PART 158—DATA REQUIREMENTS FOR PESTICIDES

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158.2200 [Reserved]

Subpart X–Z [Reserved]

158.2300–158.2500 [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

Subpart A—General Provisions

§ 158.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) *Scope.* (1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) *Scope of individual subparts.* (1) *Conventional pesticides.* Subparts A, B, C, D, F, G, K, L, N, and O apply to conventional pesticides.

(2) *Biochemical pesticides.* Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides.* Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides.* [Reserved]

§ 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and

are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

Applicant means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

(1) An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.

(2) A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.

(3) An application for an experimental use permit under FIFRA sec. 5.

(4) A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).

(5) A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.

Registration includes a new registration, amended registration and reregistration, unless stated otherwise.

§ 158.5 Applicability.

(a) The requirements of this part apply to the following submissions:

(1) An application for new or amended registration under FIFRA sec. 3 or 24.

(2) An application for experimental use permit under FIFRA sec. 5.

(3) A submission of data or information to support the continuation of a registration under FIFRA sec. 3, 4, or 24.

(4) A petition to establish, modify or revoke a tolerance or exemption from a tolerance under FFDCA sec. 408.

(b) The information specified in this part must be furnished with each submission described in paragraph (a) of this section if it has not been submitted previously, or if any previous submission is not accurate or complete.

§ 158.30 Flexibility.

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

§ 158.32 Format of data submissions.

(a) *General.* (1) All data submitted under this part must be formatted in accordance with this section.

(2) The requirements of this section do not apply to administrative materials accompanying a data submission, including forms, labeling, and correspondence.

(b) *Transmittal document.* Each submission in support of a regulatory action must be accompanied by a transmittal document, which includes:

(1) Identity of the submitter.

(2) The transmittal date.

(3) Identification of the regulatory action with which the submission is associated, e.g., the registration or petition number.

(4) A list of the individual documents included in the submission.

(c) *Individual documents.* Unless otherwise specified by the Agency, each

submission must be in the form of individual documents or studies. Previously submitted documents should not be resubmitted unless specifically requested by the Agency, but should be cited with adequate information to identify the previously submitted document. Each study or document should include the following:

(1) A title page including the following information:

(i) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.

(ii) The author(s) of the study.

(iii) The date the study was completed.

(iv) If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.

(v) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review.

(vi) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(2) The appropriate statement(s) regarding any data confidentiality claims as described in § 158.33.

(3) A statement of compliance or noncompliance with respect to Good Laboratory Practice Standards as required by 40 CFR 160.12, if applicable.

(4) A complete and accurate English translation must be included for any information that is not in English.

(5) A flagging statement as prescribed by § 158.34, if applicable.

§ 158.33 Confidential data.

(a) *Definitions.* For the purposes of this section:

(1) *Registered or previously registered pesticide* means any pesticide containing an active ingredient contained in a product that is, or has ever been, an active ingredient in a product registered under sec. 3 of FIFRA. A registered pesticide that is the subject of an application for a new use falls within the category of ''registered or previously registered pesticide.''

(2) *Safety and efficacy information* means information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism.

(b) *Applicability.* (1) This section applies to information submitted pursuant to this part. It supplements the general confidentiality procedures in 40 CFR part 2, subpart B, including FIFRA confidentiality procedures at 40 CFR 2.307. To the extent that provisions in this section conflict with those in 40 CFR part 2, subpart B, the provisions in this section take precedence. The provisions of 40 CFR 2.308 do not apply to information to which this section applies. In addition to complying with the requirements of this section, any confidentiality claims for information subject to 40 CFR part 174 (plant-incorporated protectants) must be substantiated at the time of submission as described in § 174.9 of this chapter.

(2) FFDCA sec. 408(i) protects confidential information submitted in connection with an application for a tolerance or exemption to the same extent as FIFRA sec. 10. References in this section to FIFRA sec. 10 are deemed to apply equally to information submitted pursuant to FFDCA sec. 408, pursuant to the authority in sec. 408(i).

(c) *Method of asserting business confidentiality claims*—(1) *Claim required.* Information to which this section applies (and which is submitted on or after the effective date of this regulation) will be deemed as not subject to a confidentiality claim unless a claim for that information is made in accordance with the procedures specified in this paragraph. Information not subject to a confidentiality claim may be made available to the public without further notice, subject to the requirements of FIFRA sec. 10(g).

(2) *Statement required.* Upon submission to EPA, each document must be accompanied by a signed and dated document containing either the statements in paragraph (c)(2)(i) or (ii) of this section. No claims or markings on the document or any attachments, other than these statements and attachments submitted in accordance with paragraph (c)(3) of this section, will be recognized as asserting a claim of confidentiality. The format of data submissions is set forth in § 158.32.

(i) *No claim of confidentiality.*

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA sec. 10(g).

(ii) *Claim of confidentiality.*

Information claimed as confidential has been removed to a confidential attachment.

(3) *Confidential attachment.* (i) All information claimed as confidential must be submitted in a separate confidential attachment to the document and cross referenced to the specific location in the document from which it was removed. The confidential attachment must have its own title page and be paginated separately from the non-confidential document.

(ii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) manufacturing or quality control processes must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(A).

(iii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(B).

(iv) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(C).

(v) Information in the confidential attachment that is designated in accordance with paragraphs (c)(3)(ii) - (iv) of this section must be on a separate page from information that is not so designated.

(4) *Voluntary release of information to States and foreign governments.* (i) Submitters are encouraged to include with the statement required under paragraph (c)(2) of this section an additional statement to allow EPA to share information with State and foreign governments. EPA will not consider such a statement to be a waiver of confidentiality or proprietary claims for the information. The statement is as follows:

I authorize the Environmental Protection Agency to release any information contained in this document to State or foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.

(ii) Information designated as releasable to state or foreign governments in accordance with this section may be released to such a government without further notice to the submitter. EPA will inform the State or foreign government of any of the confidentiality claims associated with the information.

(d) *Release of information.* (1) Safety and efficacy information that was submitted to EPA on or after May 4, 1988 and that has not been designated by the submitter as FIFRA sec. 10(d)(1)(A), (B), or (C) information in accordance with the applicable requirements of this section is not entitled to confidential treatment and may be disclosed to the public without further notice to the submitter, in accordance with paragraph (d)(2) of this section. Safety and efficacy information which has been designated by the submitter as FIFRA sec. 10(d)(1) (A), (B), or (C) information is entitled to confidential treatment only to the extent provided by FIFRA sec. 10(b), this section, and 40 CFR 2.208.

(2) Information that is not entitled to be protected as confidential in accordance with FIFRA sec. 10(b), this section and with EPA confidentiality regulations at 40 CFR part 2, subpart B, may be released to the public without the affirmation of non-multinational status provided under FIFRA sec. 10(g), provided that the information does not contain or consist of any complete unpublished report submitted to EPA, or excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any applicant who submits a study of a type listed in paragraph (b) of this section must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates the study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in paragraph (c) of this section when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Study Type(s)	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined carcinogenicity/chronic feeding study	870.4200 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend p≤ 0.05); or	1
		A statistically significant (pairwise p≤ 0.05) increase of any type of neoplasm in any test group, males or females at any dose level, compared to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional or behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90–day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) Study does not meet or exceed criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study.

This study neither meets nor exceeds any of the applicable criteria.

(2) Study meets or exceeds criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

§ 158.45 Waivers.

(a) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(b)(1) Applicants are encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials.

(2) All waiver requests must be submitted to the Agency in writing. The request must clearly identify the data requirement(s) for which a waiver is sought along with an explanation and supporting rationale why the applicant believes the data requirement should be waived. In addition, the applicant must describe any unsuccessful attempts to generate the required data, furnish any other information which the applicant(s) believe(s) would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) The Agency will review each waiver request and subsequently inform the applicant in writing of its decision. If the decision could apply to more than the requested product, the Agency, in its discretion, may choose to send a notice to all registrants or publish a notice in the FEDERAL REGISTER announcing the decision. An Agency decision denying a written request to waive a data requirement is a final Agency action.

§ 158.60 Minor use data policies.

FIFRA sec. 2(ll) defines the term ''minor use''and FIFRA provides a number of statutory provisions concerning minor uses. In addition, EPA has established policies with respect to minor uses of pesticides, including, but not limited to, the following:

(a) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registration.

(b) EPA will accept appropriate and adequate extrapolations and regional data to support establishment of individual minor use tolerances.

§ 158.70 Satisfying data requirements.

(a) *General policy*. The Agency will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated, were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(1) The provisions in this part 158 should be read in conjunction with the

provisions in §152.85 to claim eligibility for the formulators' exemption.

(2) [Reserved]

(b) *Good laboratory practices.* Applicants must adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160 when conducting studies. Applicants must also adhere to GLP standards when conducting a study in support of a waiver request of any data requirement which is within the scope of the GLP requirements.

(c) *Agency guidelines.* EPA has published Test Guidelines that contain standards for conducting acceptable tests, guidance on the evaluation and reporting of data, definition of terms, and suggested study protocols. Copies of the Test Guidelines may be obtained by visiting the agency's website at *www.epa.gov/pesticides.*

(d) *Study protocols*—(1) *General.* Any appropriate protocol may be used to generate the data required by this part, provided that it meets the purpose of the test standards specified in the pesticide assessment guidelines, and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(2) *Organization for Economic Co-Operation and Development (OECD) protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Applicants should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(e) *Combining studies.* Certain toxicology studies may be combined to satisfy data requirements. For example, carcinogenicity studies in rats may be combined with the rat chronic toxicity study. Combining appropriate studies may be expected to reduce usage of test animals as well as reduce the cost of studies. EPA encourages this practice by including standards for acceptable combined tests in the Pesticide Assessment Guidelines. Registrants and applicants are encouraged to consider combining other tests when practical and likely to produce scientifically acceptable results. Registrants and applicants, however, must consult with the EPA before initiating combined studies.

§ 158.75 Requirements for additional data.

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.

§ 158.80 Use of other data.

(a) *Data developed in foreign countries.* With certain exceptions, laboratory and field study data developed outside the United States may be submitted in support of a pesticide registration. Data generated in a foreign country which the Agency will not consider include, but are not limited to, data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. Applicants submitting foreign data must take steps to ensure that U.S. materials are used, or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the U.S. material or test site. Once submitted, the Agency will determine whether or not the data meet the data requirements.

(b) *Data generated for other purposes.* Data developed for purposes other than satisfaction of FIFRA data requirements, such as monitoring studies,

may also satisfy data requirements in this part. Consultation with the Agency should be arranged if applicants are unsure about suitability of such data.

Subpart B—How To Use Data Tables

§ 158.100 Pesticide use patterns.

(a) *General use patterns.* There are six broad use categories used in the data tables. The six broad categories include terrestrial outdoor uses, aquatic outdoor uses, greenhouse uses, forestry uses, residential outdoor uses, and indoor uses of all types. The 6 broad use categories are further subdivided into 12 general use patterns which are the bases for data requirements established by use pattern. Within the data tables, general use patterns have been combined into single columns when the data requirements are the same for the combined uses. If there are no data requirements for a specific use, the column for that use is not included in the table. The 12 general use pattern groups used in the data table in this part are:

(1) Terrestrial food crop use.
(2) Terrestrial feed crop use.
(3) Terrestrial nonfood crop use.
(4) Aquatic food crop use.
(5) Aquatic nonfood use.
(6) Greenhouse food crop use.
(7) Greenhouse nonfood crop use.
(8) Forestry use.
(9) Residential outdoor use.
(10) Residential indoor use.
(11) Indoor food use.
(12) Indoor nonfood use.

(b) *Pesticide use site index.* The Pesticide Use Site Index is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all nonagricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's website at *http://www.epa.gov/pesticides.*

(c) Applicants unsure of the correct use pattern for their particular product should consult the Agency.

§ 158.110 Required and conditionally required data.

The tables in this part use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

(a) EPA requires data designated as ''required''(R) for products with a given use pattern in order to evaluate the risks or benefits of a product having that use pattern under any conditions established by the test notes.

(b) Data designated as ''conditionally required'' (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement. The determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (for example, tier testing). Applicants must evaluate each applicable test note for the conditions and criteria to be considered in determining whether conditionally required data must be submitted.

(c) Data not required for the Agency's assessment of the risks and benefits of a particular use pattern are designated ''not required'' (NR) in data tables.

§ 158.120 Determining data requirements.

As with current practice, the actual data and studies required may be modified on an individual basis to fully characterize the use and properties of specific pesticide products under review. While EPA is attempting to assist the applicant in this subpart, it is important to emphasize that it is the applicant's obligation under FIFRA to demonstrate that an individual product meets the standard under FIFRA and/or FFDCA. Accordingly, applicants are

encouraged to consult with the Agency on the appropriate data requirements as set forth here as they relate to their specific product prior to and during the registration process.

(a) *Finding the appropriate data table.* (1) Pesticide data requirements for conventional chemical active ingredients and related substances are presented in subparts D, E, F, G, K, L, N, and O of this part in the form of a series of data tables, each addressing a particular scientific discipline or data topic. Data requirements for biochemical and microbial pest control agents are contained and are described separately within subparts U and V of this part, respectively.

(2) Key to table notations. R = required data; CR = conditionally required data; NR = Not required; MP = manufacturing-use product; EP = end-use product; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = pure active ingredient; PAIRA = pure active ingredient, radiolabeled; Choice = choice of several test substances depending on studies required.

(b) *Identifying required studies.* To determine the specific kinds of data needed to support the registration use of each pesticide product, the applicant may:

(1) Refer to the applicable subpart(s) of this part. These subparts describe the data requirements including data tables for each subject area.

(2) Select the general use pattern(s) that best cover the use pattern(s) specified on the pesticide product label as explained in § 158.100. All applicable use patterns must be included.

(3) Proceed down the appropriate general use pattern column in the table and note which tests are required (R), conditionally required (CR), or not required (NR). Required and conditionally required studies are described in § 158.110.

(4) Review the notes for each requirement to determine its applicability to the specific product proposed for registration.

(5)(i) Proceed down the Test substance columns and determine the appropriate test substance needed for that study. If the data are intended to support a manufacturing-use product, use the MP column. If the data are intended to support an end-use product, use the EP column.

(ii) The test substances columns specify which substance is to be used for testing. Applicants should note that the substance that must be used when performing the study may or may not be the product itself. For example, the data from a certain study may be required to support the registration of an end-use product, but the test substance column may state that the particular test shall be performed using the technical grade of the active ingredient(s) in the end-use product.

(iii) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no intentionally added inert ingredients are considered identical in composition to each other, and to the technical grade of the active ingredient (TGAI) from which they were derived. Therefore, the data from a test conducted using any one of these as the test substance is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances.

(6) Refer to the Pesticide Assessment Guideline reference number for each study located in the first column. See § 158.70(c) for information pertaining to the guidelines and how to obtain copies.

§ 158.130 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) *Product chemistry*—(1) *Product composition.* Data on product composition are needed:

(i) To support the conclusions expressed in the statement of formula;

(ii) To compare to the composition of materials used in required testing under this part; and

(iii) To determine whether a product is ''identical or substantially similar''to another product, a determination that involves the comparison of product composition.

(2) *Nominal concentration and certified limits.* The nominal concentration of a product, defined as that concentration that is expected to be present in a product as a result of the production or formulation process, is used to gauge the acceptability of the certified limits, which define the outer limits of the range of the product's ingredients. The certified limits are used to enforce the composition of the product and to ensure the accuracy of hazard assessments.

(3) *Physical and chemical characteristics.* The physical and chemical characteristics of an active ingredient or product are used:

(i) To confirm or provide supportive information on the identity and composition of the product;

(ii) To assess the hazards of the ingredient or product; and

(iii) To trigger or evaluate certain other studies required by this part.

(c) *Product performance.* Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will perform as intended and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

(d) *Toxicology-humans and domestic animals.* Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies.* Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies.* Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

(3) *Chronic studies.* Chronic toxicity studies (usually conducted by feeding the test substance to the test species) are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term carcinogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Developmental toxicity and reproduction studies.* The developmental toxicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning,

and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on prenatal developmental toxicity and serve as a guide for subsequent tests.

(5) *Mutagenicity studies.* For each test substance a battery of tests is required to assess the potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, carcinogenicity, and, possibly, other health effects.

(6) *Metabolism studies.* Data from studies on the absorption, distribution, metabolism, and excretion of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals to man. The main purpose of metabolism studies is to produce data which increases the Agency's understanding of the behavior of the chemical when considering the human exposure anticipated from intended uses of the pesticide.

(e) *Hazards to nontarget organisms*—(1) *General.* The information required to assess hazards to nontarget organisms is derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of testing must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determine the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short-term studies.* The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: To establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long-term and field studies.* Additional studies (*i.e.*, avian, fish, and invertebrate reproduction, life cycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: Estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(f) *Applicator and post-application exposure.* Data are used to evaluate exposures to persons in occupational and non-occupational settings, including agricultural, residential, commercial, institutional and recreational sites. Data include oral, dermal and inhalation exposure data, post-application residue data, post-application monitoring data, use information, and human activity information. These data, together with toxicology data, are used to determine whether application or post-application risks are of concern, and, where appropriate, to develop post-application restrictions such as reentry restrictions.

(g) *Pesticide spray drift evaluation.* Data required to evaluate pesticide

spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to the development of the overall exposure estimate and, along with data on toxicity for humans, fish and wildlife, or plants, are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: Assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertantly-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: Contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: Reentry into treated areas; hazards from residues in rotational crops and other food sources; and the loss of land as well as surface and ground water resources.

(i) *Residue chemistry.* (1) Residue chemistry data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of the pesticide application, and results of tests on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(4) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops.

These data also provide information that aids the Agency in establishing any corresponding tolerances that would be needed for residues on such crops. Data from pesticide accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shellfish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

Subpart C—Experimental Use Permits

§ 158.200 Experimental use permit data requirements tables.

Sections 158.200 through 158.270 describe how to use these tables to determine the experimental use permit data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed at the end of each table. Refer to 40 CFR part 172 for further information on experimental use permits.

§ 158.210 Experimental use permit data requirements for product chemistry.

All product chemistry data, as described in § 158.310, must be submitted to support a request for an experimental use permit.

§ 158.220 Experimental use permit data requirements for product performance.

All product performance data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for forestry and residential outdoor uses.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product.

(c) *Table.* The following table shows the experimental use data requirements for product performance. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT DATA REQUIREMENTS FOR PRODUCT PERFORMANCE

Guideline No.	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		For-estry	Resi-dential Out-doors	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food Crop	Nonfood Crop	Food Crop	Nonfood Crop						
Efficacy of antimicrobial agents													
91–8	Products for treating water systems	NR	NR	CR	NR	NR	NR	NR	NR	NR	NR	EP	1
Efficacy of fungicides and nematicides													
93–16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents													
96–5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96–6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
96–10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96–12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
95–13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. The Agency has waived the requirement to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

2. [Reserved]

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.230 Experimental use permit data requirements for toxicology.

All toxicology data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood crop use, aquatic nonfood outdoor use, greenhouse nonfood crop use, forestry use, residential outdoor use, indoor nonfood use, and indoor residential use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	MP and TGAI	TGAI, EP	1
870.1200	Acute dermal toxicity	R	R	MP and TGAI	TGAI, EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	MP and TGAI	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	MP	TGAI and EP	2, 4
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	5
Subchronic Testing						
870.3100	90–day Oral - rodent	R	NR	TGAI	TGAI	--
870.3150	90–day Oral - non-rodent	R	NR	TGAI	TGAI	--
Chronic Testing						

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
870.4100	Chronic oral - rodent	R	NR	TGAI	TGAI	6
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	NR	TGAI	TGAI	7, 8
870.3800	Reproduction	R	NR	TGAI	TGAI	6
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	NR	TGAI	TGAI	9
870.5300 870.5375	*In vitro* mammalian cell assay	R	NR	TGAI	TGAI	9, 10
870.5385 870.5395	*In vivo* cytogenetics	R	NR	TGAI	TGAI	9, 11

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Not required if test material is a gas or a highly volatile liquid.

2. Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

3. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

4. Required if repeated dermal exposure is likely to occur under conditions of use.

5. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters, thioesters, or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids, or of related phosphorothioic, phosponothioic, or phosphorothioamidic acids, or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

6. These studies are seldom required to support EUPs. They may be required if the dietary exposure for these EUPs occupies a large part, e.g., greater than 50%, of the reference dose.

7. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

8. May be combined with the 2–generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

9. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

10. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

11. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.240 Experimental use permit data requirements for ecological effects.

All data for terrestrial nontarget organisms and aquatic nontarget organisms as described in § 158.243 must be submitted to support a request for an experimental use permit. No data for nontarget plant protection must be submitted to support a request for an experimental use permit.

§ 158.243 Experimental use permit data requirements for terrestrial and aquatic nontarget organisms.

All terrestrial and aquatic nontarget organism data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; commas between the test substances (e.g. TGAI, TEP) indicate that data may be required on the TGAI or TEP depending on the conditions set forth in the test note.

(c) *Table.* The following table shows the experimental use data requirements for terrestrial and aquatic nontarget organisms. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 5, 6, 11
850.1010	Acute toxicity freshwater invertebrates	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 6, 7, 11
850.1300	Aquatic invertebrate life cycle (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 7, 8
850.1400	Fish early-life stage (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 8, 9
Accumulation Study									
850.1730	Fish	CR	CR	CR	NR	NR	NR	TGAI or PAIRA	10
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	R	R	NR	NR	NR	TGAI	1

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to, turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile

liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

6. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

7. Data are required on one freshwater aquatic invertebrate species.

8. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

9. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96 hour LC_{50} on that species must also be provided.

10. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

11. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. A freshwater invertebrate must also be tested with the EP or TEP using the same species tested with the TGAI.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.250 Experimental use permit data requirements for human exposure.

No data for applicator exposure and post-application exposure must be submitted to support a request for an experimental use permit.

§ 158.260 Experimental use permit data requirements for environmental fate.

All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, aquatic nonfood residential, and aquatic nonfood outdoors. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for environmental fate. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoors	Forestry	Residential Outdoors		
Degradation Study - Laboratory									
835.2120	Hydrolysis	R	R	R	NR	R	R	TGAI or PAIRA	1
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	NR	NR	R	NR	TGAI or PAIRA	2
835.4300	Aerobic aquatic	NR	R	NR	NR	NR	NR	TGAI or PAIRA	--
Mobility Study									
835.1230 835.1240	Leaching and adsorption/ desorption	R	NR	NR	NR	R	NR	TGAI or PAIRA	3

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.

2. Required for aquatic uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to cranberry bogs and rice paddies.

3. Adsorption and desorption using a batch equilibrium method is preferred. However, in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.270 Experimental use permit data requirements for residue chemistry.

All residue chemistry data, as described in § 158.1410, are required for an experimental use permit for which a temporary tolerance under FFDCA section 408(r) is sought. Residue chemistry data are not required for an experimental use permit issued on a crop-destruct basis.

§§ 158.280–158.290 [Reserved]

Subpart D—Product Chemistry

§ 158.300 Definitions.

The following terms are defined for the purposes of this subpart:

Active ingredient means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, defoliant, or nitrogen stabilizer, within the meaning of FIFRA sec. 2(b).

End-use product means a pesticide product whose labeling:

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and

(2) does not state that the product may be used to manufacture or formulate other pesticide products.

Formulation means:

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended

chemical reaction, to obtain a manufacturing-use product or an end-use product, or

(2) The repackaging of any registered product.

Impurity means any substance (or group of structurally similar substances if specified by the Agency), in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

Impurity associated with an active ingredient means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than the active ingredient, which is intentionally included in a pesticide product.

Integrated system means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

Manufacturing-use product means any pesticide product other than an end-use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

Nominal concentration means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

Starting material means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

Technical grade of active ingredient means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot plant production scale (whether or not it is ever held for sale).

§ 158.310 Product chemistry data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (f) of the section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use-specific.

(c) *Test substance.* Data requirements that list only the manufacturing-use product as the test substance apply to products containing solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added.

(d) *Key.* R=Required; CR=Conditionally required; MP=Manufacturing-use product; NR=Not required; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient.

(e) *Table.* The following table shows the data requirements for product chemistry. The table notes are shown in paragraph (f) of this section.

PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
Product Identity and Composition					
830.1550	Product identity and composition	R	MP	EP	1

PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
830.1600	Description of materials used to produce the product	R	MP	EP	2
830.1620	Description of production process	R	MP	EP	3
830.1650	Description of formulation process	R	MP	EP	4
830.1670	Discussion of formulation of impurities	R	MP, and possibly TGAI	EP, and possibly TGAI	5
830.1700	Preliminary analysis	CR	MP, and possibly TGAI	EP, and possibly TGAI	6, 9, 10
830.1750	Certified limits	R	MP	EP	7
830.1800	Enforcement analytical method	R	MP	EP	8
830.1900	Submittal of samples	CR	MP, PAI and TGAI	EP, PAI, TGAI	9, 11
Physical and Chemical Properties					
830.6302	Color	R	MP and TGAI	EP	9
830.6303	Physical state	R	MP and TGAI	EP and TGAI	9
830.6304	Odor	R	MP and TGAI	EP	9
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	R	MP and TGAI	EP	9, 12, 26
830.6314	Oxidation/reduction: chemical incompatibility	CR	MP	EP	13
830.6315	Flammability	CR	MP	EP	14
830.6316	Explodability	CR	MP	EP	15
830.6317	Storage stability	R	MP	EP	
830.6319	Miscibility	CR	MP	EP	16
830.6320	Corrosion characteristics	R	MP	EP	
830.6321	Dielectric breakdown voltage	CR	NR	EP	17
830.7000	pH	CR	MP and TGAI	EP and TGAI	9, 18
830.7050	UV/visible light absorption	R	TGAI or PAI	NR	--
830.7100	Viscosity	CR	MP	EP	19
830.7200	Melting point/melting range	R	TGAI or PAI	TGAI or PAI	9, 20
830.7220	Boiling point/boiling range	R	TGAI or PAI	TGAI or PA	9, 21
830.7300	Density/relative density/bulk density	R	MP and TGAI	EP and TGAI	9
830.7370	Dissociation constants in water	R	TGAI or PAI	TGAI or PAI	9, 22
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI or PAI	EP	23
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	R	TGAI or PAI	TGAI or PAI	24
830.7840 830.7860	Water solubility	R	TGAI or PAI	TGAI or PAI	9
830.7950	Vapor pressure	R	TGAI or PAI	TGAI or PAI	9, 25

(f) *Test notes.* The following test notes are applicable to the product chemistry data requirements in the table to paragraph (e) of this section:

1. Data must be provided in accordance with § 158.320.
2. Data must be provided in accordance with § 158.325.
3. Data must be provided in accordance with § 158.330.
4. Data must be provided in accordance with § 158.335.
5. Data must be provided in accordance with § 158.340.
6. Data must be provided in accordance with § 158.345.
7. Data must be provided in accordance with § 158.350.
8. Data must be provided in accordance with § 158.355.
9. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI.
10. Data are required if the product is produced by an integrated system.
11. Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis.
12. Data on the stability to metals and metal ions are required only if the TGAI is expected to come into contact with either material.
13. Required when the product contains an oxidizing or reducing agent.
14. Required when the product contains combustible liquids.
15. Required when the product is potentially explosive.
16. Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent.
17. Required when the EP is a liquid and is to be used around electrical equipment.
18. Required when the test substance is soluble or dispersible in water.
19. Required when the product is a liquid.
20. Required when the TGAI is solid at room temperature.
21. Required when the TGAI is liquid at room temperature.
22. Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).
23. Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter of ≥ 0.1 µm.
24. Required if technical chemical is organic and non-polar.
25. Not required for salts.
26. Data on stability of the MP and TGAI to storage at normal temperatures are required. Data on the stability of the TGAI to high temperatures are required if the TGAI is expected to be subjected to temperatures >50 °C (122 °F) during production or storage.

§ 158.320 Product identity and composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b), and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) of this section must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.350.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society (CAS) nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits of the active ingredient in accordance with § 158.350.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts

Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration.

(3) Upper and lower certified limits in accordance with § 158.350.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined by EPA to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 158.350.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level ≥0.1 percent by weight of the technical grade active ingredient the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient.* [Reserved]

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 158.325 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.* (1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, common name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information about each starting material used to produce the active ingredient, as follows:

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him), concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.330 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information about the formulation process, in accordance with § 158.335.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) The name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (e.g., whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, and of the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 158.335 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient) as required by the following sections:

(a) Section 158.330(b)(2), pertaining to characterization of the process.

(b) Section 158.330(b)(4), pertaining to ingredients used in the process.

(c) Section 158.330(b)(5), pertaining to process equipment.

(d) Section 158.330(b)(6), pertaining to the conditions of the process.

(e) Section 158.330(b)(8), pertaining to quality control measures.

§ 158.340 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA

would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must also be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the registrant or applicant has reason to believe may be present in his product at any time before use at a level ≥0.1 percent (1,000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which the applicant knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of these impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level ≥0.1 percent (1,000 ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredient and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information on impurities:

(1) From other possible chemical reactions.

(2) Involving other ingredients.

(3) At additional points in the production or formulation process.

§ 158.345 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0. 1 percent or greater of the technical grade of the active ingredient. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substances are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of the active ingredient must be provided. If the technical grade of the active ingredient cannot

be isolated, a statement of the composition of the practical equivalent of the technical grade of the active ingredient must be submitted.

§ 158.350 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use. If the product label bears a statement prohibiting use after a certain date, the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of standard certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

STANDARD CERTIFIED LIMITS

If the nominal concentration (N) for the ingredient and percentage by weight for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper Limit	Lower Limit
N≤1.0%	N + 10%N	N - 10%N
1.0% ≤N ≤20.0%	N + 5%N	N - 5%N
20.0%≤N≤100.0%	N + 3%N	N - 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicants must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale or distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard, or applicant proposed), the Agency will inform the registrant or applicant of its determination and will provide supporting reasons. The Agency may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*insert product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.355 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that the Agency determines to be toxicologically significant.

Subpart E—Product Performance

§ 158.400 Product performance data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product performance data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use, which includes both food and nonfood uses.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; TEP=Typical end-use product.

(d) *Table.* The following table lists the data requirements that pertain to product performance. The table notes are shown in paragraph (e) of this section.

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
Efficacy of antimicrobial agents													
91–2	Products for use on hard surfaces	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–3	Products requiring confirmatory data	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–4	Products for use on fabrics and textiles	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–5	Air sanitizers	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–7	Products for control of microbial pests associated with human and animal wastes	NR	NR	NR	NR	NR	NR	NR	NR	CR	NR	EP	1
91–8	Products for treating water systems	NR	NR	CR	NR	NR	NR	NR	NR	CR	NR	EP	1
Efficacy of fungicides and nematicides													
93–16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents													
96–5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96–6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
96–10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96–12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

95–13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(e) *Test notes.* The following notes appy to the data requirements table in paragraph (d) of this section.

1. The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

2. [Reserved]

Subpart F—Toxicology

§ 158.500 Toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use the data table in paragraph (d) of this section to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test in the table are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood use, greenhouse nonfood crop use, forestry use, residential outdoor use, and indoor nonfood use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radiolabeled; Choice=Choice of several test substances depending on study required.

(d) *Table.* The following table lists the toxicology data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirements	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI, EP, and possibly diluted EP	1, 2
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI, EP	1, 2, 3
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	4
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	3
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 3
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	3, 5
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	6
870.6200	Acute neurotoxicity - rat	R	R	TGAI	TGAI	7

TABLE—TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirements	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Subchronic Testing						
870.3100	90–day Oral - rodent	R	CR	TGAI	TGAI	8, 9
870.3150	90–day Oral - non-rodent	R	CR	TGAI	TGAI	36
870.3200	21/28–day Dermal	R	NR	TGAI	TGAI and EP	10, 11
870.3250	90–day Dermal	CR	R	TGAI	TGAI and EP	11, 12
870.3465	90–day Inhalation - rat	CR	CR	TGAI	TGAI	13, 14
870.6100	28–day Delayed neurotoxicity-hen	CR	CR	TGAI	TGAI	6, 15
870.6200	90–day Neurotoxicity - rat	R	R	TGAI	TGAI	7, 16
Chronic Testing						
870.4100	Chronic oral - rodent	R	CR	TGAI	TGAI	17, 18, 19
870.4200	Carcinogenicity - two rodent species - rat and mouse preferred	R	CR	TGAI	TGAI	9, 17, 18, 19, 20, 21
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	R	TGAI	TGAI	22, 23, 24, 25, 26
870.3800	Reproduction and fertility effects	R	R	TGAI	TGAI	26, 27, 29
870.6300	Developmental neurotoxicity	CR	CR	TGAI	TGAI	27, 28, 29
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	R	TGAI	TGAI	30
870.5300 870.5375	*In vitro* mammalian cell assay	R	R	TGAI	TGAI	30, 31
870.5385 870.5395	*In vivo* cytogenetics	R	R	TGAI	TGAI	30, 32
Special Testing						
870.7485	Metabolism and pharmacokinetics	R	CR	PAI or PAIRA	PAI or PAIRA	33
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	34
870.7600	Dermal penetration	CR	CR	Choice	Choice	35
870.7800	Immunotoxicity	R	R	TGAI	TGAI	

(e) *Test notes.* The following test notes apply to the requirements in the table to paragraph (d) of this section:

1. Not required if test material is a gas or a highly volatile liquid.

2. Diluted EP testing is required to support the end product registration if results using the EP meet the criteria for restricted use classification under § 152.170(b) or special review consideration under § 154.7(a)(1).

3. Not required if the test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

4. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

5. Required if repeated dermal exposure is likely to occur under conditions of use.

6. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters; thioesters or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids; or of related phosphorothioic, phosponothioic, or phosphorothioamidic acids; or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

7. As determined by the Agency, additional measurements may also be required, such as cholinesterase activity for certain pesticides, e.g., organophosphates and some carbamates. The route of exposure must correspond with the primary route of exposure.

8. Required for nonfood use pesticides if oral exposure could occur.

9. The 90–day study is required in the rat for hazard characterization (possibly endpoint selection) and dose-setting for the chronic/carcinogenicity study. It is not required in the mouse, but the Agency would strongly encourage the registrant to conduct a 90–day range finding for the purposes of dose selection for the mouse carcinogenicity study to achieve adequate dosing and an acceptable study. The registrant is also encouraged to consult with the Agency on the results of the 90–day mouse study prior to conducting the carcinogenicity study.

10. Required for agricultural uses or if repeated human dermal exposure may occur. Not required if an acceptable 90–day dermal toxicity study is performed and submitted.

11. EP testing is required if the product, or any component of it, may increase dermal absorption of the active ingredient(s) as determined by testing using the TGAI, or increase toxic or pharmacologic effects.

12. Required for food uses if either of the following criteria is met:

(i) The use pattern is such that the dermal route would be the primary route of exposure; or

(ii) The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite is the toxic moiety.

13. Required if there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

14. Based on estimates of the magnitude and duration of human exposure, studies of shorter duration, e.g., 21– or 28–days, may be sufficient to satisfy this requirement. Registrants should consult with the Agency to determine whether studies of shorter duration would meet this requirement.

15. Required if results of acute neurotoxicity study indicate significant statistical or biological effects, or if other available data indicate the potential for this type of delayed neurotoxicity, as determined by the Agency.

16. All 90–day subchronic studies in rats can be designed to simultaneously fulfill the requirements of the 90–day neurotoxicity study using separate groups of animals for testing. Although the subchronic guidelines include the measurement of neurological endpoints, they do not meet the requirement of the 90–day neurotoxicity study.

17. Required if either of the following are met:

(i) The use of the pesticide is likely to result in repeated human exposure over a considerable portion of the human lifespan, as determined by the Agency;

(ii) The use requires a tolerance or an exemption from the requirement of a tolerance.

18. Based on the results of the acute and subchronic neurotoxicity studies, or other available data, a combined chronic toxicity and neurotoxicity study may be required.

19. Studies which are designed to simultaneously fulfill the requirements of both the chronic oral and carcinogenicity studies (*i.e.*, a combined study) may be conducted. Minimum acceptable study durations are:

(i) Chronic rodent feeding study (food use) - 24 months.

(ii) Chronic rodent feeding study (nonfood use) - 12 months.

(iii) Mouse carcinogenicity study - 18 months.

(iv) Rat carcinogenicity study - 24 months.

20. Required if any of the following, as determined by the Agency, are met:

(i) The use of the pesticide is likely to result in significant human exposure over a considerable portion of the human life span which is significant in terms of either frequency, duration, or magnitude of exposure;

(ii) The use requires a tolerance or an exemption from the requirement of a tolerance; or

(iii) The active ingredient, metabolite, degradate, or impurity (a) is structurally related to a recognized carcinogen, (b) causes mutagenic effects as demonstrated by *in vitro* or *in vivo* testing, or (c) produces a morphologic effect in any organ (e.g., hyperplasia, metaplasia) in subchronic studies that may lead to a neoplastic change.

21. If this study is modified or waived, a subchronic 90–day oral study conducted in the same species may be required.

22. Testing in two species is required for all uses.

23. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

24. Additional testing by other routes may be required if the pesticide is determined to be a prenatal developmental toxicant after oral dosing.

25. May be combined with the 2–generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

26. Required to support products intended for food uses and to support products intended for nonfood uses if use of the product is likely to result in significant human exposure over a portion of the human life span in terms of frequency, magnitude or duration of exposure.

27. An information-based approach to testing is preferred, which utilizes the best available knowledge on the chemical (hazard, pharmacokinetic, or mechanistic data) to determine whether a standard guideline study, an enhanced guideline study, or an alternative study should be conducted to assess potential hazard to the developing animal, or in some cases to support a waiver for such testing. Registrants should submit any alternative proposed testing protocols and supporting scientific rationale to the Agency prior to study initiation.

28. Study required using a weight-of-evidence approach considering:

(i) The pesticide causes treatment-related neurological effects in adult animal studies (*i.e.*, clinical signs of neurotoxicity, neuropathology, functional or behavioral effects).

(ii) The pesticide causes treatment-related neurological effects in developing animals, following pre- and postnatal exposure (*i.e.*, nervous system malformations or neuropathy, brain weight changes in offspring, functional or behavioral changes in the offspring).

(iii) The pesticide elicits a causative association between exposures and adverse neurological effects in human epidemiological studies.

(iv) The pesticide evokes a mechanism that is associated with adverse effects on the development of the nervous system (e.g., SAR relationship to known neurotoxicants, altered neuroreceptor or neurotransmitter responses).

29. The use of a combined study that utilizes the 2–generation reproduction study in rodents as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

30. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

31. Choice of assay using either:

(i) Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

(ii) Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

(iii) CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

32. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

33. Required when chronic or carcinogenicity studies are required. May be required if significant adverse effects are seen in available toxicology studies and these effects can be further elucidated by metabolism studies.

34. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application.

35. A risk assessment assuming that dermal absorption is equal to oral absorption must be performed to determine if the study is required, and to identify the doses and duration of exposure for which dermal absorption is to be quantified.

36. A 1–year non-rodent study (*i.e.*, 1–year dog study) would be required if the Agency finds that a pesticide chemical is highly bioaccumulating and is eliminated so slowly that it does not achieve steady state or sufficient tissue concentrations to elicit an effect during a 90–day study. EPA would require the appropriate tier II metabolism and pharmacokinetic studies to evaluate more precisely bioavailability, half-life, and steady state to determine if a longer duration dog toxicity study is needed.

§ 158.510 Tiered testing options for nonfood pesticides.

For nonfood use pesticides only, applicants have two options for generating and submitting required toxicology (§ 158.500) and human exposure (§ 158.1020, § 158.1070, and § 158.1410) studies. Applicants are to select one of the following:

(a) Acute, subchronic, chronic, and other toxicological studies on the active ingredient must be submitted together. The specific makeup of the set of toxicology study requirements is based on the anticipated exposure to the pesticide as determined by the Agency. If hazards are identified based upon review of these studies, specific exposure data will be required to evaluate risk.

(b) Certain toxicological and exposure studies must be submitted simultaneously with the toxicology data submitted in a tiered system. Exposure data must be submitted along with

first tier toxicology data. The requirement for additional second and third level toxicology testing will be determined by the Agency based on the results of the first tiered studies.

(1) The required first-tier toxicology studies consist of:

(i) Battery of acute studies.

(ii) A subchronic 90–day dermal study or a subchronic 90–day inhalation study.

(iii) An acute and subchronic neurotoxicity screening battery in the rat.

(iv) Prenatal developmental toxicity studies in both the rat and rabbit.

(v) Reproduction and fertility studies in rats.

(vi) Battery of mutagenicity studies.

(vii) Immunotoxicity study.

(2) The conditionally required second-tier studies include:

(i) Subchronic 90–day feeding studies in both the rodent and nonrodent.

(ii) Dermal penetration study.

(3) The conditionally required third-tier studies include:

(i) Chronic feeding studies in the rodent.

(ii) Carcinogenicity.

(iii) Metabolism study.

(iv) Additional mutagenicity testing.

Subpart G— Ecological Effects

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50}/EC_{50} studies -- fish, mollusk and invertebrate. All other outdoor residential uses, *i.e.*, gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI=Pure active ingredient; EP=end-use product. Commas between the test substances (*i.e.*, TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) *Test notes.* The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96–hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥ 0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.660 Nontarget plant protection data requirements table.

(a) *General.* Sections 158.100 through158.130 describe how to use this table to determine the nontarget plant

data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes only the general use patterns of aquatic food crops and aquatic nonfood.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(d) *Table.* The following table shows the nontarget plant protection data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern			Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry and Residential Outdoor		
Nontarget Area Phytotoxicity - Tier I						
850.4100	Seedling emergence	R	R	R	TEP	1, 2, 7
850.4150	Vegetative vigor	R	R	R	TEP	1, 2, 3, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	R	R	R	TEP or TGAI	1, 2, 7
Nontarget Area Phytotoxicity - Tier II						
850.4100	Seedling emergence	CR	CR	CR	TEP	1, 4, 5, 7
850.4150	Vegetative vigor	CR	CR	CR	TEP	1, 3, 4, 5, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	CR	CR	CR	TEP or TGAI	1, 4, 6, 7
Nontarget Area Phytotoxicity - Tier III						
850.4300	Terrestrial field	CR	CR	CR	TEP	1, 7, 8, 10
850.4450	Aquatic field	CR	CR	CR	TEP	1, 7, 8, 10
Target Area Phytotoxicity						
850.4025	Target area phytotoxicity	CR	CR	CR	TEP	1, 7, 9, 10

(e) *Test notes.* The following test notes apply to the table in paragraph (d) of this section.

1. Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.

2. Not required for known phytotoxicants.

3. Generally not required for granular formulations. May be requested on a case-by-case basis.

4. Required for known phytotoxicants such as herbicides, desiccants and defoliants.

5. Required if a tested terrestrial species exhibits a 25 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the Tier I testing.

6. Required if the tested aquatic species exhibits a 50 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the tier I testing.

7. Not required for aquatic residential uses.

8. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

9. Tests are required on a case-by-case basis based on the results of lower tier phytotoxicity studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

10. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

Subparts H–J [Reserved]

§§ 158.700–158.900 [Reserved]

Subpart K—Human Exposure

§ 158.1000 Applicator exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA), provide adequate protection from risk under FIFRA for a particular pesticide use pattern, exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing prior to the initiation of studies.

(b) The Agency may accept surrogate exposure data estimations from other sources to satisfy applicator exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. In order to be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address applicator exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the applicator activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1010 Applicator exposure—criteria for testing.

Applicator exposure data described in paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, at least one of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide.

(b) *Exposure criteria.* (1) Dermal exposure may occur during the prescribed use.

(2) Respiratory exposure may occur during the prescribed use.

§ 158.1020 Applicator exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the applicator exposure data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood crop, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food use, and indoor nonfood use. Occupational use patterns also include commercial (''for hire'') applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and residential indoor use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed pertain to pesticide products that meet the testing criteria outlined in § 158.1010. The table notes are shown in paragraph (e) of this section.

TABLE—APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline Number	Data requirement	Use pattern		Test substance	Test Note No.
		Occupational	Residential		
875.1100	Dermal outdoor exposure	R	R	TEP	1, 2, 3
875.1200	Dermal indoor exposure	R	R	TEP	1, 2, 4
875.1300	Inhalation outdoor exposure	R	R	TEP	1, 2, 3
875.1400	Inhalation indoor exposure	R	R	TEP	1, 2, 4
875.1500	Biological monitoring	CR	CR	TEP	1, 2
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	--

(e) *Test notes.* The following notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data, provided the human pharmacokinetics of the pesticide and/or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.

3. Data are required if the product is applied outdoors.

4. Data are required if the product is applied indoors.

5. Data reporting and calculations are required when handler exposure data are submitted.

§ 158.1050 Post-application exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration, provide adequate protection for a particular pesticide use pattern, post-application exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing before the initiation of studies.

(b) The Agency may accept surrogate exposure data from other sources to satisfy post-application exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific needs of EPA. In order to be acceptable, among other things, the Agency must find that the surrogate exposure data have adequate information to address post-application exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the post-application activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1060 Post-application exposure—criteria for testing

Exposure data described in § 158.1070(d) are required based upon toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, either or both of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse health effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from post-application exposure to the pesticide.

(b) *Exposure criteria.* The need for data from potential exposure resulting from situations not covered by this paragraph should be discussed with the Agency.

(1) *For outdoor uses.* (i) Occupational human post-application exposure to

pesticide residues on plants or in soil could occur as the result of cultivation, pruning, harvesting, mowing or other work-related activity. Such uses include agricultural food, feed, and fiber commodities, forest trees, ornamental plants, and turf grass.

(ii) Residential human post-application exposure to pesticide residues on plants or in soil could occur. Such uses may include turf grass, fruits, vegetables, and ornamentals grown at sites, including, but not limited to, homes, parks, and recreation areas.

(2) *For indoor uses.* (i) Occupational human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at agricultural or commercial sites, such as, but not limited to, agricultural animal facilities and industrial or manufacturing facilities.

(ii) Residential human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at residential sites, such as, but not limited to homes, daycare centers, hospitals, schools, and other public buildings.

§ 158.1070 Post-application exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the post-application data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood use, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food, and indoor nonfood. Occupational use patterns also include commercial (''for hire'') applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and indoor residential use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed in the following table pertain to pesticide products that meet the testing criteria outlined in § 158.1060. The table notes are shown in paragraph (e) of this section.

TABLE—POST-APPLICATION EXPOSURE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test Substance	Test Note No.
		Occupational	Residential		
875.2100	Dislodgeable foliar residue and turf transferable residues	R	R	TEP	1, 2, 3, 4, 5
875.2200	Soil residue dissipation	R	CR	TEP	1, 2, 6, 7
875.2300	Indoor surface residue dissipation	R	R	TEP	1, 2, 8, 9
875.2400	Dermal exposure	R	R	TEP	1, 2, 10, 11, 12
875.2500	Inhalation exposure	R	R	TEP	1, 10, 11, 12
875.2600	Biological monitoring	CR	CR	TEP	1, 12, 13
875.2700	Product use information	R	R	TEP	--
875.2800	Description of human activity	R	R	TEP	--
875.2900	Data reporting and calculations	R	R	TEP	14
875.3000	Nondietary ingestion exposure	NR	R	TEP	1, 11, 15

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Bridging applicable residue dissipation data to dermal exposure data is required.

3. Turf grass transferable residue dissipation data are required when pesticides are applied to turf grass. Dislodgeable foliar residue dissipation data are required when pesticides are applied to the foliage of plants other than turf grass.

4. Data are required for occupational sites if (i) there are uses on turf grass or other plant foliage, and (ii) the human activity data indicate that workers are likely to have post-application dermal contact with treated foliage while participating in typical activities.

5. Data are required for residential sites if there are uses on turf grass or other plant foliage.

6. Data are required for occupational sites, if (i) there are outdoor or greenhouse uses to or around soil or other planting media, and (ii) the human activity data indicate that workers are likely to have post-application dermal contact with treated soil or planting media while participating in typical activities.

7. Data are required for residential sites if the pesticide is applied to or around soil or other planting media both outdoors and indoors, e.g., residential greenhouse or houseplant uses.

8. Data are required for occupational sites if the pesticide is applied to or around on non-plant surfaces, e.g., flooring or countertops, and if the human activity data indicate that workers are likely to have post-application dermal contact with treated indoor surfaces while participating in typical activities.

9. Data are required for residential sites if the pesticide is applied to or around non-plant surfaces, e.g., flooring and countertops.

10. Data are required for occupational sites if the human activity data indicate that workers are likely to have post-application exposures while participating in typical activities.

11. Data are required for residential sites if post-application exposures are likely.

12. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data provided the human pharmocokinetics of the pesticide and/or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.

13. Data are required when passive dosimetry techniques are not applicable for a particular exposure scenario, such as a swimmer exposure to pesticides.

14. Data reporting and calculations are required when any post-application exposure monitoring data are submitted.

15. The selection of a sampling method will depend on the nondietary pathway(s) of interest. Data must be generated to consider all potential pathways of nondietary ingestion exposure that are applicable (e.g., soil ingestion, hand-to-mouth transfer, and object-to-mouth transfer of surface residues).

Subpart L—Spray Drift

§ 158.1100 Spray drift data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the spray drift data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use.

(c) *Key.* CR=Conditionally required; NR=Not required; TEP=Typical end-use product; MP=Manufacturing use product; EP=End-use product.

(d) *Table.* The following table lists the data requirements that pertain to spray drift. The table notes are shown in paragraph (e) of this section.

TABLE—SPRAY DRIFT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern									Test substance		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
201–1	Droplet size spectrum	CR	CR	CR	CR	NR	NR	CR	NR	NR	TEP	TEP	1
202–1	Droplet size spectrum	CR	CR	CR	CR	NR	NR	CR	NR	NR	TEP	TEP	1

(e) *Test notes.* The following notes apply to the requirements in the table to paragraph (d) of this section:

1. This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants.

2. [Reserved]

Subpart M [Reserved]

§§ 158.1200 –158.1299 [Reserved]

Subpart N—Environmental Fate

§ 158.1300 Environmental fate data requirements table.

(a) *General.* All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for registration.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, and aquatic nonfood. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(d) *Table.* The following table shows the data requirements for environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoor	Forestry	Residential Outdoor		
Degradation Studies - Laboratory									
835.2120	Hydrolysis	R	R	R	CR	R	R	TGAI or PAIRA	1
835.2240	Photodegradation in water	R	R	NR	NR	R	NR	TGAI or PAIRA	2
835.2410	Photodegradation on soil	R	NR	NR	NR	R	NR	TGAI or PAIRA	3
835.2370	Photodegradation in air	CR	NR	CR	NR	CR	CR	TGAI or PAIRA	4
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	R	NR	R	R	TGAI or PAIRA	5
835.4200	Anaerobic soil	R	NR	NR	NR	NR	NR	TGAI or PAIRA	--
835.4300	Aerobic aquatic	R	R	NR	NR	R	NR	TGAI or PAIRA	--
835.4400	Anaerobic aquatic	R	R	NR	NR	R	NR	TGAI or PAIRA	--
Mobility Studies									
835.1230 835.1240	Leaching and adsorption/desorption	R	R	R	NR	R	R	TGAI or PAIRA	6

TABLE—ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoor	Forestry	Residential Outdoor		
835.1410	Volatility - laboratory	CR	NR	CR	NR	NR	NR	TEP	4
835.8100	Volatility - field	CR	NR	CR	NR	NR	NR	TEP	--
Dissipation Studies - Field									
835.6100	Terrestrial	R	CR	NR	NR	CR	R	TEP	5, 7, 12
835.6200	Aquatic (sediment)	CR	R	NR	NR	NR	NR	TEP	7, 8
835.6300	Forestry	NR	NR	NR	NR	CR	NR	TEP	7, 9, 12
835.6400	Combination and tank mixes	CR	CR	NR	NR	NR	NR	TEP	10
Ground Water Monitoring									
835.7100	Ground water monitoring	CR	NR	NR	NR	CR	CR	TEP	7, 9, 11

(e) *Test notes.* The following test notes apply to the requirements in the table to paragraph (d) of this section:

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.

2. Not required when the electronic absorption spectra, measured at pHs 5, 7, and 9, of the chemical and its hydrolytic products, if any, show no absorption or tailing between 290 and 800 nm.

3. Not required when the chemical is to be applied only by soil injection or is incorporated in the soil.

4. Requirement based on use patterns and other pertinent factors including, but not limited to, the Henry's Law Constant of the chemical. In view of methodological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

5. Required for aquatic food and nonfood crop uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to, cranberry bogs and rice paddies.

6. Adsorption and desorption using a batch equilibrium method is preferred. However in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Requirement for terrestrial uses is based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, nontarget aquatic toxicity or bioaccumulation. Not required for aquatic residential uses. Field testing under the terrestrial field dissipation requirement may be more appropriate for some aquatic food crops, such as rice and cranberry uses, that are managed to have a dry-land period for production. The registrant is encouraged to consult with the Agency on protocols.

9. Agency approval of a protocol is necessary prior to initiation of the study.

10. This study may be triggered if there is specific evidence that the presence of one pesticide can affect the dissipation characteristics of another pesticide when applied simultaneously or serially.

11. Required if the weight-of-evidence indicates that the pesticide and/or its degradates is likely to leach to ground water, taking into account other factors such as the toxicity of the chemicals(s), available monitoring data, and the vulnerability of ground water resources in the pesticide use area.

12. If the terrestrial dissipation study cannot assess all of the major routes of dissipation, the forestry study will be required.

Subpart O—Residue Chemistry

§ 158.1400 Definitions.

The following terms are defined for the purposes of this subpart:

Livestock, for the purposes of this section, includes all domestic animals that are bred for human consumption, including, but not limited to, cattle, swine, sheep, and poultry.

Plant or animal metabolite means a pesticide chemical residue that is the result of biological breakdown of the parent pesticide within the plant or animal.

Residue of concern means the parent pesticidal compound and its metabolites, degradates, and impurities of toxicological concern.

Tolerance, for the purposes of this section, includes the establishment of a new tolerance or tolerance exemption, or amended tolerance or tolerance exemption.

§ 158.1410 Residue chemistry data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Data may be required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses will be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radio-labeled; Residue of concern= the active ingredient and its metabolites, degradates, and impurities of toxicological concern; TEP=Typical end-use product.

(d) *Table.* The following table list the data requirements for residue chemistry related to food uses. The table notes are shown in paragraph (e) of this section.

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
Supporting Information								
860.1100	Chemical identity	R	R	R	R	R	TGAI	--
860.1200	Directions for use	R	R	R	R	R	--	--
860.1550	Proposed tolerance	R	R	R	CR	NR	--	1
860.1560	Reasonable grounds in support of petition	R	R	R	CR	NR	--	1
860.1650	Submittal of analytical reference standards	R	R	R	CR	NR	PAI and residue of concern	1, 2, 25
Nature of the residue								
860.1300	Nature of the residue in plants	R	R	R	CR	CR	PAIRA	3, 4, 25

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES—Continued

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	NR	PAIRA or radiolabeled plant metabolite	1, 6, 25
860.1850	Confined rotational crops	CR	CR	NR	NR	NR	PAIRA	7
Analytical methods								
860.1340	Residue analytical methods	R	R	R	CR	CR	Residue of concern	1, 3, 8, 9, 10, 25
860.1360	Multiresidue method	R	R	R	CR	NR	Residue of concern	1, 11, 25
Magnitude of the residue								
860.1380	Storage stability	R	R	R	CR	CR	TEP or residue of concern	1, 3, 10, 12, 25
860.1500	Crop field trials	R	R	R	CR	CR	TEP	3, 10, 14, 24, 25
860.1520	Processed food or feed	CR	CR	CR	CR	NR	TEP	1, 15, 25
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	NR	TGAI or plant metabolite	1, 16, 17, 18, 25
860.1400	Potable water	NR	R	NR	NR	NR	TEP	19, 25
860.1400	Fish	NR	R	NR	NR	NR	TEP	5, 25
860.1400	Irrigated crops	NR	CR	NR	NR	NR	TEP	20, 25
860.1460	Food handling	NR	NR	NR	CR	NR	TEP	1, 21, 25
860.1540	Anticipated residues	CR	CR	CR	CR	NR	Residue of concern	1, 13, 22, 26
860.1900	Field rotational crops	CR	CR	NR	NR	NR	TEP	23, 25

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section.

1. Required if indoor use could result in pesticide residues in or on food or feed.

2. Material safety data sheets must accompany standards as specified by OSHA in 29 CFR 1910.1200.

3. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

4. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

5. Data for fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

6. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

7. Required when the Agency determines that it is reasonably foreseeable that a food or feed crop could be subsequently planted on the site of pesticide application after harvest or failure of the treated crop. Typically not required for pesticide uses in permanent food crops (e.g., various tree crops, vines) or semi-permanent crops (e.g., asparagus, pineapples).

8. A residue analytical method suitable for enforcement purposes is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

9. New analytical methods to be used for enforcement purposes must include results from an independent laboratory validation.

10. A residue method, storage stability data, and crop field trials are required for the nonfood crop tobacco (green, freshly harvested). Depending on the level of residues found on the green tobacco, additional data may be required on cured/dried tobacco and pyrolysis products.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required for any magnitude of the residue study unless analytical samples are stored frozen for 30 days or less, and the active ingredient is not known to be volatile or labile.

13. Studies using single serving samples of a raw agricultural commodity may be needed for acutely toxic pesticides and/or their metabolites. These residue studies must be conducted using a statistical design accepted by the Agency.

14. Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).

15. Data on the nature and level of residues in processed food/feed are required if residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16. Required when the pesticide use is a direct application to livestock.

17. Data are required if pesticide residues are present in or on livestock feed items or intentionally added to drinking water. These studies, however, may not be required in cases where the livestock metabolism studies indicate negligible transfer of the pesticide's residues of concern to tissues, milk, and eggs at the maximum expected exposure level for the animals.

18. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock feeding study involving dosing with the plant metabolite(s) may also be required.

19. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

20. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

21. Data are required whenever a pesticide may be used in a food handling or feed handling establishment.

22. Required when residues at the tolerance level may result in a risk of concern. These data may include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

23. Typically required if pesticide residues of concern greater than 0.01 ppm are found in crops at the appropriate plant back intervals (taking into account plant back restrictions on product labels) in the confined rotational crop study. If residues of concern in the confined study are greater than 0.01 ppm but less than the limit of quantitation of the analytical method to be used on field trial samples, the Agency will consider not requiring, on a case-by-case basis, the limited field trials. If there are particular toxicological concerns with the parent pesticide or any metabolites, limited field studies may be needed if such residues are identified at levels below 0.01 ppm in the confined study.

24. Crop field trials are required to establish tolerances on rotational crops when quantifiable residues of concern are observed in the field rotational crops study.

25. Not required for an exemption from a tolerance provided that dietary exposure estimates are not needed due to low toxicity or that theoretical estimates of exposure are adequate to assess dietary risk.

26. Not required for an exemption from a tolerance.

Subparts P–T [Reserved]

§§ 158.1500–158.1900 [Reserved]

Subpart U—Biochemical Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.

§ 158.2000 Biochemical pesticides definition and applicability.

This subpart applies to all biochemical pesticides as defined in paragraphs (a), (b), and (c) of this section.

(a) *Definitions*. The following terms are defined for the purposes of subpart U of this part.

(1) A *biochemical pesticide* is a pesticide that:

(i) Is a naturally-occurring substance or structurally-similar and functionally identical to a naturally-occurring substance;

(ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticides, is equivalent to a naturally-occurring substance that has such a history; and

(iii) Has a non-toxic mode of action to the target pest(s).

(2) A *Pheromone* is a compound produced by a living organism or is a synthetically derived substance that is structurally similar and functionally identical to a naturally-occurring pheromone, which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(i) An *Arthropod Pheromone* is a pheromone produced by a member of the taxonomic phylum Arthropoda.

(ii) A *Lepidopteran Pheromone* is an arthropod pheromone produced by a member of the insect order Lepidoptera.

(iii) A *Straight Chain Lepidopteran Pheromone* is a lepidopteran pheromone consisting of an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde, or acetate functional group and containing up to three double bonds in the aliphatic backbone.

(b) *Examples*. Biochemical pesticides include, but are not limited to:

(1) Semiochemicals (insect pheromones and kairomones),

(2) Natural plant and insect regulators,

(3) Naturally-occurring repellents and attractants, and

(4) Enzymes.

(c) *Applicability*. The Agency may review, on a case-by-case basis, naturally-occurring pesticides that do not clearly meet the definition of a biochemical pesticide in an effort to ensure, to the greatest extent possible, that only the minimum testing sufficient to make scientifically sound regulatory decisions would be conducted. The Agency will review applications for registration of naturally-occurring pesticides to determine whether to review the pesticide under this subpart U.

§ 158.2010 Biochemical pesticides data requirements.

(a) Sections 158.2030 through 158.2070 identify the data requirements that are required to support registration of biochemical pesticides. Sections 158.2080 through 158.2084 identify the data requirements that are required to support Experimental Use Permits (EUPs). Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) Each data table includes ''use patterns'' under which the individual data are required, with variations including food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(c) The categories for each data requirement are ''R'', which stands for required, and ''CR'' which stands for conditionally required. Generally, ''R'' indicates that the data are more likely required than for those data requirements with ''CR.'' However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(d) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or

EP or both depending on the conditions set forth in the test note.

(e) The data requirements are organized into a tier-testing system with specified additional studies at higher tiers being required if warranted by adverse effects observed in lower tier studies. The lower tier studies are a subset of those required for conventional pesticides, and the studies overall are generally selected from those required for conventional pesticides.

(f) Two sets of guideline numbers are provided for some of the environmental fate data requirements. For ease of understanding, the current guidelines will be used as an interim measure until the new guidelines (in parentheses) are finalized.

§ 158.2030 Biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Definitions in § 158.300 apply to data requirements in this section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above.

(d) *Table.* The following table shows the data requirements for biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with § 158.320.
2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.
3. Data must be provided in accordance with §§ 158.325, 158.330, and § 158.335.
4. Data must be provided in accordance with § 158.340.
5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAIs) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis.
6. Data must be provided in accordance with § 158.350.
7. Data must be provided in accordance with § 158.355.
8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.
9. Required if the product contains combustible liquids.
10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
11. Required if the test substance is soluble or dispersible in water.
12. Required if the product is a liquid.
13. Required when the technical chemical is a solid at room temperature.
14. Required when the technical chemical is a liquid at room temperature.
15. Required for water insoluble test substances ($>10^{-6}$g/l) and fibrous test substances with diameter ≥ 0.1 µm.
16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.
17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.
19. Not required for salts.

§ 158.2040 Biochemical pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a particular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, *i.e.*, naturally occurring insect repellents and

attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data requirements table.* The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL RESIDUE DATA REQUIREMENTS FOR SPECIFIC USES

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse Food	Indoor Food		
		Food/Feed	Food				
Supporting Information							
860.1100	Chemical identity	CR	CR	CR	CR	TGAI	1, 2, 4
860.1200	Directions for use	CR	CR	CR	CR	--	1, 3, 4
Nature of the Residue							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	TGAI	1, 4, 5, 6
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	TGAI or plant metabolite	1, 7, 8, 10, 13
860.1340	Residue analytical method	CR	CR	R	CR	Residue of concern	4, 9, 10
860.1360	Multiresidue method	CR	CR	R	CR	Residue of concern	10, 11
Magnitude of the Residue							
860.1400	Potable water	NR	CR	NR	NR	TGAI	1, 12
860.1400	Fish	NR	CR	NR	NR	TGAI	1, 13
860.1400	Irrigated crops	NR	CR	NR	NR	TGAI	1, 14
860.1460	Food handling	NR	NR	NR	CR	TGAI	1, 15

TABLE—BIOCHEMICAL RESIDUE DATA REQUIREMENTS FOR SPECIFIC USES—Continued

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse Food	Indoor Food		
		Food/Feed	Food				
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or plant metabolites	1, 7, 8, 10
860.1500	Crop field trials	CR	CR	CR	CR	TEP	1, 3, 4
860.1520	Processed food/feed	CR	CR	CR	CR	TEP	1, 16
860.1540	Anticipated residues	CR	CR	CR	CR	Residue of concern	1, 10, 17
860.1550	Proposed tolerances	CR	CR	CR	CR	--	1, 18
860.1560	Reasonable grounds in support of the petition	CR	CR	CR	CR	--	1, 10
860.1650	Submittal of analytical reference standards	CR	CR	CR	CR	TGAI and residue of concern	10, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are in the last column of the table contained in paragraph (d) of this section.

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, § 158.2050.

2. The same chemical identity data are required for biochemical product chemistry data requirements, § 158.2030, with an emphasis on impurities.

3. Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

4. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

5. Required unless it is an arthropod pheromone applied at a rate less than or equal to 150 grams active ingredient per acre.

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

7. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed.

8. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

9. A residue analytical method suitable for enforcement of tolerances is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

10. Required if indoor use could result in pesticide residues in or on food or feed.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

13. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited by fish that may be caught or harvested for human consumption.

14. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

15. Data are required whenever a pesticide may be used in food/feed handling establishments.

16. Data on the nature and level of residue in processed food/feed are required when detectible residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher

than that of the raw agricultural commodity.

17. Required when residues at the tolerance level may result in risk of concern. These data may include washing, cooking, processing, or degradation studies as well as market basket surveys for a more precise residue determination.

18. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

19. Required when a residue analytical method is required.

§ 158.2050 Biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the biochemical human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	2, 4
none	Hypersensitivity incidents	R	R	All	All	5
Subchronic Testing						
870.3100	90-day oral (one species)	R	CR	TGAI	TGAI	6

TABLE—BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
870.3250	90-day dermal - rat	CR	CR	TGAI	TGAI	7
870.3465	90-day inhalation - rat	CR	CR	TGAI	TGAI	8
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	9
Mutagenicity Testing						
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	10
870.5300 870.5375	*In vitro* mammalian cell assay	R	CR	TGAI	TGAI	10, 11
Tier II						
Mutagenicity Testing (*In vivo* cytogenetics)						
870.5385 870.5895	*In vivo* Mammalian Cytogenetics	CR	CR	TGAI	TGAI	13
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	9
Special Tests						
880.3550	Immunotoxicity	CR	CR	TGAI	TGAI	12, 13
Applicator/User Exposure						
875.1100	Dermal outdoor exposure	CR	CR	TGAI	TGAI	15
875.1200	Dermal indoor exposure	CR	CR	TGAI	TGAI	15
875.1300	Inhalation outdoor exposure	CR	CR	TGAI	TGAI	15
875.1400	Inhalation indoor exposure	CR	CR	TGAI	TGAI	15
875.1500	Biological monitoring	CR	CR	TGAI	TGAI	15
Tier III						
Chronic Testing/Special Testing						
880.3800	Immune response	CR	CR	TGAI	TGAI	14
870.3800	Reproduction and fertility effects	CR	CR	TGAI	TGAI	16
870.4100	Chronic oral - rodent and nonrodent	CR	CR	TGAI	TGAI	17
870.4200	Carcinogenicity - two species - rat and mouse preferred	CR	CR	TGAI	TGAI	18
870.5380	Mammalian spermatogonial chromosome aberration test	CR	CR	TGAI	TGAI	19
Special Testing						
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	20

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure $>10^{-4}$ torr (mm/Hg)).

2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.

3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.

4. Required if repeated contact with human skin is likely to occur under conditions of use.

5. Hypersensitivity incidents must be reported as adverse effects data.

6. Required for non-food uses that are likely to result in repeated oral exposure to humans.

7. Required to support uses involving purposeful application to the human skin or which would result in comparable prolonged human exposure to the product (e.g., insect repellents) and if any of the following criteria are met:

i. Data from a 90–day oral study are not required.

ii. The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route and the metabolite is of toxicological concern.

iii. The use pattern is such that the dermal route would be the primary route of exposure.

8. Required if there is a likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

9. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

10. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen. Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

11. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

12. Required if there are effects on hematology, clinical chemistry, lymphoid organ weights, and histopathology are observed in the 90–day studies.

13. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

14. Required if adverse effects are observed in the Tier II immunotoxicity study. The protocol for evaluating adverse effects to the immune response should be developed after evaluating the effects noted in the immunotoxicity study.

15. These data are required when the data used for the human health assessment indicates that the biochemical may pose a potential hazard to the applicator/user.

16. Required if there is evidence of:

i. Endocrinological effects from the subchronic toxicity studies.

ii. Developmental effects in the prenatal developmental toxicity study(s), or

iii. Genotoxicity to mammals based on results from the mutagenicity tests.

The use of a combined study that utilizes the two-generation reproduction study in rodents (guideline 870.3800) as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

17. Required if the potential for adverse chronic effects is indicated based on any of the following:

i. The subchronic effect level established in the following Tier I studies: 90–day oral toxicity study, 90–day dermal toxicity study, or 90–day inhalation toxicity study.

ii. The pesticide use pattern (e.g., rate, frequency, and site of application).

iii. The frequency and level of repeated human exposure that is expected.

18. Required if the product meets either of the following criteria:

i. The active ingredient (or any of its metabolites, degradation products, or impurities) produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia or metaplasia) in any organ that potentially could lead to neoplastic change.

ii. Adverse cellular effects suggesting carcinogenic potential are observed in Tier II immunotoxicity and Tier III immune response study or in Tier II mammalian mutagenicity assays.

In addition, a 90–day range finding study in both rats and mice is required to determine the dose levels if carcinogenicity studies are required. If the mouse carcinogenicity study is not required, the 90–day mouse subchronic study is likewise not required.

19. Required if results from lower tiered mutation or reproductive studies indicate there is potential for chromosomal aberration to occur.

20. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application or consumption of treated feed.

§ 158.2060 Biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, one acute freshwater invertebrate study, plant toxicity testing, and a honeybee acute contact study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (*i.e.*, granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include: forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
850.2200	Avian dietary toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 4, 5

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 5
Nontarget Plant Testing								
850.4100	Terrestrial Plant Toxicity, Seedling emergence	R	R	NR	R	NR	TGAI, EP	5
850.4150	Terrestrial Plant Toxicity, Vegetative vigor	R	R	NR	R	NR	TGAI, EP	5
Insect Testing								
880.4350	Nontarget Insect Testing	R	R	R	R	NR	TGAI	14
Tier II								
Environmental Fate Testing								
163-1 (835.1230)	Sediment and soil adsorption/desorption for parent and degradates	CR	CR	CR	CR	NR	TGAI	6
163-1 (835.1240)	Soil column leaching	CR	CR	CR	CR	NR	TGAI	6
163-2 (835.1410)	Laboratory volatilization from soil	CR	NR	CR	CR	NR	TEP	7
161-1 (835.2120)	Hydrolysis	CR	CR	CR	CR	NR	TGAI	6
161-1 (835.4100)	Aerobic soil metabolism	CR	NR	CR	CR	NR	TGAI	6
161-2 (835.2240)	Photodegradation in water	CR	CR	CR	CR	NR	TGAI	6
161-3 (835.2410)	Photodegradation on soil	CR	NR	CR	CR	NR	TGAI	6
162-2 (835.4200)	Anaerobic soil metabolism	CR	NR	NR	NR	NR	TGAI	6
162-4 (835.4300)	Aerobic aquatic metabolism	CR	CR	CR	CR	NR	TGAI	6
162-3 (835.4400)	Anaerobic aquatic metabolism	CR	CR	NR	NR	NR	TGAI	6
880.4425	Dispenser - water leaching	CR	NR	CR	CR	NR	EP	8
Nontarget Plant								
850.4225	Seedling emergence	R	R	NR	R	NR	TGAI	9
850.4250	Vegetative vigor	R	R	NR	R	NR	TGAI	9
Tier III								
Aquatic Fauna Chronic, Life Cycle, and Field Studies								
850.1300 850.1400 850.1500	Freshwater fish/invertebrate testing	CR	CR	NR	CR	NR	TGAI	10

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1025 850.1035 850.1045 850.1055 850.1350 850.1400 850.1500	Marine/Estuarine fish/invertebrate animal testing	CR	CR	NR	CR	NR	TGAI	10
850.1950	Aquatic field fish/invertebrate testing	CR	CR	NR	CR	NR	EP	10
Terrestrial Wildlife								
850.2300	Avian Reproduction	CR	CR	NR	CR	NR	TGAI	11
850.2400	Wild mammal acute toxicity	CR	CR	NR	CR	NR	TGAI	11
850.2500	Terrestrial field testing	CR	CR	NR	CR	NR	EP	11
Beneficial Insects								
850.3040	Field testing for Pollinators	CR	CR	NR	CR	NR	TEP	12
Nontarget Plants								
850.4225 850.4250 850.4300 850.4450	Nontarget plant	CR	CR	NR	CR	NR	TGAI	13

(e) *Test notes*. The following test notes are applicable to the data requirements for biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, physical/chemical properties, production volume, and other pertinent factors.

3. Not required for any use groups if the pesticide is highly volatile (estimated volatility >5 X 10^{-5}atm m^3/mol).

4. Preferred test species are Upland game, waterfowl, or passerine for avian acute oral toxicity studies; Upland game and waterfowl for avian dietary studies; and coldwater fish species for acute freshwater fish studies.

5. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

6. Required on a case-by-case basis when results from Tier I studies indicate adverse effects.

7. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied on land. In view of methdological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

8. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied in a passive dispenser.

9. Required to support registration of known phytotoxicants, *i.e.*, herbicides, desiccants, defoliants, and plant growth regulators.

10. Required if environmental fate characteristics indicate that the estimated environmental concentration of the pesticide in the aquatic environment is >0.01 of any EC_{50}

or LC_{50} determined in the aquatic nontarget organism testing.

11. Required if either of the following criteria are met:

i. Environmental fate characteristics indicate that the estimated concentration of the pesticide in the terrestrial environment is > 0.20 the avian dietary LC_{50} or equal to > 0.20 the avian oral single dose LD_{50} (converted to ppm).

ii. The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian or mammalian feed.

12. Required when results of Tier I nontarget organism studies indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects. Additional insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., threatened or endangered species).

13. Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement would be determined by the results of the Tier II environmental fate studies.

14. Required depending on pesticide mode of action, method and timing of application, and results of any available efficacy data. Typically the honeybee acute toxicity guideline (guideline 850.3020) satisfies this requirement, however, additional nontarget insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., endangered species.)

§ 158.2070 Biochemical pesticides product performance data requirements.

Product performance data must be developed for all biochemical pesticides. However, the Agency typically does not require applicants to submit such efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2080 Experimental use permit data requirements—biochemical pesticides.

(a) Sections 158.2081 through 158.2084 describe the experimental use permit (EUP) data requirements for biochemical pesticides. Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) For general information on the data requirement tables, see § 158.2010(b)-(f).

§ 158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular biochemical pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Depending on the results of the required product chemistry studies, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental

use permit biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with § 158.320.
2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.
3. Data must be provided in accordance with § 158.325, § 158.330, and § 158.335.
4. Data must be provided in accordance with § 158.340.
5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAIs) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit.
6. Data must be provided in accordance with § 158.350.
7. Data must be provided in accordance with § 158.355.
8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.
9. Required if the product contains combustible liquids.
10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
11. Required if the test substance is soluble or dispersible in water.
12. Required if the product is a liquid.
13. Required when the technical chemical is a solid at room temperature.
14. Required when the technical chemical is a liquid at room temperature.
15. Required for water insoluble test substances ($>10^{-6}$g/l) and fibrous test substances with diameter ≥ 0.1 µm.
16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.
17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.
19. Not required for salts.

§ 158.2082 Experimental use permit biochemical pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a particular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, *i.e.*, naturally occurring insect repellents and attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates,and impurities of toxicological concern. All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data table.* The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns				Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse Food	Indoor Food		
		Food/Feed	Food				
Supporting Information							
860.1100	Chemical identity	CR	CR	CR	CR	TGAI	1, 2, 4
860.1200	Directions for use	CR	CR	CR	CR	--	1, 3, 4
Nature of Residue							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	TGAI	1, 4, 5, 6
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	TGAI or plant metabolite	1, 7, 8, 9, 13
Magnitude of the Residue							
860.1400	Potable water	NR	CR	NR	NR	TGAI	1, 11
860.1400	Fish	NR	CR	NR	NR	TGAI	1, 12
860.1400	Irrigated crops	NR	CR	NR	NR	TGAI	1, 13
860.1460	Food handling	NR	NR	NR	CR	TGAI	1, 14
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or plant metabolites	1, 7, 8, 9
860.1500	Crop field trials	CR	CR	CR	CR	TEP	1, 3, 4
860.1520	Processed food/feed	CR	CR	CR	CR	TEP	1, 15
860.1540	Anticipated residues	CR	CR	CR	CR	Residue of concern	1, 9, 16
860.1550	Proposed tolerances	CR	CR	CR	CR	--	1, 17
860.1560	Reasonable grounds in support of the petition	CR	CR	CR	CR	--	1, 9
860.1650	Submittal of analytical reference standards	CR	CR	CR	CR	TGAI and residue of concern	9, 18

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced referenced in the last column of the table contained in paragraph (d) of this section.

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical agents in the biochemical human health assessment data requirements, § 158.2050.

2. The same chemical identity data are required for biochemical product chemistry data requirements,§ 158.2030 with an emphasis on impurities.

3. Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

4. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is expected to produce higher residues based on the label directions.

5. Required unless it is an arthropod pheromone applied at a rate less than or equal to 150 grams active ingredient per acre.

6. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

7. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from

the plant metabolism study show differing metabolites in plants form those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

8. Livestock feeding studies are required whenever a pesticide residue is present in livestock feed or when direct application to livestock uses occurs.

9. Required if indoor use could result in pesticide residues in or on food or feed.

10. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

11. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

12. Data on fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

13. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

14. Data are required whenever a pesticide may be used in food/feed handling establishments.

15. Data on the nature and level of residue in processed food/feed are required when detectible residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16 Anticipated residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level of exposure. Data, using single serving samples of a raw agricultural commodity, on the level or residue in food as consumed would be used to obtain a more precise estimate of potential dietary exposure. These data may also include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

17. The proposed tolerance must reflect the maximum residue likely to occur in crops, in meat, milk, poultry, or eggs.

18. Required when a residue analytical method is required.

§ 158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the human health assessment data requirements for a particular biochemical pesticide product.

(2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.

(b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						

TABLE—EUP BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
none	Hypersensitivity incidents	R	R	All	All	4
Subchronic Testing						
870.3100	90-day oral (one species)	R	NR	TGAI	TGAI	--
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	5
Mutagenicity Testing						
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	6
870.5300	*In vivo* mammalian cell assay	R	CR	TGAI	TGAI	6, 7
Tier II						
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	5

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure > 10^{-4} torr (mm/Hg)).

2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.

3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.

4. Hypersensitivity incidents must be reported as adverse effects data.

5. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

6. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen.

Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

7. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing

assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vivo* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

§ 158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, and one acute freshwater invertebrate study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (*i.e.*, granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
850.2200	Avian dietary toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 3, 4

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 4

(e) *Test notes*. The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Not required for any use groups if the pesticide is highly volatile (estimated volatility >5 X 10^{-5}atm m^3/mol).

3. Preferred test species are: upland game, waterfowl, or passerine for avian acute oral toxicity studies; upland game or waterfowl for avian dietary studies; and coldwater fish for acute freshwater fish studies.

4. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

Subpart V—Microbial Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.

§ 158.2100 Microbial pesticides definition and applicability.

(a) This subpart applies to all living or dead microbial pesticides as described in paragraphs (b) and (c) of this section.

(b) *Definition*. *Microbial pesticide* is a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaebacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

(c) *Applicability*. (1) This part applies to microbial pesticides as specified in paragraphs (c)(2), (3) and (4) of this section.

(2) Each new isolate of a microbial pesticide is treated as a new strain and must be registered independently of any similar registered microbial pesticide strain and supported by data required in this subpart.

(3) Genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis depending on the particular microbial agent and/or its parental strains, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified.

(4) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in § 152.20 (a) of this chapter.

§ 158.2110 Microbial pesticides data requirements.

(a) For all microbial pesticides. (1) The following § 158.2120 through § 158.2150 identify the data requirements that are required to support registration of microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) Each data table includes ''use patterns'' under which the individual data are required, with variations including all use patterns, food and nonfood uses

for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(3) The categories for each data requirement are ''R,'' which stands for required, and ''CR'' which stands for conditionally required. If a bracket appears around the ''R'' or ''CR,'' the data are required for both the registration and experimental use permit requests. Generally, ''R'' indicates that the data are more likely required than for those data requirements with ''CR.'' However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(4) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or EP or both depending on the conditions set forth in the test note. Data requirements which list two test substances (*i.e.*, TGAI and EP) indicate that both are required to be tested. Data requirements that list only MP as the test substance apply to products containing solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added. Data requirements listing the EP as the test substance apply to any EP with an ingredient in the end-use formulation other than the active ingredient that is expected to enhance the toxicity of the product.

(b) Additional data requirements for genetically modified microbial pesticides. Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the ''new'' traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2120 Microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	--

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	--
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	1
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	2
830.6320	Corrosion Characteristics	R	MP	EP	3
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	4
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

2. Only required for emulsifiable liquid forms of microbial pesticides.

3. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

4. Only required for liquid forms of microbial pesticides.

§ 158.2130 Microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in paragraph (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides residue. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods - animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes.* The following test note is applicable to the data requirements for microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

§ 158.2140 Microbial pesticides toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
Tier I				
885.3050	Acute oral toxicity/pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/(intravenous) Acute injection toxicity/pathogenicity/(intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP , EP	1, 5
870.1200	Acute dermal toxicity	R	MP , EP	5

TABLE—MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
870.1300	Acute inhalation toxicity	R	MP , EP	5, 6
870.2400	Acute eye irritation	R	MP , EP	5
870.2500	Primary dermal irritation	R	MP , EP	5
Tier II				
885.3550	Acute toxicology	CR	TGAI	7
885.3600	Subchronic toxicity/pathogenicity	CR	TGAI	8
Tier III				
885.3650	Reproductive fertility effects	CR	TGAI	9, 13
870.4200	Carcinogenicity	CR	TGAI	10, 13
870.7800	Immunotoxicity	CR	TGAI	11, 13
885.3000	Infectivity/pathogenicity analysis	CR	TGAI	12, 13

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed-type reactions of humans or domestic animals, occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use would result in, an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

7. Data required when significant toxicity, in the absence of pathogenicity and significant infectivity, is observed in acute oral, injection, or pulmonary studies (Tier I). Route(s) of exposure correspond to route(s) where toxicity was observed in Tier I studies. The toxic component of the TGAI is to be tested.

8. Data required when significant infectivity and/or unusual persistence is observed in the absence of pathogenicity or toxicity in Tier I studies. Routes of exposure (oral and/or pulmonary) correspond to routes in Tier I studies where adverse effects were noted. Data may also be required to evaluate adverse effects due to microbial contaminants or to toxic byproducts.

9. Data are required when one or more of the following criteria are met:

i. Significant infectivity of the microbial pest control agent (MPCA) was observed in test animals in the Tier II subchronic study and in which no significant signs of toxicity or pathogenicity were observed.

ii. The microbial pesticide is a virus which can persist or replicate in mammalian cell culture lines.

iii. The microbial pesticide is not amenable to thorough taxonomic classification, and is related to organisms known to be parasitic for mammalian cells.

iv. The microbial pesticide preparation is not well purified, and may contain contaminants which are parasitic for mammals.

10. Data may be required for products known to contain or suspected to contain carcinogenic viruses or for microbial components that are identified as having significant toxicity in Tier II testing.

11. Data may be required for products known to contain or suspected to contain viruses that can interact in an adverse manner with components of the mammalian immune system.

12. An analysis of human infectivity/pathogenicity potential using scientific literature, genomic analysis, and/or actual specific cell culture/animal data may be required for products known to contain or suspected of containing intracellular parasites of mammalian cells for products that exhibit pathogenic characteristics in Tier I and/or Tier II, for products which are closely related to known human pathogens based on the product analysis data, or for known human pathogens that have been ''disarmed'' or rendered non-pathogenic for humans.

13. Test standards may have to be modified depending on the characteristics of the microorganism. Requirements may vary for

these studies depending on the active ingredient being tested. Consultation with the Agency is advised before performing these Tier III studies.

§ 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/ Feed	Nonfood	Food/ Feed/ Nonfood	Forestry	Residential Outdoor	Greenhouse Food/ Nonfood	Indoor Food/ Nonfood	Industrial		
Tier I											
885.4050	Avian oral toxicity	R	R	R	R	R	CR	CR	CR	TGAI	1, 2
885.4100	Avian inhalation toxicity/pathogenicity	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	1, 2, 3
885.4150	Wild mammal toxicity/ pathogenicity	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 4
885.4200	Freshwater fish toxicity/ pathogenicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4240	Freshwater invertebrate toxicity/pathogenicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4280	Estuarine/Marine fish testing Estuarine and marine invertebrate testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 6
885.4300	Nontarget plant testing	CR	CR	CR	R	CR	NR	CR	CR	TEP	1, 7
885.4340	Nontarget insect testing	R	R	R	R	R	CR	NR	CR	TGAI	1, 8
885.4380	Honey bee testing	R	R	R	R	R	CR	NR	CR	TGAI	1
Tier II											

TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/ Feed	Nonfood	Food/ Feed/ Nonfood	Forestry	Residential Outdoor	Greenhouse Food/ Nonfood	Indoor Food/ Nonfood	Industrial		
885.5200	Terrestrial environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	9
885.5300	Freshwater environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	10
885.5400	Marine or estuarine environmental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 12
Tier III											
885.4600	Avian chronic pathogenicity and reproduction test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 13
885.4650	Aquatic invertebrate range testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4700	Fish life cycle studies	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4750	Aquatic ecosystem test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	15
Tier IV											
850.2500 850.1950	Field testing for terrestrial wildlife and Field testing for aquatic organisms	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 16
850.2500	Simulated or actual field tests (birds, mammals)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 17, 20
850.1950	Simulated or actual field test (aquatic organisms)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.2500	Simulated or actual field tests (insect predators, parasites)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.3040	Simulated or actual field tests (insect pollinators)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.4300	Simulated or actual field tests (plants)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test the passerine if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish species are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrate testing is also required.

3. Data required when the nature of the microbial pesticide and/or its toxins indicates potential pathogenicity to birds.

4. Required on a case-by-case basis if results of tests required by § 158.2140 are inadequate or inappropriate for assessment of hazards to wild mammals.

5. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

6. Required if the product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern.

7. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

8. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

9. Required if toxic or pathogenic effects are observed in one or more of the following tests for microbial pesticides:

i. Avian acute oral or avian inhalation studies.

ii. Wild mammal studies.

iii. Nontarget plant studies (terrestrial).

iv. Honey bee studies.

v. Nontarget insect studies.

10. Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

i. Freshwater fish studies.

ii. Freshwater invertebrate studies.

iii. Nontarget plant studies (aquatic).

11. Required if product is applied on land or in fresh water or marine/estuarine environments and toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pesticides:

i. Estuarine and marine animal toxicity and pathogenicity.

ii. Plant studies - estuarine or marine species.

12. An appropriate dose-response toxicity test is required when toxic effects on nontarget terrestrial wildlife or aquatic organisms (including plants) are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the microbial agent to the affected nontarget terrestrial wildlife or aquatic organisms. The protocols for these tests may have to be modified in accordance with results from the nontarget organism and environmental expression studies.

13. Required when one or more of the following are present:

i. Pathogenic effects are observed in Tier I avian studies.

ii. Tier II environmental expression testing indicate that long-term exposure of terrestrial animals is likely.

14. Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I aquatic studies.

15. Required if, after an analysis of the microbial pesticide's ability to survive and multiply in the environment and what ecological habitat it would occupy, the intended use patterns, and the results of previous nontarget organisms and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments. Testing is to determine if applications of the microbial pest control would be expected to disrupt the balance of populations in the target ecosystem.

16. Tier IV studies may be conducted as a condition of registration as post-registration monitoring if the potential for unreasonable adverse effects appears to be minimal during that period of use due to implementation of mitigation measures.

17. Required when both of the following conditions occur:

i. Pathogenic effects observed at actual or expected field residue exposure levels are reported in Tier III; and

ii. The Agency determines that quarantine methods would not prevent the microbial pesticide from contaminating areas adjacent to the test area.

18. Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

19. Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction

and growth of natural populations are observed) are required if laboratory data indicate that adverse long-term, cumulative, or life-cycle effects may result from intended use.

20. Since test standards would be developed on a case-by-case basis, consultation with the Agency and development of a protocol is advised before performing these Tier IV studies.

§ 158.2160 Microbial pesticides product performance data requirements.

Product performance data must be developed for all microbial pesticides. However, the Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2170 Experimental use permit data requirements—microbial pesticides.

(a) For all microbial pesticides. (1) The following § 158.2171 through § 158.2174 identify the data requirements that are required to support experimental use permits for microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) For general information on the data requirement tables, see § 158.2110(a)(2)-(4).

(b) Additional data requirements for genetically modified microbial pesticides. Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the ''new'' traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2
885.1300	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 3
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	4
830.6320	Corrosion Characteristics	R	MP	EP	5
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	6
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. If an experimental use permit is being sought, and if the pesticide is not already under full-scale production, a schematic diagram and/or description of the manufacturing process suffices.

2. If an experimental use permit is being sought, and if the product is not already under full-scale production, a discussion of unintentional ingredients is required to be submitted to the extent this information is available.

3. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

4. Only required for emulsifiable liquid forms of microbial pesticides.

5. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

6. Only required for liquid forms of microbial pesticides.

§ 158.2172 Experimental use permit microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in (d) of this section, and

the procedures appear in paragraph (e) of this section.

(b) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table*. The following table shows the data requirements for experimental use permit microbial pesticides residue. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods-animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes*. The following test note is applicable to the data requirements for experimental use permit microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

§ 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular microbial pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key*. R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table*. The following table shows the data requirements for microbial pesticide toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
885.3050	Acute oral toxicity/ pathogenicity	R	TGAI	1
885.3150	Acute pulmonary toxicity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/pathogenicity/ (intravenous) Acute injection toxicity/pathogenicity/ (intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity incidents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP, EP	1, 5
870.1200	Acute dermal toxicity	R	MP, EP	5
870.1300	Acute inhalation toxicity	R	MP, EP	5, 6

TABLE—EUP MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance	Test Notes
870.2400	Acute eye irritation	R	MP, EP	5
870.2500	Primary dermal irritation	CR	MP, EP	5

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed type reactions of humans or domestic animals occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use that would result in an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/Feed	Nonfood	Food/Feed/Nonfood	Forestry	Residential Outdoor	Greenhouse Food/Nonfood	Indoor Food/Nonfood	Industrial		
885.4050	Avian oral toxicity	NR	R	R	R	R	NR	NR	NR	TGAI	1, 2

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
		Food/Feed	Nonfood	Food/Feed/Nonfood	Forestry	Residential Outdoor	Greenhouse Food/Nonfood	Indoor Food/Nonfood	Industrial		
885.4200	Freshwater fish toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4240	Freshwater invertebrate toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4300	Nontarget plant testing	NR	NR	NR	R	NR	NR	NR	NR	TEP	1, 4
885.4340	Nontarget insect testing	R	R	R	R	NR	NR	NR	NR	TGAI	1, 5
885.4380	Honey bee testing	R	R	R	R	NR	NR	NR	NR	TGAI	1

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.

3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

Subpart W—Antimicrobial Pesticides [Reserved]

§ 158.2200 [Reserved]

Subparts X–Z [Reserved]

§§ 158.2300–158.2500 [Reserved]

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A–C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

Sec.

159.152 What the law requires of registrants.
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159.195 Reporting of other information.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 63 FR 49388, Sept. 19, 1997, unless otherwise noted.

Subparts A–C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

§ 159.152 What the law requires of registrants.

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: ''If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.''

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment, which would be required to be reported under section 6(a)(2) if the product were registered.

(c) Compliance with this part will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter.

§ 159.153 Definitions.

(a) For the purposes of reporting information pursuant to FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this subpart:

Established level means a tolerance, temporary tolerance, food additive regulation, action level, or other limitation on pesticide residues imposed by law, regulation, or other authority.

Formal Review means Special Review, Rebuttable Presumption Against Registration (RPAR), FIFRA section 6(c) suspension proceeding, or FIFRA section 6(b) cancellation proceeding, whether completed or not.

Hospitalization means admission for treatment to a hospital, clinic or other health care facility. Treatment as an out-patient is not considered to be hospitalization.

Maximum contaminant level (MCL) means the maximum permissible level, established by EPA, for a contaminant in water which is delivered to any user of a public water system.

Non-target organism means any organism for which pesticidal control was either not intended or not legally permitted by application of a pesticide.

Pesticide means a pesticide product which is or was registered by EPA, and each active ingredient, inert ingredient, impurity, metabolite, contaminant or degradate contained in, or derived from, such pesticide product.

Qualified expert means one who, by virtue of his or her knowledge, skill, experience, training, or education, could be qualified by a court as an expert to testify on issues related to the subject matter on which he or she renders a conclusion or opinion. Under Rule 702 of the Federal Rules of Evidence, a person may be qualified as an expert on a particular matter by virtue of ''knowledge, skill, experience, training, or education.'' In general, EPA wants registrants to report information when a person has relevant expert credentials, e.g., a medical doctor giving a medical opinion, a plant pathologist giving an opinion on plant pathology, etc.

Registrant includes any person who holds, or ever held, a registration for a pesticide product issued under FIFRA section 3 or 24(c).

Similar species means two or more species belonging to the same general taxonomic groups: The general taxonomic groups for purposes of this requirement are: mammals, birds, reptiles, amphibians, fish, aquatic invertebrates, insects, arachnids, aquatic plants (including macrophyte, floating,

and submerged plants), and terrestrial (all non-aquatic) plants.

Water reference level means the level specified in paragraph (1) or (2) of this definition, whichever is lower.

(1) Ten percent of the maximum contaminant level (MCL) established by EPA, or if no MCL has been established by EPA, 10 percent of the most recent draft or final long-term health advisory level (HAL) established by EPA, or if EPA has not published or proposed an MCL or HAL, the lowest detectable amount of the pesticide.

(2) The ambient water quality criteria for the protection of aquatic life, established by EPA pursuant to section 304(a) of the Clean Water Act.

[62 FR 49388, Sept. 19, 1997, as amended at 63 FR 33582, June 19, 1998; 73 FR 75596, Dec. 12, 2008]

§ 159.155 When information must be submitted.

(a) The following reportable information must be received by EPA not later than the 30th calendar day after the registrant first possesses or knows of the information:

(1) Scientific studies described in § 159.165.

(2) Information about discontinued studies described in § 159.167.

(3) Human epidemiological and exposure studies described in § 159.170.

(4) Detection of a pesticide in or on food or feed described in § 159.178(a).

(5) Detection of metabolites, degradates, contaminates, impurities described in § 159.179.

(6) Failure of performance studies described in § 159.188(a)(2), (b)(2), and (c).

(7) Other information described in § 159.195.

(b) Reportable information concerning detections of pesticides in water described in § 159.178(b), adverse effects incidents described in § 159.184(a), and efficacy failure incidents described in § 159.188(a)(1) and (b)(1) must be reported according to the time frames set forth in § 159.184(d).

(c) EPA may, in its discretion, notify a registrant in writing of a different reporting period that will apply to specific types of reportable information or eliminate reporting requirements entirely. Such notification supersedes otherwise applicable reporting requirements set forth in this part.

(d) For purposes of this part, a registrant possesses or knows of information at the time any officer, employee, agent, or other person acting for the registrant first comes into possession of, or knows of, such information; provided that, such person performs any activities for the registrant related to the development, testing, sale or registration of a pesticide or the person could be reasonably expected to come into possession of information otherwise reportable under this part. In the case of information known to or possessed by an agent or other person acting for the registrant, a registrant is responsible for such information only if the agent or other person acquired such information while acting for the registrant.

[63 FR 33582, June 19, 1998]

§ 159.156 How information must be submitted.

A submission under FIFRA section 6(a)(2) must be delivered to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(a) Include a cover letter which contains the information requested in paragraphs (d) and (e) of this section, and a prominent statement that the information is being submitted in accordance with FIFRA section 6(a)(2).

(b) Contain the name of the submitter, registrant name and registration number, date of transmittal to EPA, the type of study or incident being reported under §§ 159.165 through 159.195, and a statement of why the information is considered reportable under this part.

(c) Identify the substance tested or otherwise covered by the information (including, if known, the EPA registration number(s) to which the information pertains, and if known, the CAS Registry Number).

(d) In reporting incidents, provide the data listed in § 159.184, to the extent such information is available.

(e) In submitting scientific studies, follow the procedures set forth in § 158.32 or § 161.32 of this chapter, as applicable.

(f) If the information is part of a larger package being submitted in order to comply with another provision of FIFRA (e.g., sections 3(c)(2)(B), 4(e)(1)(E)), identify in the transmittal the individual studies being submitted under this part.

(g) If a claim of confidentiality is made under FIFRA section 10 for information relating to any part of a study or incident report contained in the submission, follow the procedures set forth in § 158.33 or § 161.33 of this chapter, as applicable regarding the identification and segregation of information claimed to be confidential.

(h) If a submission includes a study subject to the flagging requirements of § 158.34 or § 161.34 of this chapter, as applicable, comply with the requirements of that section, and, if the flagging statement is positive, identify it as 6(a)(2) information in the transmittal.

(i) If a submission is a follow-up to an earlier study or incident report submitted to EPA, the transmittal must state that fact, and must cite the earlier submission, as follows:

(1) If the earlier submission was a study to which EPA assigned a Master Record Identifier number (MRID), cite the MRID.

(2) If the previous submission was an incident report to which no MRID number was assigned, cite the date of the initial submission of the incident information or report.

[63 FR 49388, Sept. 19, 1997, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006; 72 FR 61028, Oct. 26, 2007]

§ 159.158 What information must be submitted.

(a) *General.* Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person who meets any of the following:

(1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.

(2) From whom the registrant requested the opinion(s) or conclusion(s) in question.

(3) Who is a qualified expert as described in § 159.153(b).

(b) *Exceptions*—(1) *Clearly erroneous information.* Information need not be submitted if before that date on which the registrant must submit such information if all of the following conditions are met:

(i) The registrant discovers that any analysis, conclusion, or opinion was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors.

(ii) Every author of each such analysis, conclusion, or opinion, or as many authors as can be contacted through the use of reasonable diligence, has acknowledged in writing that the analysis, conclusion, or opinion was improper and has either corrected the original analysis, conclusion, or opinion accordingly, or provided an explanation as to why it cannot be corrected.

(iii) As a result of the correction, the information is no longer required to be reported under FIFRA section 6(a)(2), or if no correction was possible, the authors agree that the original analysis, conclusion or opinion has no scientific validity.

(2) *Previously submitted information.* Information regarding an incident, study, or other occurrence need not be submitted if before the date on which the registrant must submit such information, the registrant is aware that the reportable information concerning that incident, study, or other occurrence is contained completely in one of the following:

(i) Documents officially logged in by the EPA Office of Pesticide Programs.

(ii) EPA publications, EPA hearing records, or publications cited in EPA FEDERAL REGISTER notices.

(iii) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

(iv) Any documents officially logged in by the EPA Office of Pollution Prevention and Toxics under the provisions of section 8(e) of the Toxic Substances Control Act, provided that if the information pertains to a chemical compound which, subsequent to the submission of data under section 8(e), becomes the subject of an application for registration as a pesticide active ingredient, information is submitted to the Office of Pesticide Programs as required by 40 CFR 152.50(f)(3).

(3) *Publications.* A published article or report containing information otherwise reportable under this part need not be submitted if it fits into either of the following categories:

(i) Any scientific article or publication which has been abstracted in a recognized database of scientific and medical literature, such as Medline, ENBASE, Toxline or Index Medicus, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains. Otherwise reportable information received by or known to the registrant prior to publication of an abstract concerning the information must be reported and may not be withheld pending such publication.

(ii) Reports or publications which have been made available to the public by any of the following Federal agencies: Centers for Disease Control and Prevention, Consumer Products Safety Commission, Department of Agriculture, Department of the Interior, Food and Drug Administration or any other agency or institute affiliated with the Department of Health and Human Services. Otherwise reportable information concerning research which was performed, sponsored, or funded by the registrant which may also appear in forthcoming Government reports or publications must be reported and may not be withheld pending publication.

(4) *Information concerning former inerts, contaminants or impurities.* Notwithstanding any other provisions of this part, a registrant need not report information concerning a chemical compound that was at one time an inert ingredient or a contaminant or impurity of a pesticide product, and would otherwise be reportable under this part, if both of the following conditions are met:

(i) The compound has been eliminated from its registered product due to changes in manufacturing processes, product formulation or by other means.

(ii) The registrant has informed the appropriate product manager in the Office of Pesticide Programs in writing of the presence previously of the inert, contaminant or impurity in the product and its subsequent elimination from the product.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.159 Information obtained before promulgation of the rule.

(a) Notwithstanding any other provision of this part, information held by registrants on August 17, 1998 which has not been previously submitted to the Agency, but which is reportable under the terms of this part, must be submitted to the Agency if it meets any of the following criteria:

(1) Information is otherwise reportable under § 159.184, and pertains to an incident that is alleged to have occurred on or after January 1, 1994, and to have involved any of the following:

(i) A fatality or hospitalization of a human being.

(ii) A fatality of a domestic animal.

(iii) A fatality or fatalities to fish or wildlife, if the incident meets the criteria for the exposure type and severity category designation ''W-A'' set forth in § 159.184(c)(5)(iii).

(2) Submission of the information is requested by the Agency pursuant to § 159.195(c).

(b) If a registrant possesses information required to be submitted by paragraph (a)(1) of this section, the registrant must submit on or before June 16, 1999 in accordance with § 159.156(c), (d), and (e) an inventory of the incidents that meet the requirements of paragraphs (a)(1) of this section. Such an inventory must include the separate number of incidents that meet the requirements of paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section, and for each type of incident, the total numbers of fatalities or hospitalizations involved.

(c) If a registrant possesses information required to be submitted by paragraph (a)(2) of this section, the information must be submitted in accordance with any schedule contained in the Agency's request for the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998, as amended at 63 FR 41193, Aug. 3, 1998]

§ 159.160 Obligations of former registrants.

(a) *General.* A former registrant is obliged to continue to submit information concerning the registration of a pesticide product previously held by the registrant and otherwise reportable under the provisions of this part for a period of 5 years after the registration of the pesticide product has been canceled or transferred to another registrant, with the exceptions provided by paragraph (b) of this section.

(b) *Exceptions.* Notwithstanding the provisions of paragraph (a) of this section, a former registrant is not obligated to report information pursuant to this part if any of the following conditions are applicable:

(1) The information is first obtained by the person more than 1 year after the date on which the person ceased to hold the registration of the product to which the information pertains, and the person holds no active pesticide registrations, or for some other reason cannot reasonably be expected to receive information concerning the formerly registered product.

(2) The information is associated solely with an inert ingredient, contaminant, impurity, metabolite, or degradate contained in a product, and the information is first obtained by the person more than 1 year after the date upon which the person ceased to hold the registration of the product.

(3) The information is associated with an active ingredient or a formerly registered product, and the active ingredient or every active ingredient contained in the formerly registered product has not been contained in any pesticide product registered in the United States for any part of the 3–year period preceding the date on which the person first obtained the information.

(4) The information pertains solely to a formerly registered product that no longer meets the definition of ''pesticide'' in section 2(u) of FIFRA.

(c) *Information arising from litigation.* Notwithstanding any other provisions of this section, a former registrant is obliged to submit information otherwise reportable under this part concerning formerly-registered pesticide products which arises in the course of litigation concerning the effects of such products, regardless of when the information is first acquired, provided that neither of the provisions of paragraphs (b)(3) or (b)(4) of this section are met. Such information shall be submitted in the same manner and according to the same schedules as it would have to be submitted by a current registrant of a pesticide product to which the information pertained.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998, as amended at 73 FR 75596, Dec. 12, 2008]

§ 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

(a) *Toxicological studies.* (1) The results of a study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(i) That is in a different organ or tissue of the test organism.

(ii) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.

(iii) At a higher incidence or frequency.

(iv) In a different species, strain, sex, or generation of test organism.

(v) By a different route of exposure.

(2) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose (LD_{50}), median lethal concentration (LC_{50}) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.62.

(b) *Ecological studies.* The results of a study of the toxicity of a pesticide to

terrestrial or aquatic wildlife or plants if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(1) At levels 50 percent or more lower than previous acute toxicity studies with similar species, including determinations of the median lethal dose (LD_{50}), median lethal concentration (LC_{50}), or median effective concentration (EC_{50}).

(2) At lower levels in a chronic study than previous studies with similar species.

(3) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC_{50} or LD_{50} for a similar species.

(4) For plants when tested at the maximum label application rate or less, if either of the following conditions is met:

(i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the FEDERAL REGISTER, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) *Incomplete studies.* Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which would otherwise be reportable under paragraphs (a), (b) or (c) of this section must be submitted if the information meets any one of the folowing three sets of criteria:

(1) *Short-term studies.* A study using a test regimen lasting 90 calendar days or less, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

(2) *Long-term studies.* A study using a test regimen lasting more than 90 calendar days, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period of completion of final analysis (not longer that 1 year following completion of testing) has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

(3) *Serious adverse effects.* Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation, and 30 days have passed from the date the registrant first has the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998; 73 FR 75597, Dec. 12, 2008]

§ 159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the

study is, or would have been, required under this part.

§ 159.170 Human epidemiological and exposure studies.

Information must be submitted which concerns any study that a person described in § 159.158(a) has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed adverse effects in humans. Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

§ 159.178 Information on pesticides in or on food, feed or water.

(a) *Food and feed.* Information must be submitted if it shows that the pesticide is present in or on food or feed at a level in excess of established levels, except that information on excess residues resulting solely from studies conducted under authority of FIFRA section 5 or under other controlled research studies conducted to test a pesticide product need not be submitted, provided that the treated crop is not marketed as a food or feed commodity. The information to be submitted is the same as that required in § 159.184(c)(1), (2), (3), and (4)(iv)(E), (F), (G), and (H).

(b) *Water.* (1) Information must be submitted if it shows that a pesticide is present above the water reference level in any of the following instances:

(i) Waters of the United States, as defined in § 122.2 of this chapter, except paragraph (d) of § 122.2.

(ii) Ground water.

(iii) Finished drinking water.

(2) If the lowest detectable amount of the pesticide is reported, the detection limit must also be reported.

(3) Information need not be submitted regarding the detection of a pesticide in waters of the United States or finished drinking water if the pesticide is registered for use in finished drinking water or surface water and the amount detected does not exceed the amounts reported by a registrant in its application for registration, as resulting in those waters from legal applications of the pesticide.

(4) Information need not be submitted concerning detections of pesticides in waters of the United States, ground water or finished drinking water if the substance detected is an inert ingredient, or a metabolite, degradate, contaminant or impurity of a pesticide product, unless EPA has established or proposed a maximum contaminant level (MCL) or health advisory level (HAL) for that substance, or has estimated a health advisory level based on an established reference dose (RfD) for that substance, and notified registrants of that level.

(5) Information to be submitted is the same as that required in § 159.184(c)(1), (2), (3), (4)(iv) and (v), and (5)(vi).

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.179 Metabolites, degradates, contaminants, and impurities.

(a) *Metabolites and degradates.* Information which shows the existence of any metabolite or degradate of a pesticide product must be submitted if either of the following conditions is met:

(1) The metabolite or degradate may occur or be present under conditions of use of the pesticide product, and the existence of the metabolite or degradate or the association of the metabolite or degradate with the pesticide product has not been previously reported to EPA.

(2) The metabolite or degradate has been previously reported, but it is detected at levels higher than any previously reported; and either of the following conditions is met:

(i) Any person described in § 159.158(a) has concluded that the metabolite or degradate may pose a toxicological or ecological risk based on any one or more of the following:

(A) The physical or chemical properties of the metabolite or degradate.

(B) Data regarding structurally analogous chemicals.

(C) Data regarding chemical reactivity of the metabolite or degradate and structurally analogous substances.

(D) Data on the metabolite or degradate.

(ii) The registrant has concluded, or has been advised by any person described in § 159.158(a) that the metabolite or degradate, or analogous chemicals, may have any experimentally determined half-life greater than 3 weeks as shown from laboratory aerobic soil metabolism studies or field dissipation studies, or may have any experimentally determined resistance to hydrolytic degradation, or photolytic degradation on soil or in water, under any conditions, resulting in degradation of less than 10 percent in a 30-day period.

(b) *Contaminants and impurities.* The presence in any pesticide product of a contaminant or impurity not previously identified by the registrant as part of the pesticide product's approved composition must be reported pursuant to this part if the contaminant or impurity is present in the product in any of the following quantities:

(1) Quantities greater than 0.1 percent by weight (1,000 parts per million).

(2) Quantities that EPA considers, and so informs registrants, to be of toxicological significance.

(3) Quantities that the registrant considers to be of toxicological significance.

(4) Quantities above a level for which the registrant has information indicating that the presence of the contaminant or impurity may pose a risk to health or the environment.

(5) Quantities that a person described in § 159.158(a) has informed the registrant is likely to be of toxicological significance.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.184 Toxic or adverse effect incident reports.

(a) *General.* Information about incidents affecting humans or other non-target organisms must be submitted if the following three conditions are met:

(1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.

(2) The registrant is aware, or has been informed that the person or non-target organism suffered a toxic or adverse effect, or may suffer a delayed or chronic adverse effect in the future.

(3) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(b) *Exceptions.* Information regarding an incident need not be submitted if any of the following conditions are met:

(1) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

(2) The registrant has been notified in writing by the Agency that the reporting requirement has been waived for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It concerns a toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

(4) It concerns non-lethal phytotoxicity to the treated crop if the label provides an adequate notice of such a risk.

(5) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

(6) It concerns minor skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the effects occurred as a result of use in a residential site.

(c) *Required information on individual incidents.* To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph (a) of this section. If the registrant acquires additional information concerning an incident previously reported to the Agency under this part, such information shall be reported if it meets the criteria set forth in paragraph (f) of this section. In the future, the Agency may by notice specify a format for such submissions.

The Administrative, Pesticide, Circumstance and Exposure Type(s) of information must be reported for individual incidents, except where the provisions of paragraph (e) of this section allow for aggregated summary forms of reporting, or if EPA in the future grants permission in writing for alternative reporting formats. The registrant must also provide one or more Exposure Type and Severity categories and their designations for each incident as set forth in paragraph (c)(5) of this section, depending on the applicability of the criteria listed below. The criteria listed should be used in assigning a category. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals might be designated ''H-B: D-B.'' When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism—for example, both humans and domestic animals are involved—all appropriate available information dealing with each of the victims must also be reported. The informational items below are grouped by sections for ease in reporting pesticide incidents.

(1) *Administrative.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Name of reporter, address, and telephone number.

(ii) Name, address, and telephone number of contact person (if different than reporter).

(iii) Incident report status (e.g., new or update); if update, include the date of original submission.

(iv) Date registrant became aware of the incident.

(v) Date of incident (if appropriate, list start and end dates).

(vi) Location of incident (city, county and state).

(vii) Is incident part of a larger study.

(viii) Source if different from reporting registrant.

(2) *Pesticide.* Pesticide incident reports must be submitted for each pesticide that may have contributed to the incident, if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Product name.

(ii) Active ingredient(s).

(iii) EPA Registration Number.

(iv) Diluted for use, or concentrate.

(v) Formulation, if known.

(3) *Circumstance.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, drift, equipment failure, container failure, mislabeling, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe)).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other.

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) *Other incident specific information.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) If the incident involves humans:

(A) Route of exposure (skin, eye, respiratory, oral).

(B) List signs/symptoms/adverse effects.

(C) If laboratory tests were performed, list name of test(s) and results.

(D) If available, submit laboratory report(s).

(E) Time between exposure and onset of symptoms.

(F) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(G) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital

inpatient, private physician, clinic, other).

(H) Demographics (sex, age, occupation).

(I) If female, pregnant?

(J) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(K) Was exposure occupational; days lost due to illness.

(L) Was protective clothing worn (specify).

(ii) If domestic animal:

(A) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(B) List signs/symptoms/adverse effects.

(C) Breed/species (name and number affected, per adverse effect).

(D) Route of exposure (e.g., skin, eye, respiratory, oral).

(E) Time between exposure and onset of symptoms.

(F) If laboratory test(s) performed, list name of tests and results.

(G) If available, submit laboratory report(s).

(iii) If fish, wildlife, plants or other non-target organisms:

(A) List species affected, and number of individuals per species.

(B) List symptoms or adverse effects.

(C) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(D) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(E) Description of the habitat and the circumstances under which the incident occurred.

(F) If plant, type of plant life (*i.e.*, crop, forest, orchard, home garden, ornamental, forage).

(G) Formulation of pesticide if not indicated by brand name (granular, flowable).

(H) Distance from treatment site.

(I) If laboratory test(s) performed, list name of test(s) and results.

(J) If available, submit laboratory report(s).

(iv) If surface water:

(A) If raw water samples, water bodies sampled and approximate locations in each water body.

(B) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.

(C) If finished water samples, water supply systems sampled.

(D) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).

(E) Sample type (grab, composite).

(F) Sampling times/frequency.

(G) Pesticides and degredates analyzed for, the detection limits, and the amount detected.

(H) Method of analysis.

(v) If ground water:

(A) Pesticides and degredates analyzed for, the analytical method used, the detection limits, and the amount detected.

(B) Sample date.

(C) Amount pesticide applied (lbs-ai/acre).

(D) Date of last application.

(E) Depth to water.

(F) Latitude/longitude.

(G) Soil series and texture (sand/silt/clay).

(H) Frequency of applications per year.

(I) Aquifer description (confined/unconfined).

(J) Method of application.

(K) Years pesticide used.

(L) Well use and well identifier.

(M) Screened interval.

(N) Annual cumulative rainfall (inches).

(O) Maximum rainfall and date.

(P) Cumulative irrigation (inches).

(Q) Hydrologic group.

(R) Hydraulic conductivity.

(S) pH.

(T) Organic matter or organic carbon (percent).

(vi) If property damage.

(A) Provide description.

(B) [Reserved]

(5) *Exposure types and severity category designations*—(i) *Humans.* If an effect involves a human, provide the appropriate 2-letter exposure types and severity categories and their designations, based upon the following categories:

(A) H-A: If the person died.

(B) H-B: If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability.

(C) H-C: If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been Indicated. Symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

(D) H-D: If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms resolved rapidly and usually involve skin, eye or respiratory irritation.

(E) H-E: If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

(ii) *Domestic animals.* If an effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(A) D-A: If the domestic animal died or was euthanized.

(B) D-B: If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.

(C) D-C: If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated to treat the animal. Symptoms were not life threatening and the animal has returned to its pre-exposure state of health with no additional residual disability.

(D) D-D: If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respirator irritation.

(E) D-E: If symptoms are unknown or not specified.

(iii) *Fish or wildlife.* If an alleged effect involves fish or wildlife, label the incident W-A if any of the following criteria are met, or W-B if none of the criteria are met:

(A) Involves any incident caused by a pesticide currently in Formal Review forecological concerns.

(B) Fish: Affected 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species.

(C) Birds: Affected 200 or more individuals of a flocking species, or 50 or moreindividuals of a songbird species, or 5 or more individuals of a predatory species.

(D) Mammals, reptiles, amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species.

(E) Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).

(F) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.

(G) Involves adverse effects caused by a pesticide, to federally listed endangered or threatened species.

(iv) *Plants.* If an alleged effect involves damage to plants, label the incident P-A if the following criterion is met, or P-B if the criterion is not met:

(A) The effect is alleged to have occurred on more than 45 percent of the acreage exposed to the pesticide.

(B) [Reserved]

(v) *Other non-target organisms.* If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), label the incident ONT.

(vi) *Water contamination.* If a pesticide is alleged to have been detected in groundwater, surface water or finished drinking water, label the incident in accordance with the following criteria:

(A) G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (HAL) or an applicable criterion for ambient water quality.

(B) G-B: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL or a criterion for ambient water quality but does not exceed the MCL or other applicable level.

(C) G-C: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

(vii) *Property damage.* If an incident involves alleged property damage the applicable term(s) shall be included

along with any other applicable effect category label; for example, ''H-B: property damage.'' Label the incident in accordance with the following criteria:

(A) PD-A: The product is alleged to have caused damage in a manner that could have caused direct human injury, such as fire or explosion.

(B) PD-B: The product is alleged to have caused damage in excess of $5,000.

(C) PD-C: Any allegation of property damage that does not meet the criteria of paragraphs (c)(5)(vii)(A) or (B) of this section, including cases in which the level of damages is not specified.

(d) *Time requirements for submitting incident information.* Information concerning incidents reportable under this section must be submitted within the time frames listed for different exposure and severity categories, as follows:

(1) For allegations involving human fatality (H-A), registrants must submit the required information, to the extent it is available, no later than 15 days after learning of an allegation.

(2) Information concerning incidents which meet the criteria for the following exposure and severity category labels described in paragraph (c)(5) of this section, reports of detections of pesticides in water, and efficacy failure incidents may be described in § 159.188(a)(1) and (b)(1), may be accumulated for a 30–day period, and submitted to the Agency within 30 days after the end of each 30–day accumulation period for: Humans, H-B, and H-C; Wildlife, W-A; Plants, P-A; Water, G-A; Property Damage, PD-A.

(3) Incidents or reports of detections of pesticides in water meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days after the end of each 90–day accumulation period.

(e) *Aggregated reports.* For incidents that are reportable under the schedule requirements of paragraph (d)(3) of this section, in lieu of individual reports containing the information listed in paragraphs (c)(1) through (c)(4) of this section, registrants must provide an aggregated report listing:

(1) The time period covered by the report.

(2) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.

(3) A count of domestic animal incidents in categories, other than D-A or D-B, which can be added together and reported as a single number.

(f) *Reporting additional information.* If, after the submission of an incident report to the Agency, a registrant acquires additional information concerning that incident, the information should be submitted within the same time frame as applied to the original incident report, if any of the following conditions apply:

(1) The information concerns an alleged human fatality (H-A), and the information consists of any of the elements listed in paragraphs (c)(1) through (c)(4) of this section.

(2) The information concerns an incident originally reported as alleging a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife (W-A), and the additional information consists of pesticide or circumstance information listed in paragraphs (c)(2) or (c)(3) of this section, or is a laboratory report concerning persons or animals involved in the incident.

(3) The information concerns any incident not originally reported with one of the exposure and severity labels H-A, or H-B for human incidents, or at the ''A'' level of severity for any other exposure or incident type, and the new information would result in labeling the incident H-A or H-B for a human incident, or at the ''A'' level of severity for any other exposure or incident type listed in paragraph (c)(5) of this section.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

§ 159.188 Failure of performance information.

(a) *Microorganisms that pose a risk to human health.* Information must be submitted which concerns either incidents described in paragraph (a)(1) of this section or a study described in paragraph (a)(2) of this section:

(1) Information which concerns an incident which meets all of the following conditions:

(i) The registrant has been informed that a pesticide product may not have performed as claimed against target microorganisms.

(ii) The possible failures of the pesticide to perform as claimed involved the use against microorganisms which may pose a risk to human health.

(iii) The pesticide product's use site is other than residential.

(iv) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for control of microorganisms tha may pose a risk to human health, including any of the public health antimicrobials identified in part 161 of this chapter.

(b) *Animals that pose a risk to human health.* For the purposes of this section, any animal (including insects) poses a risk to human health if it may cause disease in humans, either directly or as a disease vector; produce toxins that are harmful to humans; or cause direct physical harm to humans. Information must be submitted which concerns either incidents described in paragraph (b)(1) of this section or a study described in paragraph (b)(2) of this section.

(1) Information which concerns an incident which meets all of the following conditions:

(i) The registrant has been informed by municipal, State, or Federal public health officials that a pesticide product may not have performed as claimed against target animals.

(ii) The possible failures of the pesticide to perform as claimed involved the use against animals that pose a risk to human health.

(iii) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims by the registrant regarding uses intended for control of animals that pose a risk to human health, including any of the public health pesticides identified in part 158 of this chapter.

(c) *Development of pesticide resistance.* Information must be submitted concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates and methods specified on the label if either of the following conditions is met:

(1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.

(2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

[63 FR 49388, Sept. 19, 1997, as amended at 72 FR 61029, Oct. 26, 2007]

§ 159.195 Reporting of other information.

(a) The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Examples of the types of information which must be provided if not already reportable under some other provision of this Part include but are not limited to information showing:

(1) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.

(2) Greater than anticipated drift of pesticides to non-target areas.

(3) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.

(4) Use of a pesticide promotes or creates secondary pest infestations.

(5) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

(b) A registrant is not obligated under paragraph (a) of this section to provide information to the Administrator if the registrant is aware of facts which establish that otherwise reportable information is not correct.

(c) The registrant shall submit to the Administrator information other than that described in §§159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

PART 160—GOOD LABORATORY PRACTICE STANDARDS

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AUTHORITY: 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136t, 136v, 136w; 21 U.S.C. 346a, 371, Reorganization Plan No. 3 of 1970.

SOURCE: 54 FR 34067, Aug. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 160.1 Scope and applicability.

(a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18 and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and section 408 or 409 of the Federal Food, Drug and Cosmetic Act.

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after October 16, 1989.

[73 FR 75597, Dec. 12, 2008]

§ 160.3 Definitions.

As used in this part the following terms shall have the meanings specified:

Application for research or marketing permit means any of the following:

(1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3, 4 or 24(c).

(2) An application for an experimental use permit under FIFRA section 5.

(3) An application for an exemption under FIFRA section 18.

(4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408.

(5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409 that was submitted prior to August 3, 1996.

(6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B).

(7) Any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to § 160.105(a).

Carrier means any material, including but not limited to feed, water, soil, nutrient media, with which the test substance is combined for administration to a test system.

Control substance means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for known chemical or biological measurements.

EPA means the U.S. Environmental Protection Agency.

Experimental start date means the first date the test substance is applied to the test system.

Experimental termination date means the last date on which data are collected directly from the study.

FDA means the U.S. Food and Drug Administration.

FFDCA means the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 321 *et seq*).

FIFRA means the Federal Insecticide, Fungicide and Rodenticide Act as amended (7 U.S.C. 136 *et seq*).

Person means an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or any other legal entity.

Quality assurance unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. ''Raw data'' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

Reference substance means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.

Specimen means any material derived from a test system for examination or analysis.

Sponsor means:

(1) A person who initiates and supports, by provision of financial or other resources, a study;

(2) A person who submits a study to the EPA in support of an application for a research or marketing permit; or

(3) A testing facility, if it both initiates and actually conducts the study.

Study means any experiment at one of more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term ''study''does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

Study completion date means the date the final report is signed by the study director.

Study director means the individual responsible for the overall conduct of a study.

Study initiation date means the date the protocol is signed by the study director.

Test substance means a substance or mixture administered or added to a test system in a study, which substance or mixture:

(1) Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or

(2) Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (1) of this definition, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph.

Test system means any animal, plant, microorganism, chemical or physical matrix, including but not limited to soil or water, or subparts thereof, to which the test, control, or reference substance is administered or added for study. ''Test system'' also includes appropriate groups or components of the system not treated with the test, control, or reference substance.

Testing facility means a person who actually conducts a study, *i.e.*, actually uses the test substance in a test system. ''Testing facility'' encompasses only those operational units that are being or have been used to conduct studies.

Vehicle means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

[54 FR 34067, Aug. 17, 1989, as amended at 72 FR 61029, Oct. 26, 2007; 73 FR 75597, Dec. 12, 2008]

§ 160.10 Applicability to studies performed under grants and contracts.

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.

§ 160.12 Statement of compliance or non-compliance.

Any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part; or

(b) A statement describing in detail all differences between the practices used in the study and those required by this part; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

§ 160.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also

to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements should not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, except that EPA may seek production of these records in litigation or formal adjudicatory hearings.

(b) EPA will not consider reliable for purposes of supporting an application for a research or marketing permit any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to EPA.

§ 160.17 Effects of non-compliance.

(a) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part.

(b) Submission of a statement required by § 160.12 which is false may form the basis for cancellation, suspension, or modification of the research or marketing permit, or denial or disapproval of an application for such a permit, under FIFRA section 3, 5, 6, 18, or 24 or FFDCA section 406 or 409, or for criminal prosecution under 18 U.S.C. 2 or 1001 or FIFRA section 14, or for imposition of civil penalties under FIFRA section 14.

Subpart B—Organization and Personnel

§ 160.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test, control, and reference substances and test systems.

(e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test, control, and reference substances.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, and test, control, and reference substances, and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.

§ 160.31 Testing facility management.

For each study, testing facility management shall:

(a) Designate a study director as described in § 160.33 before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

(c) Assure that there is a quality assurance unit as described in § 160.35.

(d) Assure that test, control, and reference substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

§ 160.33 Study director.

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 160.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

§ 160.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. The quality assurance unit shall conduct inspections and maintain records appropriate to the study.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance, and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

(2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible.

(3) Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for

inspection to authorized employees or duly designated representatives of EPA or FDA.

(d) An authorized employee or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed up in accordance with this paragraph.

Subpart C—Facilities

§ 160.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies. Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

§ 160.43 Test system care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or other test system areas, as needed, to ensure: proper separation of species or test systems, isolation of individual projects, quarantine or isolation of animals or other test systems, and routine or specialized housing of animals or other test systems.

(1) In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium, or housing unit.

(2) Aquatic toxicity tests for individual projects shall be isolated to the extent necessary to prevent cross-contamination of different chemicals used in different tests.

(b) A testing facility shall have a number of animal rooms or other test system areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test, control, and reference substances known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory test system diseases. These areas shall provide effective isolation for the housing of test systems either known or suspected of being diseased, or of being carriers of disease, from other test systems.

(d) Facilities shall have proper provisions for collection and disposal of contaminated water, soil, or other spent materials. When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(e) Facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the protocol.

(f) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol.

(g) For freshwater organisms, an adequate supply of clean water of the appropriate hardness, pH, and temperature, and which is free of contaminants capable of interfering with the study, shall be available as specified in the protocol.

(h) For plants, an adequate supply of soil of the appropriate composition, as specified in the protocol, shall be available as needed.

§ 160.45 Test system supply facilities.

(a) There shall be storage areas, as needed, for feed, nutrients, soils, bedding, supplies, and equipment. Storage areas for feed nutrients, soils, and bedding shall be separated from areas where the test systems are located and shall be protected against infestation or contamination. Perishable supplies

shall be preserved by appropriate means.

(b) When appropriate, plant supply facilities shall be provided. As specified in the protocol, these include:

(1) Facilities for holding, culturing, and maintaining algae and aquatic plants.

(2) Facilities for plant growth, including, but not limited to greenhouses, growth chambers, light banks, and fields.

(c) When appropriate, facilities for aquatic animal tests shall be provided. These include, but are not limited to, aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.

§ 160.47 Facilities for handling test, control, and reference substances.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test, control, and reference substances.

(2) Mixing of the test, control, and reference substances with a carrier, e.g., feed.

(3) Storage of the test, control, and reference substance mixtures.

(b) Storage areas for test, control, and/or reference substance and for test, control, and/or reference mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.

§ 160.49 Laboratory operation areas.

Separate laboratory space and other space shall be provided, as needed, for the performance of the routine and specialized procedures required by studies.

§ 160.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

Subpart D—Equipment

§ 160.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

§ 160.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.

(b) The written standard operating procedures required under § 160.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/ or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the dates of the operations, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

Subpart E—Testing Facilities Operation

§ 160.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be

authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Test system area preparation.

(2) Test system care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and reference substances.

(4) Test system observations.

(5) Laboratory or other tests.

(6) Handling of test systems found moribund or dead during study.

(7) Necropsy of test systems or postmortem examination of test systems.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of test systems.

(c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

§ 160.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

§ 160.90 Animal and other test system care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals and other test systems.

(b) All newly received test systems from outside sources shall be isolated and their health status or appropriateness for the study shall be evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice or scientific methods.

(c) At the initiation of a study, test systems shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If during the course of the study, the test systems contract such a disease or condition, the diseased test systems should be isolated, if necessary. These test systems may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, adult reptiles, and adult terrestrial amphibians used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require these test systems to be removed from and returned to their test system-housing units for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, color code, ear tag, ear punch, etc.). All information needed to specifically identify each test system within the test system-housing unit shall appear on the outside of that unit. Suckling mammals and juvenile birds are excluded from the requirement of individual identification unless otherwise specified in the protocol.

(e) Except as specified in paragraph (e)(1) of this section, test systems of different species shall be housed in separate rooms when necessary. Test systems of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to test, control, or reference substances or test system mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(1) Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in separate rooms, provided that they are adequately segregated to avoid mixup and cross contamination.

(2) [Reserved]

(f) Cages, racks, pens, enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding, rearing and breeding areas, and accessory equipment, shall be cleaned and sanitized at appropriate intervals.

(g) Feed, soil, and water used for the test systems shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed, soil, or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

(j) All plant and animal test systems shall be acclimatized to the environmental conditions of the test, prior to their use in a study.

Subpart F—Test, Control, and Reference Substances

§ 160.105 Test, control, and reference substance characterization.

(a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference substance shal1 be determined for each batch and shall be documented before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented by the sponsor or the testing facility, and the location of such documentation shall be specified.

(b) When relevant to the conduct of the study the solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date. The stability of the test, control, or reference substance shall be determined before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(c) Each storage container for a test, control, or reference substance shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or reference substance. Storage containers shall be assigned to a particular test substance for the duration of the study.

(d) For studies of more than 4 weeks experimental duration, reserve samples from each batch of test, control, and reference substances shall be retained for the period of time provided by § 160.195.

(e) The stability of test, control, and reference substances under storage conditions at the test site shall be known for all studies.

§ 160.107 Test, control, and reference substance handling.

Procedures shall be established for a system for the handling of the test, control, and reference substances to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

§ 160.113 Mixtures of substances with carriers.

(a) For each test, control, or reference substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test, control, or reference substance in the mixture.

(2) When relevant to the conduct of the study, to determine the solubility

of each test, control, or reference substance in the mixture by the testing facility or the sponsor before the experimental start date.

(3) To determine the stability of the test, control, or reference substance in the mixture before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(b) Where any of the components of the test, control, or reference substance carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

(c) If a vehicle is used to facilitate the mixing of a test substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.

Subpart G—Protocol for and Conduct of a Study

§ 160.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test, control, and reference substance by name, chemical abstracts service (CAS) number or code number.

(3) The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The proposed experimental start and termination dates.

(5) Justification for selection of the test system.

(6) Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(7) The procedure for identification of the test system.

(8) A description of the experimental design, including methods for the control of bias.

(9) Where applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or reference substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(10) The route of administration and the reason for its choice.

(11) Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or reference substance to be administered and the method and frequency of administration.

(12) The type and frequency of tests, analyses, and measurements to be made.

(13) The records to be maintained.

(14) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(15) A statement of the proposed statistical method to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol.

§ 160.130 Conduct of a study.

(a) The study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) In animal studies where histopathology is required, records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

§ 160.135 Physical and chemical characterization studies.

(a) All provisions of the GLP standards shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies) of test, control, or reference substances.

(b) The following GLP standards shall not apply to studies, other than those designated in paragraph (a) of this section, designed to determine physical and chemical characteristics of a test, control, or reference substance:

§ 160.31 (c), (d), and (g)
§ 160.35 (b) and (c)
§ 160.43
§ 160.45
§ 160.47
§ 160.49
§ 160.81(b) (1), (2), (6) through (9), and (12)
§ 160.90
§ 160.105 (a) through (d)
§ 160.113
§ 160.120(a) (5) through (12), and (15)
§ 160.185(a) (5) through (8), (10), (12), and (14)
§ 160.195 (c) and (d)

Subparts H–I [Reserved]

Subpart J—Records and Reports

§ 160.185 Reporting of study results.

(a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed, terminated, or discontinued.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics.

(5) Stability and, when relevant to the conduct of the study the solubility of the test, control, and reference substances under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens

from the study after data generation was completed.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 160.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible. Modification of a final report to comply with the submission requirements of EPA does not constitute a correction, addition, or amendment to a final report.

(d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the test facility.

§ 160.190 Storage and retrieval of records and data.

(a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

§ 160.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for whichever of the following periods is longest:

(1) In the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor holds any research or marketing permit to which the study is pertinent.

(2) A period of at least 5 years following the date on which the results of the study are submitted to the EPA in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens, samples of test, control, or reference substances, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by §160.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by §160.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by §160.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

(h) Specimens, samples, or other nondocumentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.

(i) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

PART 161—DATA REQUIREMENTS FOR REGISTRATION OF ANTIMICROBIAL PESTICIDES

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APPENDIX A TO PART 161—DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated at 72 FR 60253, Oct. 24, 2007.

Subpart A—General Provisions

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253, 60254, Oct. 24, 2007.

§ 161.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136–136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or 3(c)(7). Use of the term ''registration'' in this part will pertain to new registrations and amended registrations as well as reregistration accomplished under section 3(g), unless stated otherwise.

(c) *Availability of related guidelines.* The data requirements for pesticide registration specified in this part pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation, wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides. The standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, definition of most terms, and examples of protocols are not specified in this part. This information is available in advisory documents (collectively referred to as Pesticide Assessment Guidelines) through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone: 703–487–4650).

§ 161.25 Applicability of data requirements.

(a) Some kinds of data and information are specified in subparts C and D of this part as ''required'' (''R'') for the evaluation of some or all types of products. Other kinds of data and information are specified in those sections as ''conditionally required'' (''CR''), that is, they are required if the product's proposed pattern of use, results of other tests, or other pertinent factors meet the criteria specified in those sections. The terms ''required'' and ''conditionally required'' are further discussed in §§ 161.100 and 161.101.

(b) The Agency recognizes that certain data requirements may not be applicable to (or should be waived for) some products, and has made provisions for such cases in this part as specified in § 161.35 *Flexibility of the data requirements,* § 161.40 *Consultation with the Agency,* § 161.45 *Waivers,* and § 161.60 *Minor uses.*

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 161.30 Timing of the imposition of data requirements.

This part establishes requirements for the types of data which are necessary to support the unconditional registration of a pesticide product under section 3(c)(5) of the Act. While every registered pesticide product must eventually be supported by the data required by part 161, when an applicant or registrant must initially satisfy these data requirements depends on the factors listed below in this section.

(a) *Existing Registrations.* A registrant of a currently registered pesticide product is not obligated to satisfy any data requirement in part 161 with respect to that product until he receives a notice under section 3(c)(2)(B) of the

Act that additional data are required to support the continued registration of the product, until he applies for an amendment to the registration, or until the product is subject to reregistration.

(b) *Applications.* The amount of data required by the Agency to evaluate an application for initial or amended registration depends on whether the product is being reviewed under section 3(c)(5) of the Act (unconditional registration) or section 3(c)(7) of the Act (conditional registration). Refer to § 152.111 of this chapter or consult with the appropriate EPA Product Manager to determine under which section of the Act the application will be reviewed. The following paragraphs identify, for each different type of application, the minimum amount of data that must be available for EPA review to permit EPA to make the statutory risk-benefit determinations required by section 3(c)(5) or 3(c)(7) of the Act. In addition to satisfying these minimum data requirements, applicants may be required to submit or cite additional data, either to permit EPA to assess the safety or efficacy of the product (refer to § 161.75) or to comply with the statutory requirements of section 3(c)(1)(D) of the Act, or both.

(1) *Applications for unconditional registration under section 3(c)(5) of the Act.* EPA will not approve an application for unconditional registration unless all data required by this part which have not been waived are available for EPA to review.

(2) *Applications for conditional registration of a new chemical under section 3(c)(7)(C) of the Act.* EPA will not approve an application for conditional registration of a pesticide containing an active ingredient not contained in any currently registered product unless data required by this part are available for EPA to review except for:

(i) Those data for which the requirement has been waived.

(ii) Those data for which the requirement was imposed so recently that the applicant has not had sufficient time to produce the data.

(3) *Applications for conditional registration of products which are identical or substantially similar to currently registered products under section 3(c)(7)(A) of the Act.* EPA will not approve an application for conditional registration of a pecticide product which is identical or substantially similar to a currently registered pesticide unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by § 161.160.

(4) *Applications for conditional registration of new uses of currently registered products under section 3(c)(7)(B) of the Act.* EPA will not approve an application for registration of a pesticide for a new use of a currently registered pesticide product unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by § 161.160.

(iii) Other data pertaining solely to the new use. The applicant may generally determine which data pertain solely to the new use by comparing the data requirements for all existing uses of all currently registered products containing the same active ingredient(s) with those for all uses including the new use. Any differences are attributable to the new use and must be submitted with the application.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 161.32 Format of data submission.

(a) *Transmittal document.* All data submitted at the same time and for review in support of a single administrative action (e.g., an application for registration, reregistration, experimental use permit, or in response to a requirement for data under the authority of FIFRA sec. 3(c)(2)(B), must be accompanied by a single transmittal document including the following information:

(1) The identity of the submitter, or the identity of each joint submitter and of the agent for joint submitters;

(2) The date of the submission;

(3) The identification of the Agency action in support of which the data are being submitted, such as the registration number or file symbol, petition

number, experimental use permit number, or registration standard review; and

(4) A bibliography of all specific documents included in the submission and covered by the transmittal.

(b) *Individual studies.* (1) All data must be submitted in the form of individual studies. Unless otherwise specified by the Agency, each study should address a single data requirement, and be listed separately in the bibliography.

(2) Each study must include the following elements in addition to the study itself:

(i) A title page, as described in paragraph (c) of this section;

(ii) A Statement of Data Confidentiality Claims and, if desired, a Supplemental Statement of Data Confidentiality Claims, in accordance with § 161.33;

(iii) A certification with respect to Good Laboratory Practice standards, if required by § 160.12 of this chapter;

(iv) If the original study is not in the English language, a complete and accurate English translation under the same cover; and

(v) If the study is of a type listed in § 161.34(b), the statement prescribed by paragraph (c) of that section.

(3) Three identical copies of each study must be submitted. If the study is submitted in conjunction with a pending Special Review or Registration Standard under development, four copies must be submitted. Three copies must be identical and must conform to the requirements of § 161.33 with respect to claims of confidentiality. The fourth copy will be placed in the public docket and must conform to the requirements of § 154.15(c) of this chapter or § 155.30(c) of this chapter with respect to claimed confidential business information.

(4) All copies must be in black ink on uniform pages of white, 8½ × 11 inch paper. Copies must have high contrast and good resolution for microfilming. Frayed or oversize pages and glued bindings are not acceptable.

(c) *Contents of title page.* Each individual study must have a title page bearing the following identifying information:

(1) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed;

(2) The author(s) of the study;

(3) The date the study was completed;

(4) If the study was performed in a laboratory, the name and address of the laboratory and any laboratory project numbers or other identifying codes;

(5) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review; and

(6) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(d) *EPA identification number.* EPA will assign each study an EPA Master Record Identification (MRID) number, and will promptly notify the submitter of the number assigned. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data.* Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action, he should cite the data by providing:

(1) The title or adequate description of the study;

(2) The transmittal information required by paragraph (a) (1), (2), and (3) of this section; and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

[53 FR 15991, May 4, 1988]

§ 161.33 Procedures for claims of confidentiality of data.

(a) *General.* A data submitter must clearly identify any information which he claims is entitled to confidential treatment under FIFRA sec. 10. The procedures in this section must be followed to assert a claim of confidentiality.

(b) *Claims of confidentiality for information described by FIFRA sec. 10(d)(1)*

(A), (B), and (C). Any information claimed to be confidential under FIFRA sec. 10(d)(1) (A) through (C) must be submitted in accordance with the following procedures:

(1) The information must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a claim of confidentiality for such information under FIFRA sec. 10(d)(1) (A), (B), or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA sec. 10(d)(1) (A), (B), or (C).

(3) Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA sec. 10(d)(1) (A), (B), or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (*i.e.*, identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims:

> Information claimed confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

The statement must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

(c) *No claim of confidentiality under FIFRA sec. 10(d)(1)(A), (B), or (C).* If no claim of confidentiality is being made for information described by FIFRA sec. 10(d)(1)(A), (B), or (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement:

> No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA sec. 10(d)(1) (A), (B), or (C).* Any information not described by FIFRA sec. 10(d)(1) (A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

(1) The information must be clearly marked in the body of the study as being claimed confidential.

(2) A separate Supplemental Statement of Data Confidentiality Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

[53 FR 15991, May 4, 1988]

§ 161.34 Flagging of studies for potential adverse effects.

(a) Any person who submits a study of a type listed in paragraph (b) of this section to support an application for new or amended registration, or to satisfy a requirement imposed under FIFRA sec. 3(c)(2)(B), must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates that study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in paragraph (c) of this section when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study] or Subchronic feeding study	83–2 82–1	Treated animals show any of the following: An incidence of neoplasms in male or female animals which increases with dose; or A statistically significant (p ≤0.05) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex; or An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals or A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	1 2 3 4
Teratogenicity	83–3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels	5
Neurotoxicity	81–7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/ oncogenicity study	83–1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI. or General (systemic) toxicity NOEL less than 100 times the current existing ADI.	7 8
Reproduction study	83–4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82–1	Cholinesterase inhibition NOEL less than 100 times the current existing ADI. or General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	10 11

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.''

(2) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]''

[53 FR 15992, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in § 161.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to

consult with the Product Manager for his product to resolve questions relating to the protocols or the data requirements before undertaking extensive testing under § 161.40.

(b) Any applicant who believes that a data requirement is inapplicable to a specific pesticide product may request a waiver of a data requirement under § 161.45.

(c) The Agency may require an applicant to provide additional data or information beyond that specified in subparts C and D of this part when these data are not sufficient to permit EPA to evaluate the applicant's product under § 161.75.

(d) Several policies are in effect that govern the data requirements for registration of products having minor uses. These policies reduce substantially the data requirements that need to be met on the basis of limited exposures and economic equity, and allow case-by-case decision making to determine the specific needs for each kind of use under § 161.60.

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator ''shall revise such guidelines from time to time.'' Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies under § 161.80.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 161.40 Consultation with the Agency.

This part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product's use pattern or composition may result in the need for conferences between registration applicants and the Agency. Such conferences may be initiated by the Agency or by registration applicants. Applicants are expected to contact their respective Product Managers to arrange discussions. The Agency welcomes suggestions for changes to improve the clarity, accuracy, or some other aspect of the data requirements set forth in this part. Specific suggestions should be forwarded to the Director of the Hazard Evaluation Division.

§ 161.45 Waivers.

(a) *Rationale and policy.* (1) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(2) The Agency will waive data requirements on a case-by-case basis in response to specific written requests by applicants. Because of the wide variety of types and use patterns of pesticides, it is impossible to spell out all of the circumstances which might serve as a basis for waiving data requirements. The Agency, however, will take into account, as appropriate, the factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request.

(2) To request a waiver, an applicant must submit a written request to the appropriate Product Manager. The request must specifically identify the data requirement for which a waiver is requested, explain why he thinks data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which he believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) *Notification of waiver decision.* The Agency will review each waiver request and inform the applicant in writing of its decision. In addition, for decisions that could apply to more than a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the FEDERAL REGISTER announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

(d) *Availability of waiver decisions.* Agency decisions under this section granting waiver requests will be available to the public at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c). Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR part 2.

[49 FR 42881, Oct. 24, 1984, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

§ 161.55 Agricultural vs. non-agricultural pesticides.

Section 25(a)(1) of FIFRA instructs the Administrator to ''take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides.'' This part distinguishes the various classes of pesticide use (e.g., crop *vs.* non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table. In addition, the Use Pattern Index (appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 161.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a ''minor crop'' (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA's policy concerning data requirements for minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.

(3) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances.

(4) Group tolerances will be established to assist applicants for registration of products for minor uses as described in 40 CFR 180.34.

(b) *Advice on data requirements to support minor uses.* Applicants for registration are advised to contact the appropriate EPA Product Manager of the Minor Use Officer for advice on developing data to support new applications for minor uses of pesticides.

§ 161.70 Acceptable protocols.

The Agency has published Pesticide Assessment Guidelines, as indicated in § 161.20(d), which contain suggested protocols for conducting tests to develop the data required by this part.

(a) *General policy.* Any appropriate protocol may be used provided that it meets the purpose of the test standards specified in the guidelines and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(b) *Organization for Economic Cooperation and Development (OECD) Protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be

used to develop data necessary to meet the requirements specified in this part. Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(c) *Procedures for requesting advice on protocols.* Normally, all contact between the Agency and applicants or registrants is handled by the assigned Product Manager in the Registration Division of the Office of Pesticide Programs. Accordingly, questions concerning protocols should be directed, preferably in writing, to the Product Manager responsible for the registration or application which would be affected.

§ 161.75 Requirements for additional data.

(a) *General policy.* The data routinely required by part 161 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties of pesticide.

(b) *Policy on test substance.* In general, where the technical grade of the active ingredient is specified as the substance to be tested, tests may be performed using a technical grade which is substantially similar to the technical grade used in the product for which registration is sought. In addition to or in lieu of the testing required in subparts C and D of this part the Administrator will, on a case-by-case basis, require testing to be conducted with:

(1) An analytical pure grade of an active ingredient, with or without radioactive tagging.

(2) The technical grade of an active ingredient.

(3) The representative technical grade of an active ingredient.

(4) An intentionally added inert ingredient in a pesticide product.

(5) A contaminant or impurity of an active or inert ingredient.

(6) A plant or animal metabolite or degradation product of an active or inert ingredient.

(7) The end-use pesticide product.

(8) The end-use pesticide product plus any recommended vehicles and adjuvants.

(9) Any additional substance which could act as a synergist to the product for which registration is sought.

(10) Any combination of substances in paragraphs (b) (1) through (9) of this section.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 161.80 Acceptability of data.

(a) *General policy.* The Agency will determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this part would be satisfactory to support applications provided good laboratory

practices were followed, the data meet the purposes of this part, and the data permit sound scientific judgments to be made. Such data will not be rejected merely because they were not developed in accordance with suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registrations except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. When studies at test sites or with materials of this type are anticipated, applicants should take steps to assure that United States materials are used or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the United States material or test site. Once comparability has been established, the Agency will assess the acceptability of the data as described in paragraph (a) of this section.

(d) *Data from monitoring studies.* Certain data are developed to meet the monitoring requirements of FIFRA sections 5, 8 or 20. Applicants may wish to determine whether some of these data may meet the requirements of this part. In addition, data developed independently of FIFRA regulations or requirements may also satisfy data requirements in this part. Consultation with appropriate EPA Product Managers would be helpful if applicants are unsure about suitability of such data.

§ 161.85 Revision of data requirements and guidelines.

(a) Data requirements will be revised from time to time to keep up with policy changes and technology. Revisions to this part will be made in accordance with the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, will be made only after public notice and opportunity for comment. Until final rules reflecting a change have been promulgated, the Agency can implement changes in the data requirements on a case-by-case basis.

(b) The Agency invites registration applicants, registrants, and the general public to suggest changes in the data requirements or the Pesticide Assessment Guidelines. Suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the Director of the Hazard Evaluation Division. When suggestions consist of new suggested methods, representative test results should accompany the submittals.

Subpart B—How To Use Data Tables

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007.

§ 161.100 How to determine registration data requirements.

To determine the specific kinds of data needed to support the registration of each pesticide product, the registration applicant should:

(a) Refer to subparts C and D (§§ 161.150 through 161.640). These subparts describe the data requirements, including data tables for each subject area. The corresponding subdivisions in the Pesticide Assessment Guidelines are listed in § 161.108.

(b) Select the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label. Selection of the appropriate general use pattern(s) will usually be obvious. However, unique or ambiguous cases will arise occasionally. These situations may be clarified by reference to the Use Pattern Index presented in the appendix to the Data Requirements for Registration. The applicant can look up a specific use pattern in appendix A and it will be cross referenced to the appropriate general use patterns to be used in each Data Requirement table.

(c) Proceed down the appropriate general use pattern column in the table and note which tests (listed along the left hand side of the table) are required (''R''), conditionally required (''CR'') or usually not required (''—''). After reading through each data requirement table, the applicant will have a complete list of required and conditionally

required data for the pesticide product and the substance to be tested in developing data to meet each requirement. The data EPA must have available to review the registration of a specific product consists of all the data designated as required for that product and all the applicable data designated as conditionally required for that product.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15993, May 4, 1988]

§ 161.101 Required vs. conditionally required data.

(a) Data designated as ''required'' (''R'') for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern unless the data requirement has been waived under § 161.45 for that particular product or unless the product is covered by a specific exception set forth in a note accompanying the requirement.

(b) Data designated as ''conditionally required'' (''CR'') for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the corresponding notes accompanying the data requirements table. As indicated in the notes, the determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (e.g., tier testing). Applicants must evaluate each applicable note to determine whether or not conditionally required data must be submitted as indicated by the conditions and criteria specified in the accompanying notes unless the Agency has granted a waiver request submitted by the registrant in accordance with § 161.45.

(c) For certain of the required or conditionally required data, the ''R'' or ''CR'' designations and are enclosed in brackets (*i.e.*, [R], [CR]). The brackets designate those data that are required or conditionally required to support a product when an experimental use permit is being sought. In all other situations (*i.e.*, other than support of an experimental use permit), the brackets have no meaning and the designations R and CR are equivalent to [R] and [CR], respectively.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

§ 161.102 Distinguishing between what data are required and what substance is to be tested.

(a) Readers should be careful to distinguish between what data are required and what substance is to be tested, as specified in this part and in each corresponding section of the guidelines. Each data requirement table specifies whether a particular data requirement is required to support the registration of manufacturing-use products, end-use products, or both. The test substance column specifies which substance is to be subjected to testing. Thus, the data from a certain kind of study may be required to support the registration of each end-use product, but the test substance column may state that the particular test shall be performed using, for example, the technical grade of the active ingredient(s) in the end-use product.

(b) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no inert ingredients are identical in composition to each other and to the technical grade of the active ingredient (TGAI) from which they were derived, and therefore, the data from a test conducted using any one of these as the test substance (e.g., TGAI) is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances (*i.e.*, MP or EP).

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 161.108 Relationship of Pesticide Assessment Guidelines to data requirements.

The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–605–6000). The following Subdivisions of the Pesticide

Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D	Product Chemistry	PB83–153890	161.150 – 161.190
E	Hazard Evaluation: Wildlife and Aquatic Organisms	PB83–153908	161.490
F	Hazard Evaluation: Humans and Domestic Animals	PB83–153916	161.340
G	Product Performance	PB83–153924	161.640
I	Experimental Use Permits	PB83–153932	161.20 – 161.640
J	Hazard Evaluation: Nontarget Plants	PB83–153940	161.540
K	Reentry Protection	PB85–120962	161.390
L	Hazard Evaulation: Nontarget Insect	PB83–153957	161.590
N	Environmental Fate	PB83–153973	161.290
O	Residue Chemistry	PB83–153961	161.240
R	Spray Drift Evaluation	PB84–189216	161.440

[72 FR 60255, Oct. 24, 2007]

Subpart C—Product Chemistry Data Requirements

SOURCE: 53 FR 15993, May 4, 1988, unless otherwise noted. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007.

§ 161.150 General.

(a) *Applicability*. This subpart describes the product chemistry data that are required to support the registration of each pesticide product. The information specified in this subpart must be submitted with each application for new or amended registration or for reregistration, if it has not been submitted previously or if the previously submitted information is not complete and accurate. References in this subpart to the ''applicant'' include the registrant if the information is required for a registered product.

(b) *Purpose*—(1) *Product composition*. (i) Data on product composition are needed to support the conclusions expressed in the statement of formula. These data include information on the starting materials, production or formulating process, possible formation of impurities, results of preliminary analysis of product samples, a description of analytical methods to identify and quantify ingredients and validation data for such methods. In addition, an applicant is required to certify the limits for ingredients of his product.

(ii) Product composition data are compared to the composition of materials used in required testing under subpart D of this part. This comparison indicates which components of a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product's composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(iii) Product composition data, including certified limits of components, are used to determine whether a product is ''identical or substantially similar'' to another product or ''differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment'' (FIFRA sec. 3(c)(7)(A)). In nearly every case,

this determination involves a comparison of the composition of an applicant's product with that of currently registered products.

(2) *Certified limits.* Certified limits required by § 161.175 are used in two ways. First, the Agency considers the certified limits in making the registration determination required by sections 3(c)(5), 3(c)(7) and 3(d) of the Act and making other regulatory decisions required by the Act. Second, the Agency may collect commercial samples of the registered products and analyze them for the active ingredient(s), inert ingredients, or impurities determined by the Agency to be toxicologically significant. If, upon analysis the composition of such a sample is found to differ from that certified, the results may be used by the Agency in regulatory actions under FIFRA sec. 12(a)(1)(C) and other pertinent sections.

(3) *Nominal concentration.* The nominal concentration required by § 161.155 is the amount of active ingredient that is most likely to be present in the product when produced. Unlike the certified limits, which are the outer limits of the range of the product's ingredients and thus are present only in a small proportion of the products, the nominal concentration is the amount that typically is expected to result from the applicant's production or formulating process. The nominal concentration together with production process information is used to gauge the acceptability of the certified limits presented by the applicant. The nominal concentration is used by the Agency as the basis for enforceable certified limits if the applicant has chosen not to specify certified limits of his own (thereby agreeing to abide by the standard limits in § 161.175).

(4) *Physical and chemical characteristics.* (i) Data on the physical and chemical characteristics of pesticide active ingredients and products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product. For example, data that indicate significant changes in production or formulation might indicate the need for additional information on product composition.

(ii) Certain information (e.g., color, odor, physical state) is needed for the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills. Physicians, hospitals, and poison control centers also request this information to aid in their identification of materials implicated in poisoning episodes.

(iii) Certain physical and chemical data are used directly in the hazard assessment. These include stability, oxidizing and reducing action, flammability, explodability, storage stability, corrosion, and dielectric breakdown voltage. For example, a study of the corrosion characteristics of a pesticide is needed to evaluate effects of the product formulation on its container. If the pesticide is highly corrosive, measures can be taken to ensure that lids, liners, seams or container sides will not be damaged and cause the contents to leak during storage, transport, handling, or use. The storage stability study provides data on change (or lack of change) in product composition over time. If certain ingredients decompose, other new chemicals are formed whose toxicity and other characteristics must be considered.

(iv) Certain data are needed as basic or supportive evidence in initiating or evaluating other studies. For example, the octanol/water partition coefficient is used as one of the criteria to determine whether certain fish and wildlife toxicity or accumulation studies must be conducted. Vapor pressure data are needed, among other things, to determine suitable reentry intervals and other label cautions pertaining to worker protection. Data on viscosity and miscibility provide necessary information to support acceptable labeling for tank mix and spray applications.

§ 161.153 Definitions.

The following terms are defined for the purposes of this subpart:

(a) *Active ingredient* means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as

a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(b) *End use product* means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(c) *Formulation* means

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing use product or an end use product, or

(2) The repackaging of any registered product.

(d) *Impurity* means any substance (or group of structurally similar substances if specified by the Agency) in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

(e) *Impurity associated with an active ingredient* means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

(f) *Inert ingredient* means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(g) *Integrated system* means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

(h) *Manufacturing use product* means any pesticide product other than an end use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

(i) *Nominal concentration* means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

(j) *Starting material* means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

(k) *Technical grade of active ingredient* means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot-plant production scale (whether or not it is ever held for sale).

§ 161.155 Product composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b) and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 161.175.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae, and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits in accordance with § 161.175.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration in the product.

(3) Upper and lower certified limits in accordance with § 161.175.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 161.175.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) Chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient.* [Reserved]

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 161.160 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.* (1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information on each starting material used to produce the active ingredient, as follows:

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 161.162 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information on the formulation process, in accordance with § 161.165.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) the name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (e.g., whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 161.165 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient), as required by the following sections:

(a) Section 161.162(b)(2), pertaining to characterization of the process.

(b) Section 161.162(b)(4), pertaining to ingredients used in the process.

(c) Section 161.162(b)(5), pertaining to process equipment.

(d) Section 161.162(b)(6), pertaining to the conditions of the process.

(e) Section 161.162(b)(8), pertaining to quality control measures.

§ 161.167 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the applicant has reason to believe may be present in his product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which he knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of those impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredients and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information of impurities:

(1) From other possible chemical reactions;

(2) Involving other ingredients; or

(3) At additional points in the production or formulation process.

§ 161.170 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must

provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

§ 161.175 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

If the nominal concentration (N) for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper limit	Lower limit
N ≤ 1.0%	N + 10%N	N − 10%N
1.0% < N ≤ 20.0%	N + 5%N	N − 5%N
20.0% < N ≤ 100.0%.	N + 3%N	N − 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicant must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale of distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard or applicant-proposed), the Agency will inform the applicant of its determination and will provide supporting reasons. EPA may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 161.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 161.190 Physical and chemical characteristics.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the physical and chemical characteristics data requirements and the substance to be tested.

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Color		[R]	MP and TGAI	EP* and TGAI	63–2
Physical state		[R]	MP and TGAI	EP* and TGAI	63–3
Odor		[R]	MP and TGAI	EP* and TGAI	63–4
Melting point	(1)	[R]	TGAI	TGAI	63–5
Boiling point	(2)	[R]	TGAI	TGAI	63–6
Density, bulk density, or specific gravity		[R]	MP and TGAI	EP* and TGAI	63–7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63–8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63–9
Dissociation constant		[R]	TGAI or PAI	TGAI or PAI	63–10
Octanol/water partition coefficient	(3)	[CR]	PAI	PAI	63–11
pH	(4)	[CR]	MP and TGAI	EP* and TGAI	63–12
Stability		[R]	TGAI	TGAI	63–13
Oxidizing or reducing action	(5)	[CR]			
Flammability	(6)	[CR]	MP	EP*	63–15
Explodability	(7)	[R]	MP	EP*	63–16
Storage stability		[R]	MP	EP*	63–17
Viscosity	(8)	[CR]	MP	EP*	63–18
Miscibility	(9)	[CR]	MP	EP*	63–19
Corrosion characteristics		[R]	MP	EP*	63–20
Dielectric breakdown voltage	(10)	[CR]		EP*	63–21
Other requirements: Submittal of samples	(11)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64–1

Key: R = Required; CR = Conditionally Required; [ ] = Brackets (*i.e.*, [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (*i.e.*, formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

(b) *Notes.* The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required if technical chemical is a solid at room temperature.

(2) Required if technical chemical is a liquid at room temparature.

(3) Required if technical chemical is organic and non-polar.

(4) Required if test substance is dispersible with water.

(5) Required if product contains an oxidizing or reducing agent.

(6) Required if product contains combustible liquids.

(7) Required if product is potentially explosive.

(8) Required if product is a liquid.

(9) Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.

(10) Required if end-use product is a liquid and is to be used around electrical equipment.

(11) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end use products produced by an integrated system must be submitted on a case-by-case basis.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

Subpart D—Data Requirement Tables

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007.

§ 161.202 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) [Reserved]

(c) *Residue chemistry.* (1) Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of test on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(d) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: reentry into treated areas; hazards from residues in rotational crop and other food sources; and the loss of land as well as surface and ground water resources.

(6) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues

on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops. These data also provide information that aids the Agency in establishing any corresponding tolerances that would be needed for residues on such crops. Data from pesticides accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

(e) *Hazard to humans and domestic animals.* Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies.* Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also: provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies.* Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

(3) *Chronic studies.* Chronic toxicity (usually conducted by feeding the test substance to the test species) studies are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term oncogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Teratogenicity and reproduction studies.* The teratogenicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on teratogenesis and serve as a guide for subsequent tests.

(5) *Mutagenicity studies.* For each test substance a battery of tests are required to assess potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health effects.

(6) *Metabolism studies.* Data from studies on the absorption, distribution, excretion, and metabolism of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals to man. The main purpose of metabolism studies is to produce data which increase the Agency's understanding of the behavior of the chemical in its consideration of the human exposure anticipated from intended uses of the pesticide.

(f) *Reentry Protection.* Data required to assess hazard to farm employees resulting from reentry into areas treated with pesticides are derived from studies on toxicity, residue dissipation, and human exposure. Monitoring data generated during exposure studies are used to determine the quantity of pesticide to which people may be exposed after application and to develop reentry intervals.

(g) *Pesticide Spray Drift Evaluation.* Data required to evaluate pesticide spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to development of the overall exposure estimate and along with data on toxicity for humans, fish and wildlife, or plants are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Hazard to nontarget organisms*—(1) *General.* The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchial or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determines the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short term studies.* The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: to establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long term and field studies.* Additional studies (*i.e.*, avian, fish, and invertebrate reproduction, lifecycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(i) *Product performance.* Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific

performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, May 4, 1988]

§ 161.240 Residue chemistry data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food corp	Nonfood	Food corp	Nonfood						
Chemical identity	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171–2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]			171–3
Nature of the residue:													
Plants	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	PAIRA	PAIRA	171–4
Livestock	(3), (13), (14)	[CR]		[CR]		[CR]			[CR]	[CR]	PAIRA and plant metabloites.	PAIRA and plant metabolites.	171–4
Residue analytical method.	(4), (13), (14), (15)	[R]		[R]		[R]			[CR]	[CR]	TGAI and metabolites.	TGAI and metabolites.	171–4
Magnitude of the residue:													
Crop field trials	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	TEP	TEP	171–4
Processed food/feed.	(5), (14)	[CR]		[CR]		[CR]				[CR]	EP	EP	171–4
Meat/milk/poultry/eggs.	(6), (14)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171–4
Potable water	(7)			[R]	[R]						EP	EP	171–4
Fish	(8)			[R]	[R]						EP	EP	171–4
Irrigated crops	(9)			[CR]	[CR]						EP	EP	171–4
Food handling	(10), (14)									[CR]	EP	EP	171–4
Reduction of residue	(11), (14)	[CR]		[CR]		[CR]				[CR]	Residue of concern.	Residue of concern.	171–5
Proposed tolerance	(12), (14)	[R]		[R]		[R]				[CR]	Residue of concern.	Residue of concern.	171–6
Reasonable grounds in support of the petition.	(14)	[R]		[R]		[R]				[CR]			171–7
Submittal of analytical reference standards.	(14)	[R]		[R]		[R]				[CR]	PAIRA	PAIRA	171–13

Key: R=Required data; CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; EP=End-use product; TEP=Typical end-use product; MP=Manufacturing-use product; [ ]=Brackets (*i.e.*, [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The same chemical identity data as required under subpart C of this part are required, with emphasis on impurities that could constitute a residue problem.

(2) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(4) A residue method for enforcement of tolerances is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(5) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

(6) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.
(7) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.
(8) Data on residue in fish are required whenever a pesticide is to be applied directly to water inhabited by fish.
(9) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
(10) Data on residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments. Disinfectants and sanitizers used in food or feed handling establishment are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.
(11) Reduction of residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in case new data are revealed which indicates the pesticide is more toxic than initially determined.
(12) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry eggs.
(13) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerance was established.
(14) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.
(15) For all food uses, data on whether the FDA/USDA multiresidue methodology would detect and identify the pesticide are required.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 161.290 Environmental fate data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the environmental fate data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Degradation studies-lab													
Hydrolysis	.....	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	.....	TGAI or PAIRA.	TGAI or PAIRA.	161–1
Photodegradation:													
In water	.....	R	R	R	R	.....	.....	R	.....	.....	TGAI or PAIRA.	TGAI or PAIRA.	161–2
On soil	(1)	CR	.....	.....	.....	.....	.....	CR	.....	.....	TGAI or PAIRA.	TGAI or PAIRA.	161–3
In air	(2)	CR	.....	.....	.....	.....	.....	.....	.....	.....	TGAI or PAIRA.	TGAI or PAIRA.	161–4
Metabolism studies-lab													
Aerobic soil	.....	[R]	[R]	.....	.....	R	R	[R]	R	.....	TGAI or PAIRA.	TGAI or PAIRA.	162–1
Anaerobic aquatic	.....	.....	.....	R	R	.....	.....	R	.....	.....	TGAI or PAIRA.	TGAI or PAIRA.	162–3
Aerobic aquatic	.....	.....	.....	[R]	[R]	.....	.....	.....	.....	.....	TGAI or PAIRA.	TGAI or PAIRA.	162–4
Mobility studies													
Leaching and adsorption/desorption.	.....	[R]	[R]	R	R	R	R	[R]	R	.....	TGAI or PAIRA.	TGAI or PAIRA.	163–1

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Volatility:													
(Lab)	(2)	CR				CR	CR				TEP	TEP	163–2
(Field)	(2)	CR				CR	CR				TEP	TEP	163–3
Dissipation studies-field													
Soil		R	R						R		TEP	TEP	164–1
Aquatic (sediment)				R	R						TEP	TEP	164–2
Forestry								R			TEP	TEP	164–3
Combination and tank mixes.	(2)												164–4
Soil, long-term	(4)	CR		CR							TEP	TEP	164–5
Accumulation studies													
Rotational crops:													
(Confined)	(5)	[CR]		[CR]							PAIRA	PAIRA	165–1
(Field)	(6)	CR		CR							TEP	TEP	165–2
Irrigated crops	(7)			[CR]	CR						TEP	TEP	165–3
In fish	(8)	[CR]	[CR]	[CR]	[CR]			[CR]			TGAI or PAIRA.	TGAI or PAIRA.	165–4
In aquatic non-target organisms.	(8), (9)				CR			CR			TEP	TEP	165–5

Key: R=Required: CR=Conditionally required; [ ]=Brackets (ie. [R], [CR], indicate data requirements that apply when an experimental use permit is being sought; TGAI=Technical grade of the active ingredient, PAIRA=''Pure'' active ingredient-radio labeled; TEP=typical end use product; EP =End use product.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

AAA(2) Required on case by case basis depending on product use pattern and other pertinent factors.

AAA(3) Not required if anaerobic aquatic metabolism study has been conducted.

AAA(4) Required if pesticide residues do not readily dissipate in soil.

AAA(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

AAA(6) Field accumulation study is required if significant pesticide residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

AAA(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

AAA(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

AAA(9) Required unless tolerance or action level for fish has been granted.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988]

§ 161.340 Toxicology data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Acute testing													
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81–1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81–2
Acute inhalation toxicity—rat.	(16)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	81–3
Primary eye irritation—rabbit.	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–4
Primary dermal irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–6
Acute delayed neurotoxicity—hen.	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81–7
Subchronic testing													
90-day feeding studies—rodent and nonrodent.	(17)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	82–1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP*.	82–2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–4
90-day neurotoxicity:													
Hen	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–5
Mammal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–5
Chronic testing													
Chronic feeding—2 spp. rodent and nonrodent.	(9), (13), (20)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–1
Oncogenicity study—2 Spp. rat and mouse preferred.	(9), (21)	R	CR	R	CR	R	CR	CR	CR	CR	TGAI	TGAI	83–2
Teratogenicity—2 species	(10), (15)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–3
Reproduction, 2-generation.	(11), (14)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–4
Mutagenicity testing													
Gene mutation	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–2
Structural chromosomal aberration.	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–2
Other genotoxic effects	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–4

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Special testing													
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	PAI or PAIRA.	PAI or PAIRA.	85–1
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	85–2
Domestic animal safety	(12)	CR	CR	CR	CR	.....	.....	CR	CR	.....	Choice	Choice	86–1

AAAKey: R=Required data; CR=Conditionally required; [ ]=Brackets (ie [R], [CR] indicate data requirements that apply when an experimental use permit is being sought; MP=manufacturing-use product; EP*=End-Use Product; (asterisk identifies those data requirements that end-use applicants (*i.e.*, ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; PAI=''Pure'' active ingredient; PAIRA=''Pure'' active ingredient, radio-labeled; Choice=choice of several test substances, depending on studies required.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if test material is a gas or highly volatile.

(2) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as toxicity category I on the basis of potential eye and dermal irritation effects.

(3) Required unless repeated dermal exposure does not occur under conditions of use.

(4) Not required unless test material, is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.

(5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.

(6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.

(7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.

(8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.

(9)(i) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (*i.e.*, a combined study) can be conducted.

(ii) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:

(A) Chronic rodent feeding study (food use pesticides)—24 months.

(B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.

(C) Chronic nonrodent (*i.e.*, dog) feeding study—12 months.

(D) Mouse oncogenicity study—18 months.

(E) Rat oncogenicity study—24 months.

(10) Required to support products intended for food uses and to supoort products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.

(11) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(12) Required on a case by case basis.

(13) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feed study is required to support a temporary tolerance.

(14) In most cases, where theoretical maxium residue contribution (TMRC) exceeds 50 percent of the maxium permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.

(15) A teratology study in one species is required to support a temporary tolerance.

(16) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).

(17) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via the oral route.

(ii) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).

(18) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via skin contact.

(ii) Expected human skin contact is not purposeful, and such exposure is of limited frequence and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).

(iii) Data from a subchronic 90-day dermal toxicity study are not required.

(19) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:
(i) Data from a subchronic oral study are not required.
(ii) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.
(20) Required if either of the following criteria are met:
(i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).
(ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.
(21) Required if any of the following criteria are met:
(i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
(A) Is structually related to a recognized carcinogen.
(B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.
(C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.
(ii) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
(iii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
(22)(i) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 161.202:
(A) Gene mutations.
(B) Structural chromosomal aberrations.
(C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome abberations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.
(ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.
(iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).
(23) Required if chronic feeding or oncogenicity studies are required.
(24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 161.390 Reentry protection data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Foliar dissipation	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	132–1
Soil dissipation	(1), (4)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	132–1
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	133–3
Inhalation exposure ...	(1), (2), (3)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	133–4

Key: CR=Conditionally required; TEP=Typical end-use product.
(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required if the following conditions are met:
(i)(A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
(B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m^3 (for a one-hour exposure); or
(C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
(D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
(E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
(ii) And if: end-use product is to be registered for:
(A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.
(B) Application to outdoor tree nursery and forestry operations.
(C) Application to turf crops and commercial applications to turf.
(D) Application to parks and arboretums; or (E) application to aquatic crops.
(iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
(2) Data required if appropriate surrogate data are not available.
(3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
(4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.440 Spray drift data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	201–1
Drift field evaluation	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	202–1

Key: CR=Conditionally required; TEP=Typical end use product.
(b) NOTES. The following are referenced in column two of the table contained in paragraph (a) of this section.
(1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
(2) [Reserved]

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.490 Wildlife and aquatic organisms data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian and mammalian testing													
Avian oral LD_{50} (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71–1
Avian dietary LC_{50} (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71–2
Wild mammal toxicity	(2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	71–3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	71–4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	71–5
Aquatic organism testing													
Freshwater fish LC_{50} (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72–1
Acute LC_{50} freshwater invertebrates (preferably *Daphnia*).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72–2
Acute LC_{50} estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	72–3
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	72–4
Fish—life-cycle	(6)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	72–5
Aquatic organism accumulation.	(8)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72–6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	72–7

Key: R=Required; CR=Conditonally required; [ ]=Brackets (ie. [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; TGAI=Techical grade of the active ingredient; TEP=Typical end-use product; PAI=''Pure'' active ingredient.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1)(i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD_{50} (bobwhite), avian dietary LC_{50} (bobwhite), freshwater fish LC_{50} (rainbow trout) and acute LC_{50} freshwater invertebrate (*Daphnia*).

(B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral LD_{50}.
(ii) Data are not required to support:
(A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.
(B) Indoor end-use products for which there is a manufacturing use product registration.
(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.
(3) Data required if one or more of the following criteria are met:
(i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
(ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.
(iii) The pesticide or any of its major metalolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
(iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.
NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.
(4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.
(5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:
(i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
(ii) If any LC_{50} or EC_{50} value determined in acute toxicity testing is less than 1 mg/l; or
(iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing.
(iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing and any of the following conditions exist:
(A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
(B) Physiochemical properties indicate cumulative effects.
(C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
(6) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:
(i) if the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.
(7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:
(i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.
(ii) The LC_{50} or EC_{50} of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.
(iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.540 Plant protection data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity ..	(1)	.....	.....	.....	.....	.....	.....	.....	.....	.....	EP	EP	121–1

Nontarget area phytotoxicity.													
Tier I:													
Seed germination/ seedling emergence.	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Vegetative vigor	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Aquatic plant growth	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–2
Tier II:													
Seed germination/ seedling emergence.	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Vegetative vigor	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Aquatic plant growth	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–2
Tier III:													
Terrestrial field	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–1
Aquatic field	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–2

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.
(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Data are required for Special Review and certain public health situations.
(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the acquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:
(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.
(ii) The product may pose hazards to endangered or threatened species.
(iii) Special Review has been initiated on the product.
(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.
(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.590 Nontarget insect data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use pattern									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect testing—pollinators													
Honey bee acute contact LD_{50}.	(1)	[CR]	[CR]	[CR]	[CR]	.....	.....	[CR]	[CR]	.....	TGAI	TGAI	141–1
Honey bee—toxicity of residues on foliage.	(1), (2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	141–2
Honey bee subacute feeding study.	(3)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	141–4

Kind of data required	(b) Notes	General use pattern									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Field testing for pollinators	(4)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	141–5
Nontarget insect testing—aquatic insects													
Acute toxicity to aquatic insects.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–1
Aquatic insect life-cycle study.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–1
Simulated or actual field testing for aquatic insects.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–3
Nontarget insect testing—predators and parasites.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	143–1 thru 143–3

Key: CR=Conditionally required; [ ]=Brackets (ie, [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required only if proposed use will result in honey bee exposure.

(2) Required only when formulation contains one or more active ingredients having an acute LD_{50} of less than 1 microgram/bee.

(3) This requirement is reserved pending development of test methodology.

(4) May be required under the following conditions:

(i) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).

(ii) Data from residual toxicity studies indicate extended residual toxicity.

(iii) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.

(5) This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.640 Product performance data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–2

Products requiring confirmatory data.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–3
Products for use on fabrics and textiles.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–4
Air sanitizers	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–5
Products for control of microbial pests associated with human and animal wastes.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–7
Products for treating water systems.	(1)	.....	.....	[CR]	.....	.....	.....	.....	.....	CR	.....	EP*	91–8
Efficacy of fungicides and nematicides													
Products for control of organisms producing mycotoxins.	(1)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	.....	EP*	93–16
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–5
Avian repellents	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–6
Avian frightening agents ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–7
Bat toxicants and repellents.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	(R)	.....	EP*	96–9
Commensal rodenticides ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	TEP	EP*	96–10
Rodenticides on farm and rangelands.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–12
Rodent fumigants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–13
Rodent reproductive inhibitors.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–16
Mammalian predacides	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (*i.e.*, [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (*i.e.*, ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(b) Notes: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

(2) [Reserved]

[49 FR 42881, Oct. 24, 1984, as amended at 50 FR 46766, Nov. 13, 1985. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

APPENDIX A TO PART 161—DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX

How to use this Index:

1. Identify the Pesticide Use Site Group listed below (e.g., agricultural crops, forests, ornamental plants) that covers the specific use pattern of interest to you.
2. Find your specific use pattern under the appropriate Pesticide Use Site Group.
3. Identify the general use pattern that corresponds to your specific use pattern.
4. Use the general use pattern in determining applicable data requirements on the Data Requirements tables presented in §§161.155 through 161.640.

Pesticide use site group

1. Agricultural Crops.
2. Ornamental Plants and Forest Trees.
3. General Soil Treatment and Composting.
4. Processed or Manufactured Products, and food or feed containers or dispensers.
5. Pets and Domestic Animals.
6. Agricultural Premises and Equipment.
7. Household.
8. Wood or Wood Structure Protection Treatments.
9. Aquatic sites.
10. Noncrop, wide area, and general indoor/outdoor treatments.
11. Antifouling treatments.
12. Commercial and Industrial Uses.
13. Domestic and Human Use.
14. Miscellaneous Indoor Uses.

Specific use patterns—listed according to use site group	Corresponding general use pattern
1. *Agricultural crops*	
Small fruits	Terrestrial food crop
Caneberries (e.g., raspberry, dewberry)	
Bushberries (e.g., blueberry, currant)	
Vine fruits (e.g., grape, kiwi fruit)	
Strawberry	
Cranberry	
Pome fruits (e.g., apple, quince)	
Stone fruits (e.g., peach, cherry)	
Nut crops—tree & shrub (e.g., pecan, filbert)	
Other temperate fruits (e.g., persimmon, pawpaw)	
Tropical and subtropical fruits	
Citrus	
Banana and plantain	
Palm fruits and nuts (e.g., date, coconut)	
Pineapple	
Other fruits and nuts	
Beverage crops	
Woody—cocoa, coffee, tea	
Herbaceous—chicory, mint	
Flavoring and spice crops	
Woody—leaf/stem, root, seed and pod	
Herbacleaf/stem, root, seed and pod	
Vegetables—leaf/stem, root, seed and pod, fruiting vegetables, cucurbits	
Commercial annual (e.g., tomato, bean)	
Commercial perennial (e.g., asparagus, rhubarb)	
Greenhouse (commercial)	Greenhouse food crop
Mushrooms	
Nursery/seed crop/medical crop/tobacco	Greenhouse nonfood crop
Fiber crops	Terrestrial food crop
Cotton	
Others—(e.g., flax)	
Forage crops	
Typical grasses—annual (e.g., sudan grass)	
Typical grasses—perennial (e.g., bromegrass)	
Corn and sorghum	
Small grains for forage (e.g., rye)	
Perennial legumes (e.g., white clover)	
Annual legumes (e.g., crotalaria, soybean)	
Crop harvest residue (peanut vines, beet tops, etc.)	
Grain and edible seed crops	
Corn	
Rice	Aquatic food crop
Wheat, barley, rye, oats	Terrestrial food crop
Sorghum	
Alfalfa	
Other grains	
Other nongrains (e.g., squash, pumpkin)	
Buckwheat	
Sesame	
Peanut	
Sunflower	
Seed sprout crops	
Mung bean, red clover, soybean, alfalfa, etc.	
Nonlegume crops (e.g., wheat, radish, black mustard)	
Crops grown exclusively for seed for planting	
Sugar crops	
Stored raw agricultural commodities	Indoor
Honey (principal nectar-producing crops)	
Sugar beet	
Sugarcane	
Sugar maple	
Sorghum (for sugar)	
Crops for smoking and chewing	Terrestrial nonfood crop
—field	
—shade	
—storage	
—greenhouses	
Sapodilla (for chewing gum)	Terrestrial food crop
Oil crops	
Annual herbaceous crops	
Perennial herbaceous crops	
Tropical/subtropical woody crops	
Drug and medicinal crops	Terrestrial nonfood crop
Annual herbaceous crops	
Perennial herbaceous crops	
Temperate woody crops	
Tropical/subtropical wood crops	

Specific use patterns—listed according to use site group	Corresponding general use pattern
2. *Ornamental plants and forest trees*	
Ornamental plants	Terrestrial nonfood crop
Annual garden plants	
Temperate perennial nonfood garden herbs	
Commercial greenhouse crops	Greenhouse nonfood crop
Houseplants	Indoor
Home and retail greenhouse and conservatory plants	
Public display plantings	Terrestrial nonfood crop
Bulb, corm, and tuber ornamentals	
Subtropical/tropical garden evergreen plants (dry—e.g., agave)	
Subtropical/tropical garden evergreen plants (moist—e.g., ferns)	
Groundcovers	
Aquatic plants (e.g., waterlilies)	Aquatic nonfood use
Ornamental trees, shrubs, and vines (woody)	Terrestrial nonfood crop
Deciduous temperate broadleaf	
Evergreen temperate broadleaf	
Deciduous temperate conifer	
Evergreen temperate conifer	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Tropical/subtropical miscellaneous (e.g., cycad, tree fern, bamboo)	
Lawn and turf grasses—ornamental	Terrestrial nonfood crop or domestic outdoor
Cool season Winter grasses (bent, bluegrass, fescue, etc.)	
Summer grasses (zoysia, bermudagrass, etc.)	
Ornamental bunch grasses (pampasgrass, blue fescue)	
Forest trees—nonornamental—trees forests, plantings	Forestry
Deciduous temperate (broadleaf)	
Evergreen temperate (broadleaf)	
Deciduous and evergreen conifers	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Forest tree nurseries—Temperate broadleaf trees	
Temperate conifer trees	
Forest trees: dead trees/logs/stumps in the forest or in plantings	
3. *General soil treatment and composting*	
General soil treatments	Terrestrial nonfood crop
Soil application with no mention of crops to be grown (potting soil, top soil).	
Manure	
Composts	
Cull piles	
Mulches	
4. *Processed or manufactured products, and food or feed containers or dispensers*	
Processed vegetables, fruits, and nuts	Indoor
Fruits	
Leafy vegetables	
Root vegetables	
Fruited vegetables	
Nuts	
Peanuts	
Seeds (sesame, sunflower)	
Dried processed	
Fruits	
Vegetables	
Tobacco	
Beverages (tea, coffee)	
Herbs and spices	
Animal Feeds	
Cattle (beef)	
Cattle (dairy)	
Goat (nondairy)	
Goat (dairy)	
Horse, mule, donkey	
Poultry (chicken, turkey, etc.)	
Sheep (meat)	
Sheep (wool)	
Swine	
Dog	
Cat	
Other pets (including birds)	
Fur-bearing stock	
Other meat-producing stock (e.g., rabbit)	
Fish food (commercial)	
Fish food (pet)	
Birdseed	
Processed grain products for human consumption	
Corn	
Soybean	
Wheat	
Other grains (rice, barley, etc.)	
Cereal foods	
Flour	
Baked goods	
Farinaceous products	
Processed animal products for human consumption	
Cheese	
Egg yolks	
Meats, including fish and poultry	
Milk	
Processed plant products for human consumption	
Chocolate	
Candy	
Sugar	
Yeast	
Citrus pulp	
Chewing gum	
Cigarettes, etc.	
Herbs and spices	
Pickles	
Glazed fruits	
Jellies	
Seed oils	
Fruit syrups (e.g., cola)	
Fruit juices	
Fermentation beverages (wine, beer, whiskey, vinegar)	
Processed or manufactured nonfood plant and animal products	
Textiles, fabrics, fibers	
Fur and hair products	
Leather products	
Food and feed containers, dispensers, and processing equipment	
Airtight storages—large (empty/full)	
Airtight storages—small (empty/full)	
Fumigation chambers	
Bins	
Elevators	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Storage areas—(empty/full)	
Processing or handling equipment and machinery (other than food processing)	
5. *Pets and domestic animals—animals and their man-made premises*	
Dairy cattle—lactating	Indoor
Dairy cattle—nonlactating	
Dairy cattle—heifers, calves	
Goats—lactating	
Goats—nonlactating	
Goats—young (kids)	
Fur- and wool-bearing animals	
Goats	
Sheep	
Mink	
Chinchilla	
Rabbit	
Fox	
Nutria	
Meat animals (mammals)	
Cattle (and calves)	
Goats (and kids)	
Horses	
Rabbits	
Sheep (and lambs)	
Swine	
Bison	
Reindeer	
Poultry (meat, eggs)	
Chickens	
Turkeys	
Ducks, geese	
Guineas, pheasants, quail, etc.	
Honey production	
Bees	
Beehives	
Honeycombs	
Fish and shellfish production	Aquatic food use
Hatchery buildings	
Culture ponds, containers	
Animals for labor, display, riding, racing, lab use, etc.	Indoor
Dogs	
Horses, donkeys, mules	
Guinea pigs	
Mice	
Rats	
Gerbils	
Hamsters	
Monkeys	
Cats	
Chickens, birds	
Wild rodents	
Alfalfa leafcutting bee (pollinator)	
Alkaline bee (pollinator)	
Zoo ruminants	
Zoo ungulates	
Zoo canines	
Zoo felines	
Zoo primates	
Zoo reptiles	
Zoo amphibians	
Zoo birds	
Zoo—others	
Aquarium fish	
Animals for pets, including their cages, bedding, nests, etc.	
Dogs	
Cats	
Birds	
Rodents	
Lagomorphs	
Fish	
Amphibians	
Reptiles	
Primates	
Other vertebrates	
6. *Agricultural premises and equipment*	
Egg handling facilities and equipment	Indoor
Egg washers	
Egg rooms	
Hatching egg treatments	
Hatching egg rooms	
Hatching egg equipment	
Egg packing plants and hatcheries	
Milk handling facilities and equipment	
Milk storage rooms	
Milking stalls and parlors	
Milking machines, milk tanks, etc.	
Teat cups, liners, etc.	
Milk processing equipment	
7. *Household*	
Non-food area and sites	Indoor
Closets, storage areas	
Basements, cellars	
Bedrooms	
Attics	
Recreation rooms	
Living rooms	
Baseboards, window sills, etc.	
Plumbing fixtures	
Sickrooms	
Food-handling and food storage areas	
Kitchens	
Dining rooms	
Pantry and food storage shelving	
Household contents and space	
Air	
Beds	
Rugs	
Book cases	
Furs, fabrics, blankets	
Play pens	
Sickroom utensils	
Filters for air vents, air conditioners, furnaces, etc.	
Outdoor areas (Noncommercial homeowner use)	Domestic outdoor or terrestrial food crop
Home garden, orchards	
Porches	Domestic outdoor
Patios	
Foundations	
Steps	
Eaves	
Yards, lawn, turf	
Domestic ornamental plantings	
8. *Wood or Wood Structure Protection Treatments*	
Buildings (for termite, powderdust beetle controls, etc.)	Domestic outdoor or indoor
Unseasoned forest products	
Seasoned forest products	
Finished wood products	
Wood pressure treatments	
Plant-growing wood structures and containers	
Wood containers for nonfood, nonfeed uses	
9. *Aquatic sites*	
Food processing water systems	Aquatic food crop
Poultry and livestock drinking water	
Pulp and papermill systems	Aquatic noncrop
Swimming pool water	
Industrial disposal systems	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Industrial ponds	
Human drinking water	Aquatic food crop
Cooling water towers	Aquatic noncrop
Agricultural irrigation water, and ditches	Aquatic food crop
Agricultural drainage water and ditches	
Sewage systems and drainfields	Aquatic noncrop
Dishwashing water	Indoor
Domestic and commercial nonpotable water	Aquatic noncrop
Lakes, ponds, impounded water	
Streams, rivers, canals	
Swamps, marshes, wetlands	
Air conditioner water	
Humidifier water	
Air washer water systems	
Secondary oil recovery injection water	
Heat exchange water system	
Polluted water	
Bait boards (floating—for vertebrate control)	
Catch basins, puddles, tree holes	
Estuaries, tidal marshes	
Commercial and sport fish-bearing waters	Aquatic food crop
10. *Noncrop, wide area, and general indoor/outdoor treatments*	
Uncultivated agricultural areas (nonfood producing)	Terrestrial noncrop
Farmyards	
Fuel storage areas	
Fence rows	
Rights-of-way	
Fallow land	Terrestrial food crop
Soil bank land	Terrestrial noncrop
Barrier strips	
Uncultivated nonagricultural areas (outdoor)	
Airports	
Recreation areas, fairgrounds, race tracks, tennis courts, etc.	
Campgrounds	
Recreation area structures	
Highway rights-of-way	
Railroad rights-of-way	
Utility rights-of-way	
Sewage disposal areas	
Industrial sites (lumberyards, tank farms, etc.)	
Paved areas	
Private roads and walks	
Fencerows and hedgerows (nonagricultural)	
Directed Pest Control to Pests' Nests, etc., and for Traps	Terrestrial noncrop or indoor
Diseased beehives	
Nuisance bee nests	
Ant mounds, hills, dens	
Termite mounds	
Insect traps (chemical lures)	
Repellents and irritants to pests (when not covered by other sites)	
Wide area and general indoor/outdoor treatments	
Rural areas (unspecified)	
Urban areas (unspecified)	
Public buildings and structures	
Animal burrow entrances, dens, tunnels	
Animal nests	
Animal trails	
Mammal feeding areas	
Nonagricultural areas for public health treatments	
Bird roosting, nesting areas	
Bird feeding areas	
11. *Antifouling Treatments*	
Sites for marine exposures	Aquatic noncrop
Boat bottoms and other submersed structures	
Steel	
Fiberglass	
Aluminum	
Wood	
Plastic	
Other substances and materials	
Crab pots and lobster pots	
Sites for fresh water exposures	
Cooling tower influent conduits	
12. *Commercial and Industrial Uses*	
Transportation Facilities	Indoor
Bus	
Truck and Trailer	
Containerized units	
Railroad cars	
Aircraft	
Ships/barges	
Auto, taxis	
Recreational vehicles	
Shipping containers	
Food and feed processing plants	
Bakeries	
Bottlers	
Canneries	
Dairies, creameries, milk processing plants	
Feed mills, feed stores	
Fresh fruit packing and processing	
Meat processing	
Poultry processing	
Wineries, wine cellars	
Flour mills, machinery, warehouses, bins, elevators	
Egg processing	
Candy and confectionary plants	
Sugar processing, cane mills, etc.	
Cider mills	
Dry food products plants	
Tobacco processing	
Air treatment for processing and transportation of foods	
Beverage processing	
Nut processing	
Cereal processing	
Seafood processing	
Vegetable oil processing	
Spice mills	
Vinegar processing	
Farinaceous processing (noodles, etc.)	
Mushroom processing	
Dried fruit processing	
Pickle processing	
Ice plants	
Chocolate processing	
Fruit juice processing	
Eating establishments (all)	
Food handling areas	
Food serving areas	
Eating establishment nonfood areas	
Air treatment for eating establishments	
Food storage equipment (coolers, refrigerators, etc.)	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Eating and serving utensils (spoons, etc.)	
Food marketing, storage, and distribution	
Food dispensing and vending equipment	
Food stores, markets, stands	
Meat and fish markets	
Food catering facilities	
Food marketing, storage, and distribution equipment and utensils	
Hospitals and related institutions and facilities	
Critical premises (e.g., burn wards, etc.)	
Hospital patient premises (wards, emergency rooms, etc.)	
Noncritical premises (labs, lounges, lobbies, storage)	
Critical items (hypodermic needles, dental instruments, catheters, etc.)	
Noncritical items (bedpans, carpets, furniture, etc.)	
Air treatment (also to ambulances)	
Janitorial equipment	
Barber and beauty shop instruments and equipment	
Morgues, mortuaries, and funeral homes	
Premises (embalming rooms, etc.)	
Equipment (tables, etc.)	
Instruments	
Burial vaults, mausoleums	
Air treatment	
Commercial, institutional, and industrial	
Maintenance, Buildings, and Structures	
Locker rooms, equipment	
Gyms, bowling alleys, and equipment	
Telephones and booths	
Shower rooms, mats, and equipment	
Cotton mill premises and equipment	
Auditoriums and stadiums	
Factories	
Rendering plants	
Loading areas, ramps	
School buildings and equipment	
Office buildings	
Laundries	
Fuels from Crops (alcohol, methane)	
Fossil fuels (e.g., oils, jet fuel)	
Seed oils	
Paper	
Pesticide materials preservation and protection	
Rodenticide baits (protection against insects)	
Dried plant parts (pyrethrum, red squill, rotenone, sabadilla)	
Paints	
Preservatives and protectants	
Grains	
Hay, silage	
Adhesives	
Coatings (asphalt and lacquer)	
Fuels	
Leather and leather products	
Leather processing liquors	
Metalworking cutting fluids	
Oil recovery drilling muds and packer fluids	
Paints (latex)	
Paper and paper products	
Plastic products	
Resin emulsions	
Rubber (natural) products	
Specialty products (polishes, cleansers, dyes, etc.)	
Textiles, textile fibers, and cordage	
Wet-end additives, etc. (pulp sizing, alum, casein, printing pastes)	
Disposable diapers	
Wool, hair, mohair, furs, felt, feathers, etc.	
Electrical supplies, cables, and equipment	
13. *Domestic and Human Use*	
Human Body and Hair	Indoor
Fiber product protection (Moth, mildew-proofing)	
Clothing	
Upholstery	
Ornamental fabrics (draperies, tapestries)	
Ropes	
Sail cloth	
Human articles and materials	
Bedding, blankets, mattresses	
(Treatments to) hair, body, clothing (while being worn)	
Clothing	
Face gear (goggles, face masks, etc.)	
Headgear (safety helmets, headphones, etc.)	
Wigs	
Contact lenses	
Dentures, toothbrushes, mouthpieces to musical instruments, etc.	
Brick, asbestos, etc.	
Wood surfaces	
Leather surfaces	
Fabric surfaces	
Paper/paperboard surfaces	
Specialty uses	
Museum collectors (preserved animal and plant specimens)	
Military uses—not specified	
Quarantine uses—not specified	
DHHS/FDA uses—not specified	
Filters (air conditioning, air, and furnace)	
Biological specimens	
Underground cables	
Cuspidors, spittoons	
Vomitus	
Human wastes	
Air sanitizers	
Diapers	
Laundry equipment (carts, chutes, tables, etc.)	
Dust control—products and equipment (mops, etc.)	
Dry cleaning	
Carpets	
Upholstery	
Bathrooms, toilets bowls, and related sites	
Bathroom premises	
Toilet bowls and urinals	
Toilet tanks	
Portable toilets, chemical toilets	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Vehicular holding tanks	
Bathroom air treatment	
Diaper pails	
Refuse and soild waste	
Refuse and solid waste containers	
Refuse and solid waste transportation and handling equipment	
Garbage dumps	
Household trash compactors	
Garbage disposal units, food disposals	
Incinerators	
14. *Miscellaneous Indoor Uses*	
Surface Treatments	Indoor
Hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.)	
Hard porous surfaces (cement, plaster)	
Camping equipment and gear	
Grooming instruments (brushes, clippers, razors, etc.)	
Laundry, cleaning, and dry cleaning	

[40 FR 42881, Oct. 24, 1984. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007]

PART 162—STATE REGISTRATION OF PESTICIDE PRODUCTS

Subparts A–C [Reserved]

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

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Subparts A–C [Reserved]

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

AUTHORITY: 7 U.S.C. 136v, 136w.

SOURCE: 46 FR 2014, Jan. 7, 1981, unless otherwise noted.

§ 162.150 General.

(a) *Scope.* This subpart sets forth regulations governing the registration by any State of pesticide products, or uses thereof, formulated for distribution and use within the State to meet special local needs under sec. 24(c) of the Act. It also sets forth regulations governing the exercise by the Administrator of the power to disapprove specific State registrations and to suspend a State's registration authority under sec. 24(c). Unless otherwise indicated, any reference herein to registrations issued by a State includes amendments of registrations issued by States.

(b) *Applicability.* This subpart applies only to State registration authority granted by sec. 24(c) of FIFRA. It does not apply to any authority granted, or procedures established, by State law with respect to registration, licensing, or approval required for use within the State of federally registered pesticide products.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988; 60 FR 32097, June 19, 1995]

§ 162.151 Definitions.

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this subpart, the following terms shall apply:

Federally registered means currently registered under section 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 by the Secretary of Agriculture or under FIFRA by the Administrator.

Manufacturing-use product means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after reformulation or repackaging.

New product means a pesticide product which is not a federally registered product.

Pest problem means:

(1) A pest infestation and its consequences, or

(2) Any condition for which the use of plant regulators, defoliants, or desiccants would be appropriate.

Product or pesticide product means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

Similar composition means a pesticide product which contains only the same active ingredient(s), or combinations of

active ingredients, and which is in the same toxicity category, as defined in § 156.62 of this chapter, as a federally registered pesticide product.

Similar product means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

Similar use pattern means a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under part 156 of this chapter, and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

Special local need means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

State or State lead agency means the State agency designated by the State to be responsible for registering pesticides to meet special local needs under section 24(c) of the Act.

[73 FR 75597, Dec. 12, 2008]

§ 162.152 State registration authority.

(a) *Statutory limitations.* In accordance with sec. 24(c) of the Act, each State is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

(1) There is a special local need for the use within the State;

(2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 *et seq.*), if the use is a food or feed use;

(3) Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and

(4) The registration is in accord with the purposes of FIFRA.

(b) *Types of registrations*—(1) *Amendments to federal registrations.* (i) Subject to the provisions of paragraphs (a) and (b)(1)(ii) through (iv) of this section, States may register any new use of a federally registered pesticide product.

(ii) A State may register any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended, or cancelled by the Administrator, provided that the State may register a use not considered by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.

(iii) Except as provided in paragraph (a)(3) of this section, a State may register any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant, provided that a State may register such a use only after the State has consulted with appropriate EPA personnel.

(iv) A State may not register an amendment to a federally registered manufacturing-use product.

(2) *New products.* (i) Subject to the provisions of paragraph (a) and subparagraphs (b)(2) (ii) and (iii) of this section, a State may issue registrations to meet special local needs for the following types of new end-use products:

(A) A product which is identical in composition to a federally registered product, but which has differences in packaging, or in the identity of the formulator.

(B) A product which contains the same active and inert ingredients as a federally registered product, but in different percentages.

(C) Subject to the requirements of paragraph (b)(2)(ii) of this section, a product containing a new combination of active, or active and inert, ingredients.

(ii) A State may register a new product only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product.

(iii) A State may not register a new manufacturing-use product.

(iv) A State may register any use of a new product containing an ingredient described in paragraph (a)(3) of this section, if the new product registration is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily cancelled without a prior notice of intent to cancel by the Administrator. However, a formulation or use of such a new product which was not considered by the Administrator during such proceedings, or which was not the subject of a notice of intent to cancel, may be registered by a State only after the State consults with appropriate EPA personnel regarding the registration application.

(c) *Effect of State registration.* (1) A State registration issued under FIFRA sec. 24(c) which meets the conditions described in paragraphs (a) and (b) of this section, and which is not disapproved by the Administrator under § 162.154, shall be considered a federal registration, but shall authorize distribution and use only within that State. Accordingly, such registrations are subject to all provisions of FIFRA which apply to currently registered products, including provisions for cancellation and suspension of registrations, and reregistration of products.

(2) A State may require, as a condition of distribution or use of a pesticide product within the State, that the pesticide product be registered under State law as well as under FIFRA. Neither FIFRA sec. 24(c) nor §§ 162.150–162.156 affects a State's right under its own law to revoke, suspend, cancel, or otherwise affect such a registration issued under State law. However, the federal registration, whether issued under FIFRA sec. 3 or 24(c), is not affected by such a State action.

[46 FR 2014, Jan. 7, 1981, as amended at 73 FR 75597, Dec. 12, 2008]

§ 162.153 State registration procedures.

(a) *Application for registration.* States shall require all applicants for registration to submit the following information:

(1) Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.

(2) The name of the pesticide product, and, if the application is for an amendment to a federally registered product, the EPA registration number of that product.

(3) A copy of proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of:

(i) For a new product, a copy of the complete proposed labeling; or,

(ii) For an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product.

(4) The complete formula of the product, if the application is for a new product registration.

(5) Any other information which is required to be reviewed prior to registration under this section.

(b) *Special local need determination.* In reviewing any application for registration, the State shall determine whether there is a special local need for the registration. Situations which a State may consider as not involving a special local need may include, but are not limited to, applications for registrations to control a pest problem present on a nationwide basis, or for use of a pesticide product registered by other States on an interregional or nationwide basis.

(c) *Unreasonable adverse effects determination.* (1) Prior to issuing a registration in the following cases, the State shall determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices:

(i) For use of a product which has a composition not similar to any federally registered product.

(ii) For use of a project involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition.

(iii) For use of a product for which other uses of the same product, or of a product with a similar composition, have had registration denied, disapproved, suspended, or cancelled by the Administrator.

(2) Determinations required by paragraph (c)(1) of this section shall be based on data and criteria consistent with those sections of part 152 of this chapter, applicable to the type of product or use under consideration. Such determinations may also involve consideration of the effect of the anticipated classification of the product or use under paragraph (g) of this section.

(d) *Efficacy determination.* Prior to registration of any use of a product for public health purposes—that is, a use which could result in substantial harm to the public health if the product does not perform its intended function, the State shall determine that the product warrants the claims made for it in the registration application. Such determinations shall be based on criteria specified in applicable sections of part 152 of this chapter and on any additional criteria established by the State.

(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practical after a registration is issued in order to verify compliance with this paragraph.

(2) For a new product, the State must, as a condition of the registration, require that the product be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria of § 156.10 of this chapter. New product labeling must all contain:

(i) A statement identifying the State where registration is to be valid.

(ii) The special local need registration number assigned by the State.

(3) Except as provided in paragraph (e)(4) of this section, as a condition for a registration of an additional use of a federally registered product, the State must require that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid.

(ii) Directions for use to meet the special local need which satisfy the criteria of § 156.10(i) of this chapter.

(iii) The trade name of the product.

(iv) The name and address of the section 24(c) registrant.

(v) The EPA registration number of the federally registered product.

(vi) The special local need registration number assigned by the State.

(vii) A statement prohibiting use of the product in a manner inconsistent with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product and accompanying supplemental labeling.

(4) When a federally registered product is already in the stream of commerce at the time the State issues a registration for an additional use of that product, the State must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph (e)(3) of this section, is made available to purchasers and users of the product within 45 days of the date on which the State approves the final printed supplemental labeling.

(5) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

(f) *Packaging and coloration standards.* All products registered by a State must meet all appropriate packaging standards prescribed by the Administrator under sec. 25(c)(3) of FIFRA. State registered products must also meet all appropriate standards for coloration, or discoloration, established by regulation under sec. 25(c) of FIFRA, including the standards contained in subpart H of part 153 of this chapter. Prior to issuing any registration, the State

shall determine that the product will conform to these requirements.

(g) *Classification.* (1) As part of the registration of any product or use, a State shall classify the product or use as a restricted use pesticide if:

(i) The product is identical or similar in composition to a federally registered product:

(A) For which all federally registered uses have been classified as restricted by the Administrator; or

(B) For which a use similar to the State registered use has been classified as restricted by the Administrator; or

(ii) The State registered product or use meets the criteria for classification as a restricted use pesticide under the applicable provisions of § 152.170 of this chapter.

(2) [Reserved]

(h) *Notification and submission of data.* (1) Within ten working days from the date a State issues, amends, or revokes a registration, the State shall notify EPA, in writing, of the action. Notification of State registrations, or amendments thereto, shall include the effective date of the registration or amendment, a confidential statement of the formula of any new product, and a copy of the draft labeling reviewed and approved by the State, provided that labeling previously approved by the Administrator as part of a federal registration need not be submitted.

(2) Notification of State registrations or amendments shall be supplemented by the State sending to EPA a copy of the final printed labeling approved by the State within 60 days after the effective date of the registration or amendment.

(3) Notification of revocation of a registration by a State shall indicate the effective date of revocation, and shall state the reasons for revocation.

(4) The Administrator or his designee may request, when appropriate, that a State submit to EPA any data used by the State to determine that unreasonable adverse effects will not be caused when the State registers any use described in paragraph (c)(1) of this section. Within 15 working days of receipt of such a request from EPA, the State shall submit two copies of the requested data.

(i) *Federal Register publication.* The Administrator shall publish in the FEDERAL REGISTER, on a regular basis, a summary of all State registrations made under sec. 24(c) during a previous reporting period established by the Administrator. For each product or use registered, the notice shall indicate:

(1) The name of the product.

(2) The name of the registrant.

(3) The registered use(s) of the product.

(4) The effective date of the State registration.

(5) If the registration is for an additional use of a federally registered product, whether the State registration involves a changed use pattern.

(j) *Electronic reporting under State registration of pesticide products for special local needs.* States that choose to receive electronic documents under the regulations pertaining to state registration of pesticides to meet special local needs, must ensure that the requirements of 40 CFR Part 3—(Electronic reporting) are satisfied by their state procedures for such registrations.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988; 60 FR 32097, June 19, 1995; 70 FR 59888, Oct. 13, 2005; 73 FR 75597, Dec. 12, 2008]

§ 162.154 Disapproval of State registrations.

(a) *General disapprovals.* (1) Except as provided in paragraph (b) of this section, the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have both a similar composition and a similar use pattern; provided that the Administrator may not disapprove such a registration solely because of a lack of essentiality. Grounds for disapproval of State registrations not involving similar products may include, but are not limited to:

(i) Probable creation of unreasonable adverse effects on man or the environment by the registered use.

(ii) Refusal of the registering State to submit information supporting the registration as required by § 162.153(h).

(iii) Failure of information submitted by the State to support the State's decision to issue the registration under standards established by § 162.153.

(2) Prior to disapproval of any State registration under this paragraph, the Administrator shall notify the registering State, in writing, of the Administrator's intent to disapprove, and of the reasons for disapproval. The notice of intent will provide a reasonable time, not less than ten days from the date the notice is received by the State, for the State to respond, and will invite the State to consult with the Administrator or his designee. If the grounds for disapproval are based on actions or omissions by the State, the notice will, if possible, also provide the State with a reasonable amount of time in which to take corrective action, not to exceed the time allowed for disapproval under paragraph (c) of this section.

(3) The registering State may, within ten days of receipt of a notice of intent to disapprove, request that the Administrator, or his designee, consult with appropriate State officials prior to the Administrator's final decision on disapproval. The Administrator will consider any relevant information presented at such a consultation, or in any other timely and appropriate fashion, in deciding whether to withdraw the notice of intent to disapprove.

(b) *Special disapprovals.* (1) The Administrator may disapprove any State registration, including a registration for a similar product, at any time, if the Administrator determines that use of the product under the State registration:

(i) Would constitute an imminent hazard.

(ii) May result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a *et seq.*).

(2) If the Administrator disapproves a registration under this paragraph, the Administrator shall provide the registering State with written notification of disapproval, in accordance with paragraph (c) of this section, as soon thereafter as practicable. Such notification will specify the grounds for disapproval and invite the State to comment on the decision.

(3) If requested by the State within ten days of its receipt of a notice of disapproval, the Administrator, or his designee, will consult with appropriate State officials. The Administrator may consider any information presented at such a consultation, or in any other appropriate fashion, in determining whether the disapproval should be rescinded.

(c) *Decision and notification of disapproval.* Except as provided in paragraph (b)(1) of this section, the Administrator will make a final decision on disapproval of a State registration, and provide written notification thereof to the State, within 90 days of the effective date of the registration; provided that, if the State does not notify the Agency of a registration within ten days of its effective date, then the Administrator will make a final decision on disapproval within 90 days of the date on which EPA receives notification of the State registration. The notice of disapproval will specify an appropriate date on which the disapproval will become effective. Disapproval may become effective immediately, or at anytime within the period allowed for the Administrator to make a final decision on disapproval. The notice of disapproval will also, when appropriate, give instructions for use or disposal of the pesticide. Each notice of disapproval will be published in the FEDERAL REGISTER.

(d) *Effect of disapproval.* If a registration issued by a State is disapproved by the Administrator, that registration will not be valid for any purpose under FIFRA, as of the date the disapproval becomes effective. Thereafter, distribution or sale of the pesticide, in either interstate or intrastate commerce, for uses subject to the disapproval will be a violation of sec. 12(a)(1) of FIFRA.

(e) *Rescission of disapproval.* If the Administrator determines, after consultation with the State lead agency, that a registration, previously issued by the State and disapproved by the Administrator, should not have been disapproved under FIFRA, then the Administrator shall rescind the disapproval. The Administrator shall send written notification of the rescission to

the State. In addition, the Administrator shall publish notice of any rescission of disapproval in the FEDERAL REGISTER.

(f) *Notification of registrants.* Any State that issues a registration which has been disapproved, or which is subject to a notice of intent to disapprove, shall be responsible for notifying the affected registrant of any such notice of intent or disapproval, and of any recession of disapproval by the Administrator.

§ 162.155 Suspension of State registration authority.

(a) *General.* (1) If the Administrator finds that a State is not capable of exercising, or has failed to exercise, adequate control over its registration program, so that the State cannot ensure that registrations issued by it will be in accord with the purposes of FIFRA, then the Administrator may suspend the State's authority to register pesticides under sec. 24(c) of the Act. Registrations issued by the State after suspension of its authority will not be considered valid under FIFRA. Registrations issued by the State prior to suspension will not be affected by the suspension.

(2) The Administrator may suspend all or any part of a State's registration authority, as appropriate.

(b) *Grounds for suspension.* (1) The Administrator may suspend a State's registration authority due to lack of, or failure to exercise, adequate control by the State over its sec. 24(c) registration program. Adequate control includes, but is not limited to, all of the following:

(i) Access to appropriate scientific and technical personnel to review data and make determinations as required by § 162.153.

(ii) Registration procedures satisfying § 162.153.

(iii) Complete and accurate records of State registrations.

(iv) Adequate legal authority. (A) To deny, suspend, revoke, or amend a State registration when the registration is not in compliance with FIFRA, this subpart, or State law, or when necessary to prevent unreasonable adverse effects on the environment.

(B) To enter, at reasonable times, by consent, warrant, or other legal means, any establishment where pesticides are produced or held for distribution or sale, to inspect, sample, and observe whether pesticides are being produced or distributed in compliance with FIFRA, this subpart, State law, and the terms of any State registration.

(2) The Administrator may suspend a State's registration authority if the State fails to exercise the controls specified in paragraph (b)(1) of this section, or if the State refuses to correct within a reasonable time any other significant deficiencies in its regulatory program, as specified by the Administrator in a notice of intent to suspend.

(c) *Procedures for suspension.* (1) Prior to suspending the registration authority of any State, the Administrator will notify the State lead agency, in writing, of the Administrator's intent to suspend, and of the specific grounds for suspension. The notice of intent will specify whether the suspension will be complete or partial, and will provide the State an opportunity to respond and a reasonable amount of time, not less than 30 days from the date the notice is received, in which to correct the deficiencies specified in the notice. If the State does not correct the specified deficiencies within the reasonable time allowed by the notice, or if the Administrator has not withdrawn the notice of intent before that time, the notice of intent will be published in the FEDERAL REGISTER, and the public given an opportunity to comment thereon.

(2) If requested by the affected State lead agency within 30 days of receipt of the notice of intent to suspend, an informal consultation between appropriate State and EPA officials will be held to discuss the proposed suspension. In such a case, the Administrator shall not make a final decision on the proposed suspension until after the consultation. The Administrator shall consider all relevant information presented at the consultation, or in any other appropriate manner, in determining whether to suspend the State's authority. If the Administrator determines, on the basis of such information, that the deficiencies listed in the notice of intent no longer exist, or will

be corrected in a reasonable time, then the Administrator will withdraw, in writing, the notice of intent to suspend.

(3) Within ten days of the date a notice of intent to suspend is published in the FEDERAL REGISTER, a State may request a public hearing to consider the proposed suspension. If a hearing is requested, the Administrator will:

(i) Schedule a public hearing to be held in that State.

(ii) Publish in the FEDERAL REGISTER a notice announcing the date, time, and location of the hearing.

(iii) Appoint a presiding officer who shall preside over the hearing.

(iv) Prescribe additional, appropriate procedures for the conduct of the hearing, including procedures for the presentation of relevant material evidence from the State, EPA, or members of the public who would be affected by the outcome of the hearing. Evidence may be presented in either oral or written form, at the discretion of the Administrator.

(4) Following the close of any hearing held under paragraph (c)(3) of this section, the presiding officer shall make a recommended decision that the State's authority to register pesticides under sec. 24(c) of FIFRA be suspended, in whole or in part, or that the State's authority not be suspended and that the notice of intent to suspend be withdrawn.

(5) Any recommended decision made by a presiding officer under paragraph (c)(4) of this section may be appealed to the Administrator within 30 days after its issuance by the State or by EPA. Any recommended decision which is not appealed, or which the Administrator does not review on his own initiative, will become a final Agency action 30 days after its issuance.

(6) If no hearing is requested under paragraph (c)(3) of this section, or if a recommended decision is appealed to the Administrator under paragraph (c)(5) of this section, the Administrator shall issue a final order either suspending the State's authority to register pesticides under section 24(c) of FIFRA, in whole or in part, or withdrawing the notice of intent to suspend.

(7) Any final order suspending State registration authority, issued under paragraph (c) (5) or (6) of this section, will specify the grounds therefor and an effective date for the suspension. If the suspension is merely partial, the notice of suspension will specify the types of registrations which will not be recognized as valid under sec. 24(c). All final orders issued under paragraph (c) (5) or (6) will be published in the FEDERAL REGISTER.

(d) *Termination of suspension.* Suspension of a State's authority will be effective for the period specified in the notice of suspension, or if no period was specified, until such time as the Administrator is satisfied that the State can and will exercise adequate control over its program. In the latter case, the Administrator will notify the State that the suspension is terminated, or that it will be terminated on a specific date. In either case, the Administrator will publish a notice of the termination of suspension in the FEDERAL REGISTER.

(e) *Judicial review.* Any State whose authority to register pesticides has been finally suspended by the Administrator may seek judicial review of the Administrator's decision under sec. 16 of FIFRA, at any time prior to termination of the suspension. Such suspension shall remain in effect during the period of judicial review unless otherwise ordered by the Administrator.

§ 162.156 General requirements.

(a) *Requirements for distribution and use.* (1) Any product whose State registration has been issued in accordance with §§ 162.152 and 162.153 may be distributed and used in that State, subject to the following provisions of the Act and the regulations promulgated thereunder:

(i) Sec. 12(a)(1) (A) through (E), in accordance with:

(A) Sec. 2(q)(1) (A) through (G).

(B) Sec. 2(q)(2) (A) through (D).

(ii) Sec. 12(a)(2) (A) through (G) and (I) through (P).

(2) A product or use classified by a State for restricted use under § 162.153(g) may be used only by, or

under the direct supervision of, an applicator certified under a plan approved by EPA in accordance with sec. 4 of FIFRA.

(3) State registrations which are not issued in accordance with §162.152 (a) and (b)(2) (i), (ii) and (iii) are not authorized by section 24(c) and are not considered valid for any purposes under FIFRA. When the Administrator determines that a registration is invalid, the Administrator shall notify the registering State that the registration is invalid, and may specify the reason for the invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with sec. 7 of FIFRA and 40 CFR part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under sec. 24(c), must maintain records in accordance with the requirements imposed under sec. 8 of FIFRA and 40 CFR part 169.

Subpart E [Reserved]

PART 164—RULES OF PRACTICE GOVERNING HEARINGS, UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, ARISING FROM REFUSALS TO REGISTER, CANCELLATIONS OF REGISTRATIONS, CHANGES OF CLASSIFICATIONS, SUSPENSIONS OF REGISTRATIONS AND OTHER HEARINGS CALLED PURSUANT TO SECTION 6 OF THE ACT

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AUTHORITY: 7 U.S.C. 136d.

SOURCE: 38 FR 19371, July 20, 1973, unless otherwise noted.

Subpart A—General

§ 164.1 Number of words.

As used in this part, a word in the singular form shall be deemed to import the plural, and vice versa, as the case may require.

§ 164.2 Definitions.

For the purposes of this part, the following terms shall be defined, as listed below:

(a) The term *Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973) and other legislation supplementary thereto and amendatory thereof.

(b) The term *Administrative Law Judge* means an Administrative Law Judge appointed pursuant to 5 U.S.C. 3105 (see also 5 CFR part 930, as amended), and such term is synonymous with the term ''Hearing Examiner'' as used in the Act or in the United States Code.

(c) The term *Administrator* means the Administrator of the United States Environmental Protection Agency.

(d) The term *Agency*, unless otherwise specified, means the United States Environmental Protection Agency.

(e) The term *Applicant* means any person who has made application to have a pesticide registered or classified pursuant to the provisions of the Act.

(f) The term *Committee* means a group of qualified scientists designated by the National Academy of Sciences according to agreement under the Act to submit an independent report to the Administrative Law Judge on questions of scientific fact referred from a hearing under subpart B of this part.

(g) *Environmental Appeals Board* shall mean the Board within the Agency described in §1.25 of this title. The Administrator delegates authority to the Environmental Appeals Board to issue final decisions in appeals filed under subparts B and C of this part. An appeal directed to the Administrator, rather than to the Environmental Appeals Board, will not be considered. This delegation does not preclude the Environmental Appeals Board from referring an appeal or a motion under subparts B and C to the Administrator when the Environmental Appeals Board, in its discretion, deems it appropriate to do so. When an appeal or motion is referred to the Administrator, all of the parties shall be so notified and the rules in subparts B and C referring to the Environmental Appeals Board shall be interpreted as referring to the Administrator.

(h) The term *Expedited Hearing* means a hearing commenced as the result of the issuance of a notice of intention to suspend or the suspension of a registration of a pesticide by an emergency order, and is limited to a consideration as to whether a pesticide presents an imminent hazard which justifies such suspension.

(i) The term *Hearing* means a public hearing which is conducted pursuant to the provisions of chapter 5, subchapter II of title 5 of the United States Code and the regulations of this part.

(j) The term *Hearing Clerk* means the Hearing Clerk, Environmental Protection Agency, Washington, DC 20460.

(k) The term *Initial Decision* means the decision of the Administrative Law Judge supported by findings of fact and conclusions regarding all material issues of law, fact, or discretion, as well as reasons therefor. Such decision shall become the final decision and order of the Administrator without further proceedings unless an appeal

therefrom is taken or the Administrator orders review thereof as herein provided.

(l) The term *Judicial Officer* means an officer or employee of the Agency designated as a judicial officer, pursuant to these rules, who shall meet the qualifications and perform functions as herein provided.

(1) *Office.* There may be designated for the Agency one or more judicial officers, one of whom may be Chief Judicial Officer. As work requires, there may be a judicial officer designated to act for the purpose of a particular case. All prior designations of judicial officer shall stay in force until further notice.

(2) *Qualification.* A judicial officer shall be a permanent or temporary employee or officer of the Agency who may perform other duties for the Agency. Such judicial officer shall not be employed by the Office of Prevention, Pesticides, and Toxic Substances or have any connection with the preparation or presentation of evidence for a hearing.

(3) *Functions.* The Administrator may delegate any or part of his authority to act in a given case under subparts B and C of this part to a judicial officer. The Administrator can separately delegate his authority to rule on interlocutory orders and motions, and may also delegate his authority to make findings of fact and draw conclusions of law in a particular proceeding, providing that this delegation shall not preclude the Judicial Officer from referring any motion or case to the Administrator when the Judicial Officer determines such referral to be appropriate. The Administrator, in deciding a case himself, may consult with and assign the preliminary drafting of conclusions of law and findings of fact to any judicial officer.

(m) The term *Party* means any person, group, organization, or Federal agency or department that participates in a hearing.

(n) The term *Person* includes any individual, partnership, association, corporation, and any organized group of persons, whether incorporated or not.

(o) The term *Petitioner* means any person adversely affected by a notice of the Administrator who requests a public hearing.

(p) The term *Presiding Officer* means any person designated by the Administrator to conduct an expedited hearing.

(q) The term *Recommended Decision* means the recommended findings and conclusions of the Presiding Officer in an expedited hearing.

(r) The term *Registrant* means any person who has registered a pesticide pursuant to the provisions of the Act.

(s) The term *Respondent* means the Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances.

Terms defined in the act and not explicitly defined herein are used herein with the meanings given in the act.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5342, Feb. 13, 1992; 57 FR 30657, July 10, 1992; 73 FR 75597, Dec. 12, 2008]

§ 164.3 Scope and applicability of this part.

The provisions of subpart B of this part shall govern proceedings, conducted pursuant to the provisions of the Act, concerning refusals to register, cancellations of registration, changes of classifications or hearings called by the Administrator; the provisions of subpart C of this part shall govern suspension proceedings conducted pursuant to the provisions of the Act.

§ 164.4 Arrangements for examining Agency records, transcripts, orders, and decisions.

(a) *Reporting of orders, decisions, and other signed documents.* All orders, decisions, or other signed documents required by the rules in this part, whether issued by the Environmental Appeals Board or the Presiding Officer shall be made available to the public.

(b) *Establishment of an Agency repository.* In addition, all transcripts and docket entries shall become part of the official docket and shall be retained by the hearing clerk. At least two copies of all final orders, decisions and a notification of any appeals taken therefrom shall be retained by the hearing clerk and filed chronologically and shall be periodically bound and indexed. All the above documents shall

be made available to the public for reasonable inspections during Agency business hours.

(c) Whenever any information or data is required to be produced or examined and any party to the proceeding claims that such information is a trade secret or commercial or financial information, other than information relating to the formulas of a pesticide, the Administrative Law Judge, the Presiding Officer, or the Environmental Appeals Board may require production or testimony *in camera* and sealed to all but the parties.

(d) All orders, decisions, or other documents made or signed by the Administrative Law Judge, the Presiding Officer, or the Environmental Appeals Board shall be filed with the hearing clerk. The hearing clerk shall immediately serve all parties with a copy of such order, decision, or other document.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5342, Feb. 13, 1992]

§ 164.5 Filing and service.

(a) All documents or papers required or authorized to be filed, shall be filed with the hearing clerk, except as provided otherwise in this part. At the same time that a party files documents or papers with the clerk, it shall serve upon all other parties copies thereof, with a certificate of service on each document or paper, including those filed with the hearing clerk. If filing is accomplished by mail addressed to the clerk, filing shall be deemed timely if the papers are postmarked on the due date except as to initial filings requesting a public hearing or responding to a notice of intent to hold a hearing, in which case such filings must be received by the hearing clerk either within the time required by statute or by the notice of intent to hold a hearing.

(b) Each document filed, other than papers commencing a proceeding, shall contain the FIFRA docket number and, if the document affects less than all of the registrations included under that docket number, the registration number or file symbol of each product which is the subject of the document.

(c) In addition to copies served on all other parties, each party shall file an original and two copies of all papers with the hearing clerk.

§ 164.6 Time.

(a) *Computation.* In computing any period of time prescribed or allowed by these rules, except as otherwise provided, the day of the act, event, or default from which the designated period of time begins to run shall not be included. Saturdays, Sundays, and legal holidays shall be included in computing the time allowed for the filing of any document or paper, except that when such time expires on a Saturday, Sunday, or legal holiday, such period shall be extended to include the next following business day.

(b) *Enlargement.* When by these rules or by order of the Administrative Law Judge, the Presiding Officer, or the Environmental Appeals Board, an act is required or allowed to be done at or within a specified time, the Administrative Law Judge (before his initial decision is filed), or the Presiding Officer (before his recommended decision is filed), or the Environmental Appeals Board (after the Administrative Law Judge's initial decision or the presiding officer's recommended decision is filed), for cause shown may at any time in their discretion: with or without motion or notice, order the period enlarged if request therefor, which may be made ex parte, is made before the expiration of the period originally prescribed or as extended by a previous order; or on motion made after the expiration of the specified period, permit the act to be done where the failure to act was the result of excusable neglect. In this connection, consideration shall be given to the fact that, under the provisions of the act, the Administrator must issue his order not later than 90 days after the completion of the hearing, unless all parties agree by stipulation to extend this period of time pursuant to § 164.103.

(c) *Additional time after service by mail.* A prescribed period of time within which a party is required or permitted to do an act shall be computed from the time of service, except that when the service is made by mail, 3 days shall be added to the prescribed period. Such addition for service by mail shall not apply in the case of filing initial

requests for hearings or responding to a notice of intent to hold a hearing, in which cases statutory filing times will run from the date of the return receipt pursuant to § 164.8.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5342, Feb. 13, 1992]

§ 164.7 Ex parte discussion of proceeding.

At no stage of a proceeding shall the Administrator, the members of the Environmental Appeals Board, the Presiding Officer, or the Administrative Law Judge discuss *ex parte* the merits of the proceeding with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate, or in an investigative or expert capacity, or with any representative of such person, *Provided,* That the Environmental Appeals Board, the Presiding Officer, or the Administrative Law Judge may discuss the merits of the case with any such person if all parties to the proceeding, or their representatives, have been given reasonable notice and opportunity to be present. Any memorandum or other communication addressed to the Administrator, the Environmental Appeals Board, the Presiding Officer, or the Administrative Law Judge during the pendency of the proceeding, and relating to the merits thereof, by or on behalf of any party, shall be regarded as an argument made in the proceeding. The Administrator, the Environmental Appeals Board, the Presiding Officer, or the Administrative Law Judge shall cause any such communication to be filed with the hearing clerk and served upon all other parties to the proceeding who will be given the opportunity to file an answer thereto.

[57 FR 5342, Feb. 13, 1992]

§ 164.8 Publication.

All notices of intention to cancel a registration, all notices of intention to change a classification, and all denials of registrations, all together with the reasons (including the factual basis therefor), and all notices of intention by the Administrator to hold a hearing, together with the statement of issues as provided by § 164.20(b) shall be sent to the registrant or applicant by registered or certified mail (return receipt requested), and published by appropriate announcement in the FEDERAL REGISTER by the Administrator. The Administrative Law Judge shall cause to be published in the FEDERAL REGISTER by appropriate announcement, a notice of the filing of any objections, pursuant to § 164.20(b) or responses pursuant to § 164.24, and a notice of the public hearing as provided by § 164.80 *et seq.* Said notice of public hearing shall designate the place where the hearing will be held and specify the time when the hearing will commence. The hearing shall convene at the place and time announced in the notice, unless amended by subsequent notice published in the FEDERAL REGISTER, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof at the hearing.

Subpart B—General Rules of Practice Concerning Proceedings (Other Than Expedited Hearings)

COMMENCEMENT OF PROCEEDING

§ 164.20 Commencement of proceeding.

(a) A proceeding shall be commenced whenever a hearing is requested by any person adversely affected by a notice of the Administrator of his refusal to register or of his intent to cancel the registration or to change the classification of a pesticide. A proceeding shall likewise be commenced whenever the Administrator decides to call a hearing to determine whether or not the registration of a pesticide should be canceled or its classification changed. Such request or notice of intent to hold a hearing shall be timely filed with the hearing clerk, and the matter shall be docketed and assigned a FIFRA docket number.

(b) If a request for a hearing is filed, the person filing the request shall, at the same time, file a document stating his objections to the Administrator's refusal to register or his intent to cancel the registration or to change the classification of a pesticide. If a notice of intent to hold a hearing is filed by

the Administrator, he shall, at the same time, file a statement of issues.

(c) Upon the filing of any objections or notice of intent to hold a hearing, the proceeding shall be referred to the Chief Administrative Law Judge by the hearing clerk. The Chief Administrative Law Judge shall refer the proceeding to himself or another Administrative Law Judge who shall thereafter be in charge of all further matters concerning the proceedings, except as otherwise provided for by order of the Chief Administrative Law Judge, the Administrator, or the Environmental Appeals Board.

[38 FR 19371, July 20, 1973, as amended at 38 FR 34117, Dec. 11, 1973; 57 FR 5342, Feb. 13, 1992]

§ 164.21 Contents of a denial of registration, notice of intent to cancel a registration, or notice of intent to change a classification.

(a) *Contents.* The denial of registration or a notice of intent to cancel a registration or to change a classification shall be accompanied by the reasons (including the factual basis) for the action.

(b) *Amendments to contents of denials and notices.* Such documents under this section may be amended or enlarged by the Administrator at any time prior to the commencement of the public hearing. If the Administrative Law Judge determines that additional time is necessary to permit a party to prepare for matters raised by such amendments, the commencement of the hearing shall be delayed for an appropriate period.

§ 164.22 Contents of document setting forth objections.

(a) *Concise statement required.* Any document containing objections to an order of the Administrator of his refusal to register, or his intent to cancel the registration, or change the classification of a pesticide, shall clearly and concisely set forth such objections and the basis for each objection, including relevant allegations of fact concerning the pesticide under consideration. The document shall indicate the registration number of the pesticide, if applicable, a copy of the currently accepted and/or proposed labeling and a list of the currently registered or proposed uses of said pesticide.

(b) *Amendments to objections byleave.* Objections may be amended at any time prior to the commencement of the public hearing by leave of the Administrative Law Judge or by written consent of all parties. The Administrative Law Judge shall freely grant such leave when justice so requires. If the Administrative Law Judge determines that additional time is necessary to permit a party to prepare for matters raised by amendments to objections, the commencement of the hearing shall be delayed for an appropriate period. This subsection shall not permit the addition, beyond the statutory deadline, of registered pesticides which are not included in the objections filed pursuant to paragraph (a) of this section.

(c) *Amendments to objections as a matter of right.* Objections may be amended as a matter of right within 30 days, or in such time as the Administrator shall designate, after the Administrator amends his notice of intent to cancel a registration, change a classification, or his refusal to register a pesticide.

§ 164.23 Contents of the statement of issues to accompany notice of intent to hold a hearing.

(a) *Concise statement required.* The statement of issues by the Administrator shall set a time in which any person wishing to participate in the hearing shall file a written response to the statement of issues as provided by § 164.24. The statement of issues shall include questions as to which evidence shall be taken at the hearing. Those questions may include questions concerning whether a pesticide's registration should be canceled or its classification changed, whether its composition is such as to warrant the claims for it, whether its labeling and other material submitted comply with the requirements of the Act, whether it will perform its intended function without unreasonable adverse effects on the environment, and whether, when used in accordance with widespread and commonly recognized practice, it will or will not generally cause unreasonable adverse effects on the environment.

(b) *Amendment to statement of issues.* The statement of issues may be amended or enlarged by the Administrator at any time prior to the commencement of the public hearing. If the Administrative Law Judge determines that additional time is necessary to permit a party to prepare for matters raised by amendments or enlargements to the statement of issues, the commencement of the hearing shall be delayed for an appropriate period.

§ 164.24 Response to the Administrator's notice of intention to hold a hearing.

Any person wishing to participate in any proceeding commenced pursuant to any notice by the Administrator of intention to hold a hearing, shall file with the hearing clerk, within the time set by the Administrator in the notice (in no case less than 30 days from the date of the notice), a written response to the statement of issues which shall include the position and interest of such person with respect thereto. If any such person is a registrant or an applicant for registration, he shall also file the registration number of the pesticide, if applicable, a copy of the currently accepted and/or proposed labeling and a list of the currently registered or proposed uses of said pesticide.

§ 164.25 Filing copies of notification of intent to cancel registration or change classification or refusal to register, and statement of issues.

After a copy of the document setting forth the objections and requesting a public hearing is filed with the hearing clerk or a response to the statement of issues is filed, the hearing clerk shall serve a copy of the document upon Respondent and the Office of the General Counsel of the Agency, Respondent shall, by counsel, thereupon file with the hearing clerk a copy of the appropriate notice of intention to cancel, the notice of intention to change the classification or the registration refusal order.

APPEARANCES, INTERVENTION, AND CONSOLIDATION

§ 164.30 Appearances.

Representatives. Parties may appear in person or by counsel or other representative. Persons who appear as counsel or in a representative capacity must conform to the standards of ethical conduct required of practitioners before the courts of the United States.

§ 164.31 Intervention.

(a) *Motion.* Any person may file a motion for leave to intervene in a hearing conducted under this subpart. A motion must set forth the grounds for the proposed intervention, the position and interest of the movant in the proceeding and the documents proposed to be filed pursuant to either § 164.22 or § 164.24.

(b) *When filed.* A motion for leave to intervene in a hearing must ordinarily be filed prior to the commencement of the first prehearing conference. Any motion filed after that time must contain, in addition to the information set forth in paragraph (a) of this section, a statement of good cause for the failure to file the motion prior to the commencement of the first prehearing conference, and shall be granted only upon a finding (1) that extraordinary circumstances justify the granting of the motion, or (2) that the intervenor shall be bound by agreements, arrangements, and other matters previously made in the proceeding.

(c) *Disposition.* Leave to intervene will be freely granted but only insofar as such leave raises matters which are pertinent to and do not unreasonably broaden the issues already presented. If leave is granted, the movant shall thereby become a party with the full status of the original parties to the proceedings. If leave is denied, the movant may request that the ruling be certified to the Environmental Appeals Board, pursuant to § 164.100 for a speedy appeal.

(d) *Amicus curiae.* Persons not parties to the proceedings wishing to file briefs may do so by leave of the Administrative Law Judge granted on motion. A motion for leave shall identify the interest of the applicant and shall state the reasons why the proposed amicus

brief is desirable. Unless all parties otherwise consent, an amicus curiae shall file its brief within the time allowed the party whose position the brief will support. Upon a showing of good cause, the Administrator or Administrative Law Judge may grant permission for later filing.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5342, Feb. 13, 1992]

§ 164.32 Consolidation.

The Chief Administrative Law Judge, by motion or sua sponte, may consolidate two or more proceedings whenever it appears that this will expedite or simplify consideration of the issues. Consolidation shall not affect the right of any party to raise issues that could have been raised if consolidation had not occurred. At the conclusion of proceedings consolidated under this section, the Administrative Law Judge shall issue one decision under § 164.90 unless one or more of the consolidated proceedings have been dismissed pursuant to § 164.91.

ADMINISTRATIVE LAW JUDGE

§ 164.40 Qualifications and duties of Administrative Law Judge.

(a) *Qualifications.* The Administrative Law Judge shall have the qualifications required by statute. He shall not decide any matter in connection with a proceeding where he has a financial interest in any of the parties or a relationship with a party that would make it otherwise inappropriate for him to act.

(b) *Disqualification of the Administrative Law Judge.* (1) Any party may, by motion made to the Administrative Law Judge, as soon as practicable, request that he disqualify himself and withdraw from the proceeding. The Administrative Law Judge shall then rule upon the motion and, upon request of the movant, shall certify an adverse ruling for appeal.

(2) Withdrawal sua sponte. The Administrative Law Judge may at any time withdraw from any proceedings in which he deems himself disqualified for any reason.

(c) *Conduct.* The Administrative Law Judge shall conduct the proceeding in a fair and impartial manner subject to the precepts of the Canons of Judicial Ethics of the American Bar Association.

(d) *Power.* Subject to review, as provided elsewhere in this part, the Administrative Law Judge shall have power to take actions and decisions in conformity with statute or in the interests of justice. The Administrative Law Judge shall not interrupt the recording of the proceedings on the record over the objection of any party.

(e) *Absence or change of the Administrative Law Judge.* In the case of the absence or unavailability of the Administrative Law Judge, or his inability to act, or his removal by disqualification or withdrawal, the powers and duties to be performed by him under this part in connection with a hearing assigned to him may, unless otherwise directed by the Administrator, be assigned to another Administrative Law Judge so designated to act by the Chief Administrative Law Judge, the Administrator or the Environmental Appeals Board.

[38 FR 19371, July 20, 1973, as amended at 38 FR 34117, Dec. 11, 1973; 57 FR 5342, Feb. 13, 1992]

PREHEARING PROCEDURES AND DISCOVERY

§ 164.50 Prehearing conference and primary discovery.

(a) *Purpose of the prehearing conference.* Except as otherwise provided in paragraph (d) of this section, the Administrative Law Judge shall, prior to the commencement of the hearing and for the purpose of expediting the hearing, file with the hearing clerk an order for a prehearing conference. More than one such conference may be held. Such order or orders shall direct the parties or their counsel to appear at a specified time and place to consider:

(1) The simplification of issues including listing of specific uses to be contested;

(2) The necessity or desirability of amendments to the objections or statement of issues, or any document filed in response thereto;

(3) The possibility of obtaining stipulations of fact and documents which will avoid unnecessary delay;

(4) Matters of which official notice may be taken;

(5) The limitation of the number of expert and other witnesses;

(6) Procedure at the hearing except as so provided in § 164.80(a);

(7) The use of verified written statements in lieu of oral direct testimony;

(8) The intent of any party to request a scientific advisory committee as defined in § 164.2(f);

(9) The issuance of subpoenas and subpoenas duces tecum for discovery and hearing purposes;

(10) A setting of a time and place for the public hearing, after giving careful consideration to the convenience of all the parties, the witnesses, the public interest and the necessity for notice in the FEDERAL REGISTER as provided by § 164.8; and

(11) Any other matter that may expedite the hearing or aid in the disposition of the proceeding.

(b) *Primary discovery* (*Exchange of witness lists and documents*). At a prehearing conference or within some reasonable time set by the Administrative Law Judge prior to the hearing, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits which the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended upon motion by a party.

(c) *Record of the prehearing conference.* No transcript of any prehearing conference shall be made unless a request therefor by one of the parties is granted by the Administrative Law Judge. Such party shall bear the cost of the taking of the transcript unless otherwise ordered by the Administrative Law Judge. The Administrative Law Judge shall prepare and file for the record a written report of the action taken at each conference, which shall incorporate any stipulations or agreements made by the parties at or as a result of such conference, all rulings upon matters considered at such conference and appropriate orders.

(d) *Unavailability of a prehearing conference.* Upon a finding that circumstances render a prehearing conference unnecessary, or impracticable, or upon a finding that a prehearing conference would serve primarily to delay the proceedings rather than to expedite them, the Administrative Law Judge, on motion or sua sponte, may order that the prehearing conference not be held. In these circumstances he may request the parties to correspond with him for the purpose of accomplishing any of the objectives set forth in this section. Such correspondence shall not be made a part of the record, but the Administrative Law Judge shall submit a written summary for the record if any action is taken.

(e) *Submission of questions to an advisory committee*—(1) *General.* At any prehearing conference, or if none is held prior to the public hearing, except as herein provided, the Administrative Law Judge shall determine whether any party desires that questions of scientific fact be referred to a committee designated by the National Academy of Sciences.

(2) *Preparation of questions.* On determining an affirmative intent, the Administrative Law Judge shall direct all parties to file and serve, within a time period subject to his discretion, proposed questions of scientific fact accompanied by reasons supporting their submission to said committee. Within 10 days of the service of such proposed questions, together with their supporting reasons, any party may respond in writing to the proposed submission of the questions to the said committee. The Administrative Law Judge shall determine whether or not a reference of questions of scientific fact to said committee is necessary or desirable. In the event he decides such reference is necessary or desirable, he shall so inform the National Academy in writing, and shall prepare in his discretion appropriate questions. If any of the questions prepared are not in substance based upon the submissions of the parties, the Administrative Law Judge shall permit any party 10 days after their preparation to respond in writing to the proposed submission of said question or questions. He shall then determine whether such questions should be referred to the committee.

(3) *Reference and report.* Not less than 30 days after he has informed the National Academy that questions of scientific fact will be referred to it, the Administrative Law Judge shall refer the questions of scientific fact as prepared. The committee shall report in writing to the Administrative Law Judge within 60 days after such referral on these questions of scientific fact and the report, its record and any other matter transmitted as provided for by the Administrator's agreement with the National Academy of Sciences shall be made public and considered as part of the hearing record.

(4) *Request and submission subsequent to prehearing conference.* At any time before the hearing is closed, the Administrative Law Judge or a party by motion may request that questions of scientific fact not previously referred be referred, or that questions previously referred be amended or expanded. The Administrative Law Judge may refer such questions if he finds that good cause exists and that reference of such questions is necessary or desirable.

[38 FR 19371, July 20, 1973, as amended at 39 FR 11884, Apr. 1, 1974]

§ 164.51 Other discovery.

(a) *General.* Except as so provided by § 164.50(b) *supra,* further discovery, under this subpart, shall be permitted only upon determination by the Administrative Law Judge (1) that such discovery shall not in any way unreasonably delay the proceeding, (2) that the information to be obtained is not otherwise obtainable and (3) that such information has significant probative value. The Administrative Law Judge shall be guided by the procedures set forth in the Federal Rules of Civil Procedure, where practicable, and the precedents thereunder, except that no discovery shall be undertaken except upon order of the Administrative Law Judge or upon agreement of the parties.

(b) *Depositions upon oral questions.* The Administrative Law Judge shall order depositions upon oral questions only upon a showing of good cause and upon a finding that (1) the information sought cannot be obtained by alternative methods, or (2) there is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

(c) *Procedure.* (1) Any party to the proceeding desiring discovery shall make a motion or motions therefor. Such a motion shall set forth (i) the circumstances warranting the taking of the discovery, (ii) the nature of the information expected to be discovered and (iii) the proposed time and place where it will be taken.

(2) If the Administrative Law Judge determines the motion should be granted, he shall issue an order and appropriate subpoenas, if necessary, for the taking of such discovery together with the conditions and terms thereof.

MOTIONS

§ 164.60 Motions.

(a) *General.* All motions, except those made orally during the course of a public hearing or as otherwise provided by this part, shall be in writing and shall state with particularity the grounds therefor, shall set forth the relief or order sought, and shall be filed with the hearing clerk and served on all parties.

(b) *Response to motions.* Within 10 days after service of any motion filed pursuant to this part, or within such other time as may be fixed by the Administrator, his designee, or the Administrative Law Judge, any party may serve and file an answer to the motion. The movant shall, if requested by the Administrator, his designee, or the Administrative Law Judge, serve and file reply papers within the time set by the request.

(c) *Decision.* The Administrative Law Judge shall rule upon all motions filed or made prior to the filing of his initial or accelerated decision at the time of filing on ex parte motions or where the movant has stated that no party objects to the granting of such motion. Otherwise, such decision shall await the answering papers and reply papers if permitted. The Environmental Appeals Board shall rule upon all motions filed after the filing of the initial or accelerated decision. Oral argument of motions will be permitted only if the

Administrative Law Judge or the Environmental Appeals Board deems it necessary.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5343, Feb. 13, 1992]

SUBPOENAS AND WITNESS FEES

§ 164.70 Subpoenas.

(a) The attendance of witnesses or the production of documentary evidence may, by subpoena, be required at any designated place of hearing or place of discovery. Subpoenas may be issued by the Administrative Law Judge sua sponte or upon a showing by an applicant that evidence sought for hearing is relevant and material to the issues involved in the hearing or that the sought discovery pursuant to § 164.51 meets the standards set forth therein. The Administrative Law Judge shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of a witness or the content of the documents produced.

(b) *Motion for subpoena duces tecum.* Subpoenas for the production of documentary evidence, unless issued by the Administrative Law Judge sua sponte, shall be issued only upon a written motion. Such motion shall specify, as exactly as possible, the documents desired.

(c) *Service of subpoenas.* Subpoenas shall be served as provided by the Federal Rules of Civil Procedure.

§ 164.71 Fees of witnesses.

Witnesses summoned before the Administrative Law Judge shall be paid the same fees and mileage that are paid witnesses in the courts of the United States, and persons whose depositions are taken, and the persons taking the same, shall be entitled to the same fees as are paid for like services in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears or the deposition is taken.

THE HEARINGS

§ 164.80 Order of proceeding and burden of proof.

(a) At the hearing, the proponent of cancellation or change in classification has the burden of going forward to present an affirmative case for the cancellation or change in classification of the registration. In the case of the denial of an application for registration, the applicant shall have the burden of going forward. In the case of a hearing called by the Administrator, the Respondent has the burden of going forward to present an affirmative case as to the statement of issues. The party having the burden of going forward shall have the opportunity to submit evidence on rebuttal.

(b) On all issues arising in connection with the hearing, the ultimate burden of persuasion shall rest with the proponent of the registration.

(c) If any party, other than Respondent, after being duly notified, fails to appear at the hearing, he shall be deemed to have authorized the Administrative Law Judge to dismiss the proceeding with or without prejudice, as the Administrative Law Judge may determine, unless a motion excusing the failure to appear has been made and granted. In the event that a party appears at the hearing and no representative of the Agency appears, the Administrative Law Judge shall proceed *ex parte* to hear the evidence of the party: *Provided,* That failure on the part of Respondent to appear at a hearing shall not be deemed to be a waiver of Respondent's right to file proposed findings of fact, conclusions of law and orders, to be served with a copy of the Administrative Law Judge's initial or accelerated decision, and to file exceptions with and to submit argument before the Administrator with respect thereto.

§ 164.81 Evidence.

(a) *General.* The Administrative Law Judge shall admit all relevant, competent and material evidence, except evidence that is unduly repetitious. Relevant, competent and material evidence may be received at any hearing even though inadmissible under the rules of evidence applicable to judicial proceedings. The weight to be given evidence shall be determined by its reliability and probative value. In all hearings the testimony of witnesses shall be taken orally, except as otherwise provided by these rules or by the

Administrative Law Judge. Parties, however, shall have the right to cross-examine a witness who appears at the hearing, provided that such cross examination is not unduly repetitious.

(b) *Report of a committee of the National Academy of Sciences.* If questions have been submitted to a committee designated by the National Academy pursuant to § 164.50(e), the report of the committee, other material that may be required by the Administrator and a list of witnesses and evidence relied upon shall be received into evidence and made part of the record of the hearing. Objections to the report may also be made part of the record and go to the weight of its evidentiary value.

(c) *Objections.* If a party objects to the admission or rejection of any evidence or the limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection. The transcript shall include any argument or debate thereon, unless the Administrative Law Judge, with the consent of all parties, orders that such argument not be transcribed. The ruling and the reasons given therefor by the Administrative Law Judge on any objection shall be a part of the transcript. An automatic exception to that ruling will follow.

(d) *Exhibits.* Except where the Administrative Law Judge finds that the furnishing of copies is impracticable, a copy of each exhibit filed with the Administrative Law Judge shall be furnished to each other party. A true copy of an exhibit may, in the discretion of the Administrative Law Judge, be substituted for the original.

(e) *Official Notice.* Official notice may be taken of Agency proceedings, any matter judicially noticed in the Federal courts, and of other facts within the specialized knowledge and experience of the Agency. Any active party shall be given adequate opportunity to show that such facts are erroneously noticed by presenting evidence to the contrary.

(f) *Offer of proof.* Whenever evidence is deemed inadmissible, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof for excluded oral testimony shall consist of a brief statement describing the nature of the evidence excluded. If the evidence consists of a document or exhibit, it shall be inserted in the record in total. In the event the Environmental Appeals Board decides that the Administrative Law Judge's ruling in excluding the evidence was erroneous and prejudicial, the hearings may be reopened to permit the taking of such evidence, or where appropriate, the Environmental Appeals Board may evaluate the evidence and proceed to a final decision.

(g) *Verified statements.* With the approval of the Administrative Law Judge, a witness may insert into the record, as his testimony, statements of fact or opinion prepared by him or written answers to interrogatories of counsel, or may submit as an exhibit his prepared statement, provided that such statements or answers must not include legal argument. Before any such statement or answer is read or admitted into evidence the witness shall deliver to the Administrative Law Judge, the reporter, and opposing counsel a copy of such. The admissibility of the evidence contained in such statement shall be subject to the same rules as if such testimony were produced in the usual manner and the witness shall be subject to oral cross-examination on the contents of such statements. Approval for such a procedure may be denied when it appears to the Administrative Law Judge that the memory or the demeanor of the witness is of importance.

[38 FR 19371, July 20, 1973, as amended at 40 FR 25815, June 19, 1975; 57 FR 5343, Feb. 13, 1992]

§ 164.82 Transcripts.

(a) *Filing and certification.* Hearings shall be stenographically reported, transcribed and made available to the public as required by statute or Agency regulations. As soon as practicable after the taking of the last evidence, the Administrative Law Judge shall certify (1) that the original transcript is a true transcript of the testimony offered or received at the hearing, except in such particulars as he shall specify and (2) that the exhibits accompanying the transcript are all the exhibits introduced at the hearing, with such exceptions as he shall specify. A copy of

such certificate shall be attached to each of the copies of the transcript.

(b) [Reserved]

INITIAL OR ACCELERATED DECISION

§ 164.90 Initial decision.

(a) *Proposed findings of fact, conclusions, and order.* Within 20 days after the last evidence is taken in a hearing, each party may file with the hearing clerk proposed orders, findings of fact, and conclusions of law based solely on the record, and a brief in support thereof. Within 10 days thereafter, each party may file a reply brief. The Administrative Law Judge may, in his discretion, extend the total time period for filing any proposed findings, conclusions, orders or briefs for an additional 30 days. In such instances, briefs and replies shall be due at such time as the Administrative Law Judge may fix by order. The hearing shall be deemed closed at the conclusion of the briefing period.

(b) *Initial decision.* The Administrative Law Judge, within 25 days after the close of the hearing, shall evaluate the record before him, and prepare and file his initial decision with the hearing clerk. A copy of the initial decision shall be served upon each of the parties, and the hearing clerk shall immediately transmit a copy to the Environmental Appeals Board. The initial decision shall become the decision of the Environmental Appeals Board without further proceedings unless an appeal is taken from it or the Environmental Appeals Board orders review of it, pursuant to § 164.101.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5343, Feb. 13, 1992]

§ 164.91 Accelerated decision.

(a) *General.* The Administrative Law Judge, in his discretion, may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence such as affidavits as he may receive, under any of the following conditions:

(1) Untimely or insufficient objections filed pursuant to § 164.20;

(2) Failure to comply with discovery orders;

(3) Failure to comply with prehearing orders;

(4) Failure to appear or to proceed at prehearing conferences;

(5) Failure to appear at the hearing;

(6) Failure to state a claim upon which relief can be granted, or direct or collateral estoppel.

(7) Theat there is no genuine issue of any material fact and that the respondent is entitled to judgment as a matter of law; or

(8) Such other and further reasons as are just.

(b) *Effect.* A decision rendered under this section shall have the same force and effect as an initial decision entered under § 164.90.

APPEALS

§ 164.100 Appeals from or review of interlocutory orders or rulings.

Except as provided herein, appeals as a matter of right shall lie to the Environmental Appeals Board only from an initial or accelerated decision of the Administrative Law Judge. Appeals from other orders or rulings shall, except as provided in this section, lie only if the Administrative Law Judge certifies such orders or rulings for appeal, or otherwise as provided. The Administrative Law Judge may certify an order or ruling for appeal to the Environmental Appeals Board when: (a) The order or ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and (b) either (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or (2) review after the final judgment is issued will be inadequate or ineffective. The Administrative Law Judge shall certify orders or rulings for appeal only upon the request of a party. If the Environmental Appeals Board determines that certification was improvidently granted, or takes no action within thirty (30) days of the certification, the appeal shall be deemed dismissed. When an order or ruling is not certified by the Administrative Law Judge, it shall be reviewed by the Environmental Appeals Board only upon appeal from the initial or accelerated decision except when the Environmental Appeals

Board determines, upon request of a party and in exceptional circumstances, that delaying review would be deleterious to vital public or private interests. Except in extraordinary circumstances proceedings will not be stayed pending an interlocutory appeal; where a stay is granted, a stay of more than 30 days must be approved by the Environmental Appeals Board. Ordinarily, the interlocutory appeal will be decided on the basis of the submission made to the Administrative Law Judge, but the Environmental Appeals Board may allow further briefs and oral argument.

[57 FR 5343, Feb. 13, 1992]

§ 164.101 Appeals from or review of initial decisions.

(a) *Exceptions and request for oral argument.* (1) Within 20 days after the filing of the Administrative Law Judge's initial decision, each party may take exception to any matter set forth in such decision or to any adverse order or ruling to which he objected during the hearing and may appeal such exceptions to the Environmental Appeals Board for decision by filing them in writing with the hearing clerk, including a section containing proposed findings of fact, conclusions, orders, or rulings. Within the same period of time each party filing exceptions and amicus curiae shall file with the hearing clerk a brief concerning each of the exceptions being appealed. The party shall include, in its brief, page references to the relevant portions of the record and to the Administrative Law Judge's initial decision.

(2) Within 7 days of the service of exceptions, and of a brief under paragraph (a)(1) of this section, any other party or amicus curiae may file and serve a brief responding to exceptions or arguments raised by any other party. Such brief shall include references to the relevant portions of the record. Such brief shall not, however, raise additional exceptions.

(3) Five copies of all material filed under this section shall be filed with the hearing clerk.

(b) *Review by Administrator when no exceptions are filed.* If no exceptions are filed within the time provided, the hearing clerk shall notify the Administrator 30 days from the date of filing of the Administrative Law Judge's initial decision. Within 10 days after said notification, the Environmental Appeals Board shall issue an order either declining review of the initial decision or expressing its intent to review said initial decision. Such order may include a statement of issues to be briefed by the parties and a time schedule concerning service and filing of briefs adequate to allow the Environmental Appeals Board to issue a final order within 90 days from the close of the hearing.

(c) *Argument before the Environmental Appeals Board.* (1) A party, if he files exceptions and a brief, shall state in writing whether he desires to make an oral argument thereon before the Environmental Appeals Board; otherwise, he shall be deemed to have waived such oral argument. The Environmental Appeals Board shall, however, on its own initiative, have the right to set an appeal for oral argument.

(2) If the Environmental Appeals Board determines that additional exceptions should be argued, counsel for the parties shall be given reasonable written notice of such determination so as to permit preparation of adequate argument on all of the exceptions to be argued.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5343, Feb. 13, 1992]

§ 164.102 Appeals from accelerated decisions.

(a) Within 20 days after filing of an accelerated decision by the Administrative Law Judge, any party may file exceptions and a supporting brief with the hearing clerk, stating with particularity the grounds upon which he asserts that the decision is incorrect. The party shall include in its brief page references to the relevant portions of the record, if applicable.

(b) Within 7 days of the service of exceptions and brief under paragraph (a) of this section, any other party or amicus curiae may file and serve a brief responding thereto, with appropriate page references to the relevant portions of the record, if applicable.

(c) Ordinarily, the appeal from an accelerated decision will be decided on the basis of the submission of briefs, but the Environmental Appeals Board

may allow additional briefs and oral argument.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5343, Feb. 13, 1992]

§ 164.103 Final decision or order on appeal or review.

Within 90 days after the close of the hearing or within 90 days from the filing of an accelerated decision, unless otherwise stipulated by the parties, the Environmental Appeals Board shall, on appeal or review from an initial or accelerated order of the Administrative Law Judge, issue its final decision and order, including its rulings on any exceptions filed by the parties; such final order may accept or reject all or part of the initial or accelerated decision of the Administrative Law Judge even if acceptable to the parties.

[57 FR 5343, Feb. 13, 1992]

§ 164.110 Motion for reopening hearings; for rehearing; for reargument of any proceeding; or for reconsideration of order.

(a) *Filing; service.* A motion for reopening the hearing to take further evidence, or for rehearing or reargument of any proceeding or for reconsideration of the order, must be made by motion to the Environmental Appeals Board filed with the hearing clerk. Every such motion must state specifically the grounds relied upon.

(b) *Motion to reopen hearings.* A motion to reopen a hearing to take further evidence may be filed at any time prior to the issuance of the Administrator's final order. Every such motion shall state briefly the nature and purpose of the evidence to be adduced, shall show that such evidence is not merely cumulative, and shall set forth good reason why such evidence was not adduced at a hearing.

(c) *Motions to rehear or reargue proceedings, or to reconsider final orders.* A motion to rehear or reargue the proceeding or to reconsider the final order shall be filed within 10 days after the date of service of the final order. Every such motion must state specifically the matters claimed to have been erroneously decided, and alleged errors must be briefly stated. Motions to rehear or reargue proceedings or to reconsider final orders shall be directed to, and heard by, the Environmental Appeals Board. Motions under this section directed to the Administrator will not be considered, except in cases that the Environmental Appeals Board has referred to the Administrator pursuant to § 164.2(g) and in which the Administrator has issued the final order. A motion for reconsideration shall not stay the effective date of the final order unless specifically so ordered by the Environmental Appeals Board.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5343, Feb. 13, 1992]

§ 164.111 Procedure for disposition of motions.

Within 7 days following the service of any motion provided for in § 164.110, any other party to the proceeding may file with the hearing clerk an answer thereto. As soon as practicable thereafter, the Environmental Appeals Board shall announce its decision whether to grant or to deny the motion. Unless the Environmental Appeals Board shall determine otherwise, operation of the order shall not be stayed pending the decision to grant or to deny the motion. In the event that any such motion is granted by the Environmental Appeals Board, the applicable rules of practice, as set out elsewhere herein, shall be followed.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5344, Feb. 13, 1992]

Subpart C—General Rules of Practice for Expedited Hearings

§ 164.120 Notification.

(a) Whenever the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, but that the hazard does not constitute an emergency, he shall notify the registrant of his intention to suspend registration of the pesticide at issue.

(b) Such notice shall include findings pertaining to the question of imminent hazard and shall either be personally served on the registrant or be sent to the registrant by registered or certified mail, return receipt requested, and filed with the hearing clerk.

§ 164.121 Expedited hearing.

(a) *Request.* (1) An expedited hearing shall be held whenever the Administrator has received from the registrant a timely request for such hearing in response to the Administrator's notice of intention to suspend.

(2) A request for an expedited hearing is timely if made in writing or by telegram and filed with the office of the hearing clerk within 5 days of the registrant's receipt of the notice of intention to suspend.

(3) At the time of filing a request for an expedited hearing, the registrant shall also file a document setting forth objections to the Administrator's notice of intention to suspend and its findings pertaining to the question of imminent hazard. Such objections shall conform to the requirements of § 164.21.

(b) *Presiding officer.* (1) An expedited hearing shall be conducted by a presiding officer appointed by the Administrator, and such officer need not be an Administrative Law Judge.

(2) The presiding officer shall not have the authority to make an initial decision on the merits but shall make a recommended decision only.

(c) *The issue.* The expedited hearing shall address only the issue of whether an imminent hazard exists.

(d) *Time of hearing.* The hearing shall commence within 5 days after the filing of the request with the office of the hearing clerk unless the registrant and respondent agree that it shall commence at a later time. As soon as possible, the presiding officer shall publish in the Federal Register notice of such hearing.

(e) *Intervention.* Any person adversely affected by the Administrator's notice may move to intervene within 5 days after the receipt by the registrant of said notice or at any time prior to the conclusion of the presentation of the evidence, upon good cause found, except

(1) Leave to intervene will be granted only if the motion to intervene meets the standards of § 164.31 and, in addition, indicates that the movant would raise matters or introduce evidence pertinent to the issue of imminent hazard which would substantially assist in its resolution.

(2) A movant denied permission to intervene under this section but who otherwise meets the standards of § 164.31 and who is adversely affected may file proposed findings and conclusions and briefs in support thereof pursuant to paragraph (j) of this section. Any person filing under this subsection shall be deemed to have been a party to the proceeding, for all purposes of its further review.

(3) When an ''emergency order'' is issued pursuant to § 164.123, no person other than the respondent and the registrant shall participate in the hearing except that any person adversely affected may file proposed findings and conclusions and briefs in support thereof pursuant to paragraph (j) of this section. Any person filing under this subsection shall be deemed to have been a party to the proceeding for all purposes of its further review.

(f) *Appearances and consolidation.* The provisions of §§ 164.30 and 164.32 apply to an expedited hearing insofar as may be practicable.

(g) *Order of proceeding and burden of proof.* At the hearing, the proponent of suspension shall have the burden of going forward to present an affirmative case for the suspension. However, the ultimate burden of persuasion shall rest with the proponent of the registration.

(h) *Evidence.* The provisions of § 164.81, where applicable, apply to an expedited hearing.

(i) *Transcripts.* The presiding officer shall make provision for daily transcripts and otherwise comply with the provisions of § 164.82.

(j) *Proposed findings or conclusions; recommended decision.* (1) Within 4 days of the conclusion of the presentation of evidence, the parties may propose findings and conclusions to the Presiding Officer. Such proposed findings and conclusions shall be accompanied by a brief with supporting reasons.

(2) Within 8 days of the conclusion of the presentation of evidence, the Presiding Officer shall submit to the parties his proposed recommended findings and conclusions and a statement of the reasons on which they are based.

(3) Within 10 days of the conclusion of the presentation of evidence the Presiding Officer shall submit to the Environmental Appeals Board his recommended findings and conclusions, together with the record.

(4) Within 12 days of the conclusion of the presentation of evidence the parties shall submit to the Environmental Appeals Board their objections to the Presiding Officer's recommended findings and conclusions and written briefs in support thereof.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5344, Feb. 13, 1992]

§ 164.122 Final order and order of suspension.

(a) *Final order.* Within 7 days of receipt of the record and of the Presiding Officer's recommended findings and conclusions, the Environmental Appeals Board shall issue a final decision and order. Such final order may accept or reject in whole or in part the recommendations of the Presiding Officer.

(b) *Order of suspension.* No final order of suspension shall be issued unless the Environmental Appeals Board has issued or at the same time issues a notice of its intention to cancel the registration or change the classification of the pesticide. Such notice shall be given as provided in § 164.8.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5344, Feb. 13, 1992]

§ 164.123 Emergency order.

(a) Whenever the Environmental Appeals Board determines that an emergency exists that does not permit him to hold a hearing before suspension, the Environmental Appeals Board may issue a suspension order in advance of notification to the registrant.

(b) The Environmental Appeals Board shall immediately notify the registrant of the suspension order. The registrant may then request a hearing in accordance with §§ 164.121 and 164.122, but the suspension order shall remain in effect during the hearing pending the issuance of a final order on suspension.

[38 FR 19371, July 20, 1973, as amended at 57 FR 5344, Feb. 13, 1992]

Subpart D—Rules of Practice for Applications Under Sections 3 and 18 To Modify Previous Cancellation or Suspension Orders

AUTHORITY: Sec. 25(a) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Federal Environmental Pesticide Control Act of 1972 (86 Stat. 997).

SOURCE: 40 FR 12265, Mar. 18, 1975, unless otherwise noted.

§ 164.130 General.

EPA has determined that any application under section 3 or section 18 of the Act to allow use of a pesticide at a site and on a pest for which registration has been finally cancelled or suspended by the Administrator constitutes a petition for reconsideration of such order. Because of the extensive notice and hearing opportunities mandated by FIFRA and the Administrative Procedures Act before a final cancellation or suspension order may be issued, EPA has determined that such orders may not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities. The procedures set forth in this subpart D shall govern all such applications.

§ 164.131 Review by Administrator.

(a) The Administrator will review applications subject to this subpart D and supporting data submitted by the applicant to determine whether reconsideration of the Administrator's prior cancellation or suspension order is warranted. The Administrator shall determine that such reconsideration is warranted when he finds that: (1) The applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or suspension determination and (2) such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order.

(b) If after review of the application and other supporting data submitted by the applicant, the Administrator determines, in accordance with paragraph (a) of this section, that reconsideration of his prior order is not warranted, then the application will be denied without requirement for an administrative hearing. The Administrator shall publish notice in the FEDERAL REGISTER of the denial briefly describing the basis for his determination as soon as practicable. Such denial shall constitute final agency action.

(c) If after review of the application and other supporting data submitted by the applicant, the Administrator determines, in accordance with paragraph (a) of this section, that reconsideration of his prior order is warranted, he will then publish notice in the FEDERAL REGISTER setting forth his determination and briefly describing the basis for the determination. Such notice shall announce that a formal public hearing will be held in accordance with 5 U.S.C. section 554. The notice shall specify: (1) The date on which the hearing will begin and end, (2) the issues of fact and law to be adjudicated at the hearing, (3) the date on which the presiding officer shall submit his recommendations, including findings of fact and conclusions, to the Administrator, and (4) the date on which a decision by the Administrator is anticipated.

§ 164.132 Procedures governing hearing.

(a) The burden of proof in the hearing convened pursuant to § 164.131 shall be on the applicant and he shall proceed first. The issues in the hearing shall be whether: (1) Substantial new evidence exists and (2) such substantial new evidence requires reversal or modification of the existing cancellation or suspension order. The determination of these issues shall be made taking into account the human and environmental risks found by the Administrator in his cancellation or suspension determination and the cumulative effect of all past and present uses, including the requested use, and uses which may reasonably be anticipated to occur in the future as a result of granting the requested reversal or modification. The granting of a particular petition for use may not in itself pose a significant risk to man or the environment, but the cumulative impact of each additional use of the cancelled or suspended pesticide may re-establish, or serve to maintain, the significant risks previously found by the Administrator.

(b) The presiding officer shall make recommendations, including findings of fact and conclusions and to the extent feasible, as determined by the presiding officer, the procedures at the hearing shall follow the Rules of Practice, set forth in subparts A and B of this part 164.

§ 164.133 Emergency waiver of hearing.

(a) In the case of an application subject to this subpart D which is filed under section 18 of FIFRA, and regulations thereunder, and for which a hearing is required pursuant to § 164.131, the Administrator may dispense with the requirement of convening such a hearing in any case in which he determines:

(1) That the application presents a situation involving need to use the pesticide to prevent an unacceptable risk: (i) To human health, or (ii) to fish or wildlife populations when such use would not pose a human health hazard; and

(2) That there is no other feasible solution to such risk; and

(3) That the time available to avert the risk to human health or fish and wildlife is insufficient to permit convening a hearing as required by § 164.131; and

(4) That the public interest requires the granting of the requested use as soon as possible.

(b) Notice of any determination made by the Administrator pursuant to paragraph (a) of this section shall be published in the FEDERAL REGISTER as soon as practicable after granting the requested use and shall set forth the basis for the Administrator's determination.

PART 165—PESTICIDE MANAGEMENT AND DISPOSAL

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AUTHORITY: 7 U.S.C. 136 through 136y.

SOURCE: 71 FR 47422, Aug. 16, 2006, unless otherwise noted.

Subpart A—General

§ 165.1 Scope.

The Part 165 regulations establish standards and requirements for pesticide containers, repackaging pesticides, and pesticide containment structures.

§ 165.3 Definitions.

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this part, the following terms shall have the meanings set forth below.

Act means the Federal Insecticide, Fungicide, and Rodenticide Act.

Agricultural pesticide means any pesticide product labeled for use in or on a farm, forest, nursery, or greenhouse.

Appurtenance means any equipment or device which is used for the purpose of transferring a pesticide from a stationary pesticide container or to any refillable container, including but not limited to, hoses, fittings, plumbing, valves, gauges, pumps and metering devices.

Capacity means, as applied to containers, the rated capacity of the container.

Container means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding any application tanks) used to enclose a pesticide. Containers that are used to sell or distribute a pesticide product and that also function in applying the product (such as spray bottles, aerosol cans and containers that become part of a direct injection system) are considered to be containers for the purposes of this part.

Containment pad means any structure that is designed and constructed to intercept and contain pesticides, rinsates, and equipment wash water at a pesticide dispensing area.

Containment structure means either a secondary containment unit or a containment pad.

Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

(1) The blend is prepared to the order of the customer and is not held in inventory by the blender;

(2) The blend is to be used on the customer's property (including leased or rented property);

(3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;

(4) The blend is prepared from registered pesticides; and

(5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.

Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

Dry pesticide means any pesticide that is in solid form and that has not been combined with liquids; this includes formulations such as dusts, wettable powders, dry flowables, water-soluble powders, granules, and dry baits.

Establishment means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person who controls, who is controlled by, or who is under common control with such person).

Nonrefillable container means a container that is not a refillable container and that is designed and constructed for one-time use and is not intended to be filled again with a pesticide for sale or distribution. Reconditioned containers are considered to be nonrefillable containers.

One-way valve means a valve that is designed and constructed to allow virtually unrestricted flow in one direction and no flow in the opposite direction, thus allowing the withdrawal of material from, but not the introduction of material into, a container.

Operator means any person in control of, or having responsibility for, the daily operation of a facility at which a containment structure is located.

Owner means any person who owns a facility at which a containment structure is required.

Pesticide compatible as applied to containers means that the container construction materials will not chemically react with the formulation. A container is not compatible with the formulation if, for example, the formulation:

(1) Is corrosive to the container;

(2) Causes softening, premature aging, or embrittlement of the container;

(3) Otherwise causes the container to weaken or to create the risk of discharge;

(4) Reacts in a significant chemical, electrolytic, or galvanic manner with the container, or

(5) Interacts in a way, such as the active ingredient permeating the container wall, that would cause the formulation to differ from its composition as described in the statement required in connection with its registration under FIFRA section 3.

Pesticide compatible as applied to containment means that the containment construction materials are able to withstand anticipated exposure to stored or transferred substances without losing the capability to provide the required containment of the same or other substances within the containment area.

Pesticide dispensing area means an area in which pesticide is transferred out of or into a container.

Portable pesticide container means a refillable container that is not a stationary pesticide container.

Produce means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the

Act, and any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

Producer means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

Refillable container means a container that is intended to be filled with pesticide more than once for sale or distribution.

Refiller means a person who engages in the activity of repackaging pesticide product into refillable containers. This could include a registrant or a person operating under contract to a registrant.

Refilling establishment means an establishment where the activity of repackaging pesticide product into refillable containers occurs.

Repackage means, for the purposes of this part, to transfer a pesticide formulation from one container to another without a change in the composition of the formulation, the labeling content, or the product's EPA registration number, for sale or distribution.

Rinsate means the liquid resulting from the rinsing of the interior of any equipment or container that has come in direct contact with any pesticide.

Runoff means surface water leaving the target site.

Secondary containment unit means any structure, including rigid diking, that is designed and constructed to intercept and contain pesticide spills and leaks and to prevent runoff and leaching from stationary pesticide containers.

Stationary pesticide container means a refillable container that is fixed at a single facility or establishment or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

Suspension concentrate means a stable suspension of solid particulate active ingredients in a liquid intended for dilution with water before use.

Tamper-evident device means a device which can be visually inspected to determine if a container has been opened.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

Washwater means the liquid resulting from the rinsing of the exterior of any equipment or containers that have or may have come in direct contact with any pesticide or system maintenance compound, such as oil or antifreeze.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

§§ 165.4–165.19 [Reserved]

Subpart B—Nonrefillable Container Standards: Container Design and Residue Removal

§ 165.20 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish design and construction requirements for nonrefillable containers used for the distribution or sale of some pesticide products.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in nonrefillable containers. If your pesticide product is subject to the regulations in this subpart as set out in § 165.23, your pesticide product must be distributed or sold in a nonrefillable container that meets the standards of these regulations.

(c) *When do I have to comply?* Any pesticide product packaged in a nonrefillable container and released for shipment by you after August 16, 2009 must be packaged in a nonrefillable container that complies with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§ 165.23 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do

not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart*? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (d) of this section.

(d) *How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?* (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the nonrefillable container regulations within the time frames established by EPA in the rule or in its notification.

(e) *What other pesticide products are subject to the regulations in this subpart*? (1) Except for manufacturing use products, plant-incorporated protectants,

and antimicrobial products that are exempt under paragraph (c) of this section, all of the regulations in this subpart apply to a pesticide product if it satisfies at least one of the following criteria:

(i) The pesticide product meets the criteria of Toxicity Category I as set out in § 156.62 of this chapter.

(ii) The pesticide product meets the criteria of Toxicity Category II as set out in § 156.62 of this chapter.

(iii) The pesticide product is classified for restricted use as set out in §§ 152.160 - 152.175 of this chapter.

(2) Except for manufacturing use products, plant-incorporated protectants, antimicrobial products that are exempt under (c) of this section, and other pesticide products that are regulated under paragraph (e)(1) of this section, a pesticide product must be packaged in compliance with 49 CFR 173.24. If the pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the Department of Transportation requires it to be packaged according to 49 CFR parts 171–180.

(f) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart*? In §§ 165.25 through 165.27, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (e) of this section.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§ 165.25 Nonrefillable container standards.

(a) *What Department of Transportation (DOT) standards do my nonrefillable containers have to meet under this part if my pesticide product is not a DOT hazardous material?* A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(b) *What DOT standards do my nonrefillable containers have to meet under this part if my pesticide product is a DOT hazardous material?* (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(c) *What will EPA do if DOT proposes to change any of the cross-referenced regulations*? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the FEDERAL REGISTER. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

(d) *What standards for closures do my nonrefillable containers have to meet*? If your nonrefillable container is a rigid container with a capacity equal to or greater than 3.0 liters (0.79 gallons), if the container is not an aerosol container or a pressurized container, and if the container is used to distribute or sell a liquid agricultural pesticide, each nonrefillable container must have at least one of the following standard closures:

(1) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5

threads per inch, National Pipe Straight (NPS) standard.

(2) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.

(3) Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch.

(4) Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch. The cap may fit on a separate rigid spout or on a flexible pull-out plastic spout.

(e) *What standards for dispensing do my nonrefillable containers have to meet*? If your nonrefillable container has a capacity of 5 gallons (18.9 liters) or less, if the container is not an aerosol container, a pressurized container, or a spray bottle, and if the container holds a liquid pesticide, your nonrefillable container must do both of the following:

(1) Allow the contents of the nonrefillable container to pour in a continuous, coherent stream.

(2) Allow the contents of the nonrefillable container to be poured with a minimum amount of dripping down the outside of the container.

(f) *What standards for residue removal do my nonrefillable containers have to meet*? Each nonrefillable container and pesticide formulation combination must meet the applicable residue removal standard of this section.

(1) If the nonrefillable container is rigid and has a capacity less than or equal to 5 gallons (18.9 liters) for liquid formulations or 50 pounds (22.7 kilograms) for solid formulations and if the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application (that is, if the pesticide is dilutable), each container/formulation combination must be capable of attaining at least 99.99 percent removal of each active ingredient when tested using the EPA test procedure ''Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers.''

(2) The test must be conducted only if the pesticide product is a suspension concentrate or if EPA specifically requests the records on a case by case basis.

(3) For the rigid container/dilutable product standard in paragraph (f)(1) of this section, percent removal represents the percent of the original concentration of the active ingredient in the pesticide product when compared to the concentration of that active ingredient in the fourth rinse. Percent removal is calculated by the formula:

percent removal = [1.0 - RR] x 100.0, where

RR = rinsate ratio = Active ingredient concentration in fourth rinsate/Original concentration of active ingredient in the product

(g) *Can I obtain a waiver from or a modification to any of the nonrefillable container standards*? Yes, it is possible for you to obtain a waiver from or a modification to the nonrefillable container standards, as follows:

(1) EPA may waive or modify the requirements of paragraph (a) of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.

(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(3) EPA may approve a non-standard closure (that is, a closure not listed in paragraph (d) of this section) if EPA determines that both of the following conditions are satisfied:

(i) The non-standard closure is necessary for the proper mixing, loading, or application of the pesticide product.

(ii) The non-standard closure offers exposure protection to handlers during mixing and loading that is the same or greater than that provided by the standard closures.

(4) EPA may waive or modify the container dispensing capability standards in paragraph (e) of this section if EPA determines that at least one of the following conditions is satisfied:

(i) The product is typically removed from the container by a method other than pouring.

(ii) Compliance with the container dispensing capability standards would increase exposure to the pesticide container handler.

(5) EPA may waive or modify the requirements of paragraph (f) of this section regarding the residue removal standard if EPA determines that both of the following conditions are satisfied:

(i) The residue remaining in the container would not cause an unreasonable adverse effect on the environment; and

(ii) The product offers significant benefits and cannot be economically reformulated or repackaged.

(h) *How do I obtain a waiver from or a modification to any of the nonrefillable container standards*? To obtain a waiver from or a modification to any of the nonrefillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a nonrefillable container that does not comply with all of the nonrefillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the nonrefillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§ 165.27 Reporting and recordkeeping.

(a) *What information must I report about my nonrefillable containers*? You are not required to report to EPA with information about your nonrefillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

(b) *What recordkeeping do I have to do for my nonrefillable containers?* For each pesticide product that is subject to §§ 165.25 through 165.27 and is distributed or sold in nonrefillable containers, you must maintain the records listed in this section for as long as a nonrefillable container is used to distribute or sell the pesticide product and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe. You must keep the following records:

(1) The name and EPA registration number of the pesticide product.

(2) A description of the nonrefillable container(s) in which the pesticide product is distributed or sold.

(3) At least one of the following records to document compliance with the requirement for closures in § 165.25(d) for each nonrefillable container used to distribute or sell the pesticide product that must comply with § 165.25(d):

(i) A letter or document from the container supplier that describes the closure.

(ii) A specification about the closure in the contract between the registrant or applicant and the container supplier.

(iii) A copy of EPA's approval of any non-standard closure.

(4) At least one of the following records pertaining to the container dispensing capability requirements in §165.25(e) for each nonrefillable container used to distribute or sell the pesticide product that must comply with §165.25(e):

(i) Test data or documentation demonstrating that the nonrefillable container meets the standards in §165.25(e) when it contains the pesticide product.

(ii) Test data or documentation demonstrating that a different nonrefillable container meets the standards in §165.25(e) when it contains the pesticide product or even a different pesticide product and a written explanation of why such data or documentation demonstrates that the container meets the standards in §165.25(e) for the pesticide product.

(iii) A copy of EPA's approval of a request for a waiver from the container dispensing requirement.

(5) At least one of the following records pertaining to the nonrefillable container residue removal requirement in §165.25(f) if the pesticide product is a suspension concentrate or if EPA specifically requests the records on a case-by-case basis:

(i) Test data showing that the nonrefillable container and pesticide formulation meet the standard in §165.25(f) .

(ii) Test data showing that a different nonrefillable container with the same or a different pesticide formulation meets the standard in §165.25(f), together with a written explanation of why such data demonstrate that the nonrefillable container and pesticide formulation meet the standard in §165.25(f).

(iii) A copy of EPA's approval of a request for a waiver from the residue removal standard requirement.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§§ 165.28–165.39 [Reserved]

Subpart C—Refillable Container Standards: Container Design

§ 165.40 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish design and construction requirements for refillable containers used for the distribution or sale of some pesticide products.

(b) *Do I have to comply with the regulations in this subpart*? (1) You must comply with all of the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers. If your pesticide product is subject to the regulations in this subpart as set out in §165.43, your pesticide product must be distributed or sold in a refillable container that meets the standards of these regulations. This includes your pesticide products that are repackaged according to subpart D of this part.

(2) You must comply with the regulations in §165.45(f) for stationary pesticide containers if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. If the pesticide product is subject to the regulations in this subpart as set out in §165.43, the stationary pesticide containers used to distribute or sell the product must meet the standards of §165.45(f).

(3) If you are a refiller of a pesticide product and you are not a registrant of the pesticide product, §165.45(a)(2) provides an exemption from some of the requirements in §165.45(a)(1) .

(c) *When do I have to comply?* Any pesticide product packaged in a refillable container and released for shipment by you after August 16, 2011 must be packaged in a refillable container that complies with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64226, Oct. 29, 2008]

§ 165.43 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do

not apply to manufacturing use products, as defined in §158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in §174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart?* The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (e) of this section.

(d) *Which requirements must an antimicrobial swimming pool product comply with if it is not exempt from these regulations?* An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except §165.45(d) regarding marking and §165.45(e) regarding openings. For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(1) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(2) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) *How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?* (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise

exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the refillable container regulations within the time frames established by EPA in the rule or in its notification.

(f) *What other pesticide products are subject to the regulations in this subpart?* The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt by paragraph (c) of this section. Antimicrobial products covered under paragraph (d) of this section are subject to the regulations indicated in paragraph (d) of this section.

(g) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart?* In § 165.43(h) through § 165.47, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

(h) *Are there any other exceptions*? (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64226, Oct. 29, 2008]

§ 165.45 Refillable container standards.

(a) *What Department of Transportation (DOT) standards do my refillable containers have to meet under this part if my pesticide product is not a DOT hazardous material*? (1) A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(2) A refiller is not required to comply with 49 CFR 173.28(b)(2) for pesticide products that are not DOT hazardous materials if the refillable container to be reused complies with the refillable container regulations in this subpart and the refilling is done in compliance with the repackaging regulations in subpart D of this part.

(b) *What DOT standards do my refillable containers have to meet under this part if my pesticide product is a DOT hazardous material?* (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable

requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(c) *What will EPA do if DOT proposes to change any of the cross-referenced regulations*? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the FEDERAL REGISTER. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

(d) *What standards for marking do my refillable containers have to meet*? Each refillable container must be marked in a durable and clearly visible manner with a serial number or other identifying code that will distinguish the individual container from all other containers. Durable marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, and marking with durable ink. The serial number or other identifying code must be located on the outside part of the container except on a closure. Placement on the label or labeling is not sufficient unless the label is an integral, permanent part of or permanently stamped on the container.

(e) *What standards for openings do my refillable containers have to meet?* If your refillable container is a portable pesticide container that is designed to hold liquid pesticide formulations and is not a cylinder that complies with the DOT Hazardous Materials Regulations in 49 CFR parts 171-180, each opening of the container other than a vent must have a one-way valve, a tamper-evident device or both. A one-way valve may be located in a device or system separate from the container if the device or system is the only reasonably foreseeable way to withdraw pesticide from the container. A vent must be designed to minimize the amount of material that could be introduced into the container through it.

(f) *What standards do my stationary pesticide containers have to meet?* If a stationary pesticide container designed to hold undivided quantities of pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide is located at the refilling establishment of a refiller operating under written contract to you, the stationary pesticide container must meet the following standards:

(1) Except during a civil emergency or any unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight, each stationary pesticide container (for liquid and dry pesticides) and its appurtenances must meet both of the following standards:

(i) Each stationary pesticide container and its appurtenances must be resistant to extreme changes in temperature and constructed of materials that are adequately thick to not fail and that are resistant to corrosion, puncture, or cracking.

(ii) Each stationary pesticide container must be capable of withstanding all operating stresses, taking into account static heat, pressure buildup from pumps and compressors, and any other foreseeable mechanical stresses to which the container may be subjected in the course of operations.

(2) Each stationary container of liquid pesticides must meet all of the following standards:

(i) Each stationary container of liquid pesticides must be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, and exclude precipitation.

(ii) External sight gauges, which are pesticide-containing hoses or tubes that run vertically along the exterior of the container from the top to the bottom, are prohibited on stationary containers of liquid pesticides.

(iii) Each connection on a stationary container of liquid pesticides that is below the normal liquid level must be equipped with a shutoff valve which is capable of being locked closed. A shutoff valve must be located within a secondary containment unit if one is required by subpart E of this part.

(g) *Can I obtain a waiver from or a modification to any of the refillable container standards*? Yes, it is possible for you to obtain a waiver from or a modification to some of the refillable container standards, as follows:

(1) EPA may waive or modify the requirements of paragraph (a) of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.

(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(h) *How do I obtain a waiver from or a modification to any of the refillable container standards?* To obtain a waiver from or a modification to any of the refillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a refillable container that does not comply with all of the refillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the refillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64226, Oct. 29, 2008]

§ 165.47 What information must I report about my refillable containers?

You are not required to report to EPA with information about your refillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

§§ 165.48–165.59 [Reserved]

Subpart D—Standards for Repackaging Pesticide Products into Refillable Containers

§ 165.60 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish requirements for repackaging some pesticide products into refillable containers for distribution or sale.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers, if you are a registrant who distributes or sells pesticide products to a refiller (that is not part of your company) for repackaging into refillable containers, or if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. Each pesticide product that is subject to the regulations in this subpart as set out in § 165.63 and that is distributed or

sold in a refillable container must be distributed or sold in compliance with the standards of these regulations.

(c) *When do I have to comply?* Any pesticide product repackaged into a refillable container and released for shipment by you after August 16, 2011 must be repackaged in compliance with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.63 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart*? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (e) of this section.

(d) *Which requirements must an antimicrobial swimming pool product comply with if it is not exempt from these regulations?* (1) An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except for the following requirements:

Requirement	Requirement for registrants who distribute or sell directly in refillable containers	Requirement for refillers who are not registrants
Recordkeeping specific to each instance of repackaging	§ 165.65(i)(2)	§ 165.70(j)(2)
Container inspection: criteria regarding a serial number or other identifying code	§ 165.65(e)(2)	§ 165.70(f)(2)
Container inspection: criteria regarding one-way valve or tamper-evident device	§ 165.65(e)(3)	§ 165.70(f)(3)
Cleaning requirement: criteria regarding one-way valve or tamper-evident device	§ 165.65(f)(1)	§ 165.70(g)(1)
Cleaning if the one-way valve or tamper-evident device is not intact	§ 165.65(g)	§ 165.70(h)

(2) For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(i) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(ii) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) *How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?* (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be repackaged in compliance with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be repackaged in compliance with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the repackaging regulations within the time frames established by EPA in the rule or in its notification.

(f) *What other pesticide products are subject to the regulations in this subpart?* The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt paragraph (c) of this section. Antimicrobial products covered under paragraph (d) of this section are subject to the regulations indicated in that section.

(g) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart?* In §§165.63(h) through 165.70, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

(h) *Are there any other exceptions?* (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) Custom blending is not subject to the regulations in this subpart.

(3) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.65 Registrants who distribute or sell pesticide products in refillable containers.

(a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a

registrant who distributes or sells pesticide products in refillable containers. This means that you conduct all of the repackaging for a pesticide product and that you do not distribute or sell the pesticide product to a refiller that is not part of your company for repackaging into refillable containers. If you are a registrant that repackages a product directly into refillable containers for sale or distribution and you also sell or distribute other quantities of that product to an independent refiller for repackaging, then you must meet the requirements in this section for those quantities you distribute or sell directly and the requirements in § 165.67 for those quantities that you distribute or sell to an independent refiller.

(b) *Am I responsible for product integrity*? Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(c) *What information must I develop*? For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under ''Directions for Use,'' or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(d) *What requirements must my individual establishments follow regarding repackaging a pesticide product into refillable containers*? A refiller at your individual establishment that repackages a pesticide product into refillable containers for distribution or sale must comply with all of the following provisions.

(1) The establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

(2) The refiller must not change the pesticide formulation unless the refiller has a registration for the new formulation.

(3) The refiller must repackage a pesticide product only into a refillable container that is identified on your description of acceptable containers for that pesticide product.

(4) The refiller may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that the refiller can use.

(5) The refiller must have all of the following items at the establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The pesticide product's label and labeling.

(ii) The written refilling residue removal procedure for the pesticide product.

(iii) The written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, the refiller must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with paragraph (f) of this section. The refiller may identify the previous pesticide product by referring to the label or labeling.

(7) The refiller must inspect each refillable container according to paragraph (e) of this section.

(8) The refiller must clean each refillable container according to paragraph (f) or (g) of this section, if required by either paragraph.

(9) The refiller must ensure that each refillable container is properly labeled according to paragraph (h) of this section.

(10) The establishment must maintain records in accordance with paragraph (i) of this section.

(11) The establishment must maintain records as required by part 169 of this chapter.

(12) The establishment must report as required by part 167 of this chapter.

(e) *How must my individual establishments inspect refillable containers*? Before repackaging a pesticide product into any refillable container, a refiller at your establishment must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in paragraph (e)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph (e)(2) or (e)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in subpart C of this part. The conditions are:

(1) The integrity of the container is compromised in at least one of the following ways:

(i) The container shows signs of rupture or other damage which reduces its structural integrity.

(ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.

(iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.

(iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

(2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

(3) The container does not have an intact and functioning one-way valve or tamper-evident device on each opening other than a vent, if required.

(f) *How must my individual establishments clean refillable containers*? A refiller at your establishment must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph (f)(1) of this section and either paragraph (f)(2) or (f)(3) of this section are satisfied:

(1) If required, each tamper-evident device and one-way valve is intact.

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied:

(i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

(ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential

statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(g) *How must my individual establishments clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve*? As required in paragraph (f) of this section, a refiller at your establishment must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(h) *How must my individual establishments label refillable containers*? Before distributing or selling a pesticide product in a refillable container, a refiller at your establishment must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, the refiller at your establishment must ensure that the net contents statement and EPA establishment number appear on the label.

(i) *What recordkeeping must my individual establishments do*? Each of your individual establishments that repackages a pesticide product into refillable containers for distribution or sale must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. The establishment must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, both of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written refilling residue removal procedure for the pesticide product.

(ii) The written description of acceptable containers for the pesticide product.

(2) Each time a refiller at your establishment repackages a pesticide product into a refillable container and distributes or sells the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number or other identifying code of the refillable container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.67 Registrants who distribute or sell pesticide products to refillers for repackaging.

(a) *Must I comply with the standards in this section*? You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products to a refiller that is not part of your company for repackaging into refillable containers.

(b) *Under what conditions can I allow a refiller to repackage my pesticide product into refillable containers*? You may allow a refiller to repackage your pesticide product into refillable containers and to distribute or sell such repackaged product under your existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.

(3) You have entered into a written contract with the refiller to repackage the pesticide product and to use the label of your pesticide product.

(4) The pesticide product is repackaged only into refillable containers

that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refiller's EPA establishment number.

(c) *What violations are applicable to illegal repackaging*? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the refiller that is repackaging your pesticide product under written contract with you may be liable for violations pertaining to the repackaged product.

(d) *When must I provide the written contract to the refiller?* If you allow a refiller to repackage your product as specified in paragraph (b) of this section you must provide the written contract referred to in paragraph (b)(3) of this section to the refiller before you distribute or sell the pesticide product to the refiller.

(e) *Am I responsible for product integrity*? Yes, for a product that you distribute or sell to a refiller that is not part of your company for repackaging into refillable containers, you are responsible for the pesticide product not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(f) *What information must I develop*? For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under ''Directions for Use,'' or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(g) *When must I provide the information to the refiller*? You must provide the refiller with all of the following information and documentation before or at the time of distribution or sale of your pesticide product to the refiller:

(1) Your written refilling residue removal procedure for the pesticide product.

(2) Your written description of acceptable containers for the pesticide product.

(3) The pesticide product's label and labeling.

(h) *What recordkeeping must I do*? You must maintain all of the records listed in this section for the current operating year and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(1) Each written contract entered into with a refiller for repackaging your pesticide product into refillable containers.

(2) Your written refilling residue removal procedure for the pesticide product.

(3) Your written description of acceptable containers for the pesticide product.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.70 Refillers who are not registrants.

(a) *Must I comply with the standards in this section*? You must comply with the standards in this section if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.

(b) *Under what conditions can I repackage a registrant's pesticide product into refillable containers*? A registrant may allow you to repackage the registrant's pesticide product into refillable containers and to distribute or sell such repackaged product under the registrant's existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.

(3) The registrant has entered into a written contract with you to repackage the pesticide product and to use the label of the registrant's pesticide product.

(4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refillers EPA establishment number.

(c) *What violations are applicable to illegal repackaging*? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the pesticide product's registrant may be liable for violations pertaining to the repackaged product.

(d) *Am I responsible for product integrity*? Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(e) *What requirements must I follow regarding repackaging a pesticide product into refillable containers*? You must comply with all of the following provisions.

(1) Your establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

(2) You must not change the pesticide formulation unless you have a registration for the new formulation.

(3) You must repackage a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product provided by the registrant.

(4) You may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that you can use.

(5) You must have all of the following items at your establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The written contract referred to in paragraph (b)(3) of this section from the pesticide product's registrant.

(ii) The pesticide product's label and labeling.

(iii) The registrant's written refilling residue removal procedure for the pesticide product.

(iv) The registrant's written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, you must identify the pesticide product previously contained in the refillable container to determine whether a residue removal

procedure must be conducted in accordance with paragraph (g) of this section. You may identify the previous pesticide product by referring to the label or labeling.

(7) You must inspect each refillable container according to paragraph (f) of this section.

(8) You must clean each refillable container according to paragraph (g) or (h) of this section, if required by either paragraph.

(9) You must ensure that each refillable container is properly labeled according to paragraph (i) of this section.

(10) You must maintain records in accordance with paragraph (j) of this section.

(11) You must maintain records as required by part 169 of this chapter.

(12) You must report as required by part 167 of this chapter.

(13) The stationary pesticide containers at your establishment must meet the standards in § 165.45(f).

(14) You may be required to comply with the containment standards in subpart E of this part.

(f) *How must I inspect refillable containers*? Before repackaging a pesticide product into any refillable container, you must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in paragraph (f)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph (f)(2) or (f)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in subpart C of this part. The conditions are:

(1) The integrity of the container is compromised in at least one of the following ways:

(i) The container shows signs of rupture or other damage which reduces its structural integrity.

(ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.

(iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.

(iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

(2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

(3) The container does not have an intact and functioning one-way valve or tamper-evident device on each opening other than a vent, if required.

(g) *How must I clean refillable containers*? You must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph (g)(1) of this section and either paragraph (g)(2) or (g)(3) of this section are satisfied:

(1) If required, each tamper-evident device and one-way valve is intact.

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied.

(i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

(ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(h) *How must I clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve*? As

required in paragraph (g) of this section, you must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(i) *How must I label refillable containers*? Before distributing or selling a pesticide product in a refillable container, you must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, you must ensure that the net contents statement and EPA establishment number appear on the label.

(j) *What recordkeeping must I do*? You must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, all of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written contract from the pesticide product's registrant for the pesticide product.

(ii) The written refilling residue removal procedure for the pesticide product.

(iii) The written description of acceptable containers for the pesticide product.

(2) Each time you repackage a pesticide product into a refillable container and distribute or sell the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number or other identifying code of the refillable container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§§ 165.71–165.79 [Reserved]

Subpart E—Standards for Pesticide Containment Structures

§ 165.80 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The purpose of the containment regulations in this subpart is to protect human health and the environment from exposure to agricultural pesticides which may spill or leak from stationary pesticide containers. This protection is achieved by the construction of secondary containment units or pads at certain facilities handling agricultural pesticides. These regulations will also reduce waste generation associated with:

(1) Storage and handling of large quantities of pesticide products.

(2) Pesticide dispensing and container-refilling operations.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are an owner or operator of one of the following businesses and if you also have a stationary pesticide container or a pesticide dispensing (including container refilling) area:

(1) Refilling establishments who repackage agricultural pesticides and whose principal business is retail sale (*i.e.*, more than 50% of total annual revenue comes from retail operations).

(2) Custom blenders of agricultural pesticides.

(3) Businesses which apply an agricultural pesticide for compensation (other than trading of personal services between agricultural producers).

(c) *When do I have to comply*? You must comply with all applicable containment regulations for new and existing structures as of August 17, 2009.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.81 Scope of stationary pesticide containers included.

(a) *What is a stationary pesticide container*? A stationary pesticide container is a refillable container that is fixed at a single facility or establishment, or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

(b) *What stationary pesticide containers are subject to the regulations in this subpart*? Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the regulations in this subpart and must have a secondary containment unit that complies with the provisions of this subpart unless any of the following conditions exists:

(1) The container is empty, that is, all pesticide that can be removed by methods such as draining, pumping or aspirating has been removed (whether or not the container has been rinsed or washed).

(2) The container holds only pesticide rinsates or wash waters, and is labeled accordingly.

(3) The container holds only pesticides which would be gaseous when released at atmospheric temperature and pressure.

(4) The container is dedicated to non-pesticide use, and is labeled accordingly.

§ 165.82 Scope of pesticide dispensing areas included.

(a) *What pesticide dispensing areas are subject to the regulations in this subpart*? A pesticide dispensing area is subject to the containment regulations in this subpart and must have a containment pad that complies with the requirements of this subpart if any of the following activities occur:

(1) Refillable containers of agricultural pesticide are emptied, cleaned or rinsed.

(2) Agricultural pesticides are dispensed from a stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide for any purpose, including refilling or emptying for cleaning. This applies when pesticide is dispensed from the container into any vessel, including, but not limited to:

(i) Refillable containers;

(ii) Service containers;

(iii) Transport vehicles;

(iv) Application equipment.

(3) Agricultural pesticides are dispensed from a transport vehicle for purposes of filling a refillable container.

(4) Agricultural pesticides are dispensed from any other container for the purpose of refilling a refillable container for sale or distribution. Containment requirements do not apply if the agricultural pesticide is dispensed from such a container for use, application or purposes other than refilling for sale or distribution.

(b) *What pesticide dispensing areas are exempt from the regulations in this subpart*? A pesticide dispensing area is exempt from the regulations in this subpart if any of the following conditions exist:

(1) The only pesticides in the dispensing area would be gaseous when released at atmospheric temperature and pressure.

(2) The only pesticide containers refilled or emptied within the dispensing area are stationary pesticide containers which are already protected by a secondary containment unit that complies with the provisions of this subpart.

(3) The pesticide dispensing area is used solely for dispensing pesticide from a rail car which does not remain at a facility long enough to meet the definition of a stationary pesticide container; that is, 30 days.

§ 165.83 Definition of new and existing structures.

(a) *What is a new containment structure*? A new containment structure is one whose installation began after November 16, 2006. Installation is considered to have begun if:

(1) You, as the owner or operator, have obtained all Federal, State, and local approvals or permits necessary to

begin physical construction of the containment structure; AND

(2) You have either begun a continuous on-site physical construction or installation program OR you have entered into contractual obligations. The contract must be such that it cannot be canceled or modified without substantial loss, and must be for the physical construction or installation of the containment structure within a specific and reasonable time frame.

(b) *What is an existing containment structure*? An existing containment structure is defined as one whose installation began on or before November 16, 2006.

§ 165.85 Design and capacity requirements for new structures.

(a) *For all new containment structures, what construction materials must I use*? These are the material specifications for a new containment structure:

(1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.

(2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.

(3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred substances and still provide containment of those same or other substances within the containment area.

(b) *For all new containment structures, what are the general design requirements*? These are the general design requirements for new containment structures:

(1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) Appurtenances, discharge outlets or gravity drains must not be configured through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart. Appurtenances must be configured in such a way that spills or leaks are easy to see.

(3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

(c) *For new secondary containment units for stationary containers of liquid pesticides and new containment pads in pesticide dispensing areas, what are the capacity requirements?* These are the capacity requirements:

(1) New secondary containment units for stationary containers of liquid pesticides, if protected from precipitation, must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(2) New secondary containment units for stationary containers of liquid pesticides, if exposed to or unprotected from precipitation, must have a capacity of at least 110 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(3) New containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.

(4) New containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

(d) *For new secondary containment units for stationary containers of liquid pesticides, what are the specific design requirements?* You must either anchor or

elevate each stationary container of liquid pesticides protected by a new secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid.

(e) *For new containment pads in pesticide dispensing areas, what are the specific design requirements*? Each new containment pad in a pesticide dispensing area must:

(1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.

(2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

(3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

(4) Have its surface sloped toward an area where liquids can be collected for removal, such as a liquid-tight sump or a depression, in the case of a single-pour concrete pad.

(f) *For new secondary containment units for stationary containers of dry pesticides, what are the specific design requirements?* These are the specific design requirements for new secondary containment units for stationary containers of dry pesticides:

(1) The stationary containers of dry pesticides within the containment unit must be protected from wind and precipitation.

(2) Stationary containers of dry pesticides must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.

(3) The storage area for stationary containers of dry pesticides must include a floor that extends completely beneath the pallets or raised concrete platforms on which the stationary containers of dry pesticides must be stored.

(4) The storage area for stationary containers of dry pesticides must be enclosed by a curb a minimum of 6 inches high that extends at least 2 feet beyond the perimeter of the container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 165.87 Design and capacity requirements for existing structures.

(a) *For all existing containment structures, what construction materials must I use*? These are the material specifications for an existing containment structure:

(1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.

(2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.

(3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred substances and still provide containment of those same or other substances within the containment area.

(b) *For all existing containment structures, what are the general design requirements*? These are the general design requirements for existing containment structures:

(1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) You must seal all appurtenances, discharge outlets and gravity drains

through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart.

(3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

(c) *For existing secondary containment units for stationary containers of liquid pesticides and existing containment pads in pesticide dispensing areas, what are the capacity requirements?* These are the capacity requirements:

(1) Existing secondary containment units for stationary containers of liquid pesticides must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(2) Existing containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.

(3) Existing containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

(d) *For existing secondary containment units for stationary containers of liquid pesticides, what are the specific design requirements?* You must either anchor or elevate each stationary container of liquid pesticides protected by an existing secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid.

(e) *For existing containment pads in pesticide dispensing areas, what are the specific design requirements*? Each existing containment pad in a pesticide dispensing area must:

(1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.

(2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

(3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

(f) *For existing secondary containment units for stationary containers of dry pesticides, what are the specific design requirements?* These are the specific design requirements for existing secondary containment units for stationary containers of dry pesticides:

(1) The stationary containers of dry pesticides within the containment unit must be protected from wind and precipitation.

(2) Stationary containers of dry pesticides must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.

(3) The storage area for stationary containers of dry pesticides must include a floor that extends completely beneath the pallets or raised concrete platforms on which the stationary containers of dry pesticides must be stored.

(4) The storage area for stationary containers of dry pesticides must be enclosed by a curb a minimum of 6 inches high that extends at least 2 feet beyond the perimeter of the container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

§ 165.90 Operational, inspection and maintenance requirements for all new and existing containment structures.

(a) *What are the operating procedures required for all new and existing containment structures?* As the owner or operator of a new or existing pesticide containment structure, you must:

(1) Manage the structure in a manner that prevents pesticides or materials containing pesticides from escaping from the containment structure (including, but not limited to, pesticide residues washed off the containment structure by rainfall or cleaning liquids used within the structure.)

(2) Ensure that pesticide spills and leaks on or in any containment structure are collected and recovered in a manner that ensures protection of human health and the environment (including surface water and groundwater) and maximum practicable recovery of the pesticide spilled or leaked. Cleanup must occur no later than the end of the day on which pesticides have been spilled or leaked except in circumstances where a reasonable delay would significantly reduce the likelihood or severity of adverse effects to human health or the environment.

(3) Ensure that all materials resulting from spills and leaks and any materials containing pesticide residue are managed according to label instructions and applicable Federal, State and local laws and regulations.

(4) Ensure that transfers of pesticides between containers, or between containers and transport vehicles are attended at all times.

(5) Ensure that each lockable valve on a stationary pesticide container, if it is required by § 165.45(f), is closed and locked, or that the facility is locked, whenever the facility is unattended.

(b) *What are the inspection and maintenance requirements for all new and existing containment structures*? As owner or operator of a new or existing pesticide containment structure, you must:

(1) Inspect each stationary pesticide container and its appurtenances and each containment structure at least monthly during periods when pesticides are being stored or dispensed on the containment structure. Your inspection must look for visible signs of wetting, discoloration, blistering, bulging, corrosion, cracks or other signs of damage or leakage.

(2) Initiate repair to any areas showing visible signs of damage and seal any cracks and gaps in the containment structure or appurtenances with material compatible with the pesticide being stored or dispensed no later than the end of the day on which damage is noticed and complete repairs within a time frame that is reasonable, taking into account factors such as the weather, and the availability of cleanup materials, trained staff, and equipment.

(3) Not store any additional pesticide on a containment structure if the structure fails to meet the requirements of this subpart until suitable repairs have been made.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

§ 165.92 What if I need both a containment pad and a secondary containment unit?

You may combine containment pads and secondary containment units as an integrated system provided the requirements set out in this subpart for containment pads and secondary containment units in §§ 165.85(a) and (b), 165.87(a) and (b) and § 165.90, and as applicable, §§ 165.85(c)-(f) and 165.87(c)-(f) are satisfied separately.

§ 165.95 What recordkeeping do I have to do as a facility owner or operator?

As a facility owner or operator subject to the requirements of this subpart, you must maintain the following records, and you must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(a) Records of inspection and maintenance for each containment structure and for each stationary pesticide container and its appurtenances must be kept for 3 years and must include the following information:

(1) Name of the person conducting the inspection or maintenance;

(2) Date the inspection or maintenance was conducted;

(3) Conditions noted;

(4) Specific maintenance performed.

(b) Records for any non-stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide that holds pesticide but is not protected by a secondary containment unit meeting these regulations must be kept for 3 years. Records on these non-stationary pesticide containers must include the time period that the container remains at the same location.

(c) Records of the construction date of the containment structure must be kept for as long as the pesticide containment structure is in use, and for 3 years afterwards.

§ 165.97 States with existing containment programs.

(a) *What options are available to States that already have containment regulations*? States that have promulgated containment regulations effective prior to August 16, 2006, and which also have primary enforcement responsibility and/or certification programs, have the option of continuing to implement their own programs in lieu of these Federal regulations.

(b) *How may a State request authority to continue implementing its State containment regulations*? A State with pesticide containment regulations may request the authority to continue implementing State containment regulations by August 16, 2007 in the following manner:

(1) The State must submit a letter and any supporting documentation to EPA. Supporting documentation must demonstrate that the State's program is providing environmental protection equivalent to or more protective than that expected to be provided by the Federal regulations in this subpart.

(2) The State must identify any significant changes to State regulations which would be necessary in order to provide environmental protection equivalent to the EPA regulations, and develop an estimated timetable to effect these changes. The letter must be signed by the designated State Lead Agency.

(c) *How will EPA notify the State if its request is granted*? EPA's Office of Pesticide Programs will review the State's correspondence and determine whether the State program is adequate to provide environmental protection equivalent to or more protective than these Federal regulations for new and existing containment structures. EPA's Office of Pesticide Programs will inform the State of its determination through a letter authorizing or declining to authorize the State to continue implementing its containment regulations and will detail any reasons for declining authorization.

(d) *How must a State inform EPA of revisions to its containment regulations*? Any state that has received authorization to continue implementing its state containment regulations must inform EPA by letter signed by the designated State Lead Agency within 6 months of any revision to the State's containment regulations. EPA will inform the state by letter if it determines that the State's containment regulations are no longer adequate based on the revisions. The State's containment regulations will remain in effect, unless and until EPA sends the state a letter making this determination.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

PART 166—EXEMPTION OF FEDERAL AND STATE AGENCIES FOR USE OF PESTICIDES UNDER EMERGENCY CONDITIONS

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AUTHORITY: 7 U.S.C. 136p, and 136w.

SOURCE: 51 FR 1902, Jan. 15, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 166.1 Purpose and organization.

(a) *Purpose and scope.* Section 18 of the Act authorizes the Administrator to exempt State and Federal agencies from any provision of the Act, if he determines that emergency conditions exist which require an exemption. The regulations in this part establish procedures whereby the Administrator may exempt a Federal or State agency from the provisions of the Act which regulate the manner in which a pesticide is made available for use or is used.

(b) *Organization.* (1) The provisions in subpart A of this part describe the four types of emergency exemptions authorized by the Agency and define terms used in this part.

(2) Subpart B of this part establishes procedures and criteria for specific, quarantine, and public health exemptions.

(3) Subpart C of this part establishes procedures and criteria for crisis exemptions.

§ 166.2 Types of exemptions.

There are four types of emergency exemptions which may be authorized: specific, quarantine, public health, and crisis exemptions.

(a) Specific exemption. A specific exemption may be authorized in an emergency condition to avert:

(1) A significant economic loss; or

(2) A significant risk to:

(i) Endangered species,

(ii) Threatened species,

(iii) Beneficial organisms, or

(iv) The environment.

(b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species, or is otherwise new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

(c) *Public health exemption.* A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.

(d) *Crisis exemption.* A crisis exemption may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4510, Jan. 27, 2006]

§ 166.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

Act means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Agency and EPA mean the U. S. Environmental Protection Agency.

Beneficial organism means any pollinating insect, or any pest predator, parasite, pathogen or other biological control agent which functions naturally or as part of an integrated pest management program to control another pest.

Emergency condition means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:

(1) No effective pesticides are available under the Act that have labeled uses registered for control of the pest

under the conditions of the emergency; and

(2) No economically or environmentally feasible alternative practices which provide adequate control are available; and

(3) The situation:

(i) Involves the introduction or dissemination of an invasive species or a pesticide new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

(ii) Will present significant risks to human health; or

(iii) Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or

(iv) Will cause significant economic loss due to:

(A) An outbreak or an expected outbreak of a pest; or

(B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

First food use means the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no tolerance or exemption from the requirements of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408 of the Federal Food, Drug, and Cosmetic Act.

Food means any article used for food or drink for man or animals.

Invasive species means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health.

IR-4 means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive for registration by the crop protection industry.

New chemical means an active ingredient not contained in any currently registered pesticide.

Significant economic loss means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop or other output, one or more of the following:

(i) Yield loss greater than or equal to 20%.

(ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues.

(iii) Economic loss, including revenue losses and cost increases greater than or equal to 50% of net revenues.

(2) For any pest activity where EPA determines that the criteria in paragraph (1) of this definition would not adequately describe the expected loss, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

Special Review means any interim administrative review of the risks and benefits of the use of a pesticide conducted pursuant to the provisions of part 154 of this chapter, or § 162.11 of this chapter prior to November 27, 1985, or any subsequent version of those rules.

Unreasonable adverse effects on the environment means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

[73 FR 75597, Dec. 12, 2008]

§ 166.7 User notification; advertising.

(a) A State or Federal agency that obtains an exemption may notify eligible users of the availability of the exempted pesticide(s) through user groups, retail dealers, and other means. Notification may include distributing copies of the section 18 approval letter, labeling, or other information to eligible persons.

(b) As set forth more fully in § 168.22 of this chapter, EPA interprets FIFRA sections 12(a)(1) (A) and (B) as making it unlawful for any person who distributes, sells, offers for sale, holds for

sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to advertise the pesticide for any use authorized by an emergency exemption, except for advertisements that are placed in media that address only persons in the geographical area to which the exemption applies, state the name and address of one or more retail dealers where users may buy the pesticide, and contain a prominent notice of the limitations on use under the emergency exemption. EPA may withdraw an exemption if the use of the pesticide covered by the exemption is advertised unlawfully.

[54 FR 1125, Jan. 11, 1989]

Subpart B—Specific, Quarantine, and Public Health Exemptions

§ 166.20 Application for a specific, quarantine, or public health exemption.

(a) *General information required in an application for a specific, quarantine or public health exemption.* An application must be submitted in writing by the head of the Federal or State agency, the Governor of the State involved, or their official designee. If a designee has been delegated authority to request exemptions, written authorization of such delegation must accompany the request or be on file with the Agency. In addition, the application must contain all applicable information specified in paragraphs (a) (1) through (11) of this section.

(1) *Identity of contact persons.* (i) Unless otherwise specified, the person who submits the application will be considered the contact person for all matters relating to administration of the emergency exemption.

(ii) Requests should identify by name and telephone number one or more qualified experts who may be contacted in case any questions arise concerning the application.

(2) *Description of the pesticide.* The application shall contain a description of the pesticide(s) proposed for use under the exemption. Such information shall include:

(i) For a federally registered pesticide product:

(A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s) requested if a specific product is not requested; and

(B) A copy of any additional labeling proposed for the emergency exemption; or

(ii) For any other pesticide products:

(A) A confidential statement of formula or reference to one already submitted to the Agency; and

(B) Complete labeling to be used in connection with the proposed exemption use.

(3) *Description of the proposed use.* The application shall identify all of the following:

(i) Sites to be treated, including their locations within the State;

(ii) The method of application;

(iii) The rate of application in terms of active ingredient and product;

(iv) The maximum number of applications;

(v) The total acreage or other appropriate unit proposed to be treated;

(vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;

(vii) All applicable restrictions and requirements concerning the proposed use which may not appear on labeling;

(viii) The duration of the proposed use; and

(ix) Earliest possible harvest dates.

(4) *Alternative methods of control.* The application shall contain:

(i) A detailed explanation of why the pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered pesticide is ineffective for the given situation, the statement must be supported by field data which demonstrate ineffectiveness of registered pesticides, or, if such data are unavailable, statements by qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control; and

(ii) A detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.

(5) *Effectiveness of proposed use.* The application shall contain data, a discussion of field trials, or other evidence which provide the basis for the conclusion that the proposed pesticide treatment will be effective in dealing with the emergency.

(6) *Discussion of residues for food uses.* If the proposed use is expected to result in residues of the pesticide in or on food, the application shall list the food likely to contain such residues and shall contain an estimate of the maximum amount of the residue likely to result from the proposed use, together with the information on which such estimates are based.

(7) *Discussion of risk information.* The application shall address the potential risks to human health, endangered or threatened species, beneficial organisms, and the environment expected to result from the proposed use, together with references to data and other supporting information.

(8) *Coordination with other affected State or Federal agencies.* If the proposed use of the pesticide is likely to be of concern to other Federal or State agencies, the application shall indicate that such agencies have been contacted prior to submission of the application, and any comments received from such agencies shall be submitted to EPA.

(9) *Acknowledgment by registrant.* The application shall contain a statement by the registrants of all pesticide products proposed for use acknowledging that a request has been made to the Agency for use of the pesticide under this section. This acknowledgment shall include a statement of support for the requested use, including the expected availability of adequate quantities of the requested product under the use scenario proposed by the applicant(s); and the status of the registration in regard to the requested use including appropriate petition numbers, or of the registrant's intentions regarding the registration of the use.

(10) *Description of proposed enforcement program.* Prior to approval, the applicant shall provide an explanation of the authority of the applicant or related State or Federal agencies for ensuring that use of the pesticide under the proposed exemption would comply with any special requirements imposed by the Agency and a description of the program and procedures for assuring such compliance.

(11) *Repeated uses.* Applications for the use of a pesticide at a site for which the applicant has previously been exempted under section 18 shall contain an interim report summarizing the results of the specific, quarantine, or public health exemption previously issued, if the application is submitted prior to the time the final report for the previous exemption is due. The interim report shall contain that information specified in §166.32 to the extent available at the time the application is made.

(b) *Information required for a specific exemption.* An application for a specific exemption shall provide all of the following information, as appropriate, concerning the nature of the emergency:

(1) The scientific and common name of the pest or pest complex;

(2) A discussion of the events which brought about the emergency condition;

(3) A discussion of the anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide; and

(4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, that addresses one or more of the following, as appropriate:

(i) Yield or utilized yield reasonably anticipated in the absence of the emergency and expected losses in quantity due to the emergency;

(ii) The information in paragraph (b)(4)(i) of this section plus prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency;

(iii) The information in paragraph (b)(4)(ii) of this section plus operating costs reasonably anticipated in the absence of the emergency;

(iv) Any other information explaining the economic consequences of the emergency.

(5) *Re-certification of an emergency condition.* Applicants for specific exemptions may submit re-certification

applications relying on previously submitted information to satisfy the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:

(i) An exemption was granted for the same pesticide at the same site to the same applicant the previous year;

(ii) The emergency condition could reasonably be expected to continue for longer than 1 year;

(iii) EPA has not declared the use ineligible for re-certification;

(iv) The use is not subject to public notice pursuant to §166.24(a)(1) through (a)(6);

(v) The applicant certifies that all of the following are true:

(A) The emergency condition described in the preceding year's application continues to exist;

(B) Except as expressly identified, all information submitted in the preceding year's application is still accurate;

(C) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;

(D) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;

(E) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.

(c) *Information required for a quarantine exemption.* An application for a quarantine exemption shall provide all of the following information concerning the nature of the emergency:

(1) The scientific and common name of pest;

(2) The origin of pest and the means of its introduction or spread if known; and

(3) The anticipated impact of not controlling the pest.

(d) *Information required for a public health exemption.* An application for a public health exemption shall provide all the following information concerning the nature of the emergency:

(1) The scientific and common name of the pest to be controlled and, if the pest is a vector, a description of the disease it is expected to transmit;

(2) A discussion of the magnitude of the health problems which are expected to occur without the pesticide use; and

(3) Discussion of the availability of medical treatment for the health problem.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4511, Jan. 27, 2006]

§ 166.22 Consultation with the Secretary of Agriculture and Governors of the States.

The Agency, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

§ 166.24 Public notice of receipt of application and opportunity for public comment.

(a) *Publication requirement.* The Administrator shall issue a notice of receipt in the FEDERAL REGISTER for a specific, quarantine, or public health exemption and request public comment when any one of the following criteria is met:

(1) The application proposes use of a new chemical;

(2) The application proposes the first food use of an active ingredient;

(3) The application proposes any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act;

(4) The application proposes use of a pesticide which:

(i) Was the subject of a notice under section 6(b) of the Act and was subsequently cancelled, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was the subject of the notice under section 6(b);

(5) The application proposes use of a pesticide which:

(i) Contains an active ingredient which is or has been the subject of a Special Review, and

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which is or has been the subject of the Special Review;

(6) The application proposes use of a pesticide which:

(i) Was voluntarily canceled under section 6(f) of the Act, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled under section 6(f);

(7) The application proposes use of a pesticide for a specific or public health exemption, if:

(i) An emergency exemption has been requested or approved for that use in any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and

(ii) A complete application for registration of that use and/or a petition for tolerance for residues in or on the commodity has not been submitted to the Agency; or

(8) The Administrator determines that publication of notice is appropriate.

(b) *Contents.* The notice of receipt of an application for an emergency exemption shall contain the following information:

(1) The name of the applicant;

(2) The name of the active ingredient requested for use, including, if available, the common name and the Chemical Abstracts Service (CAS) number;

(3) The total amount of product or active ingredient proposed for use;

(4) The geographical location where treatment is proposed;

(5) The proposed number of acres or other appropriate units proposed to be treated;

(6) A summary of the applicant's description of the emergency conditions including the pest and the site or crop to be treated;

(7) A description of the major conditions of use of the pesticide as proposed by the applicant;

(8) If the pesticide proposed for use meets the criteria of paragraph (a) (3), (4), or (5) of this section, an identification of the types of risks that were the basis for EPA's regulatory action; and

(9) The name, telephone number, and address of a person in the Agency who can provide further information.

(c) *Length of comment period.* Normally, a notice of receipt shall give the public 15 days in which to file comments on the application. The Administrator may shorten or eliminate the comment period if he determines that the time available for a decision on the application requires it and shall state reasons for such action in a notice in the FEDERAL REGISTER. The Administrator may extend the comment period if additional time for comment is requested and such an extension would not interfere with a timely decision on the application.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.25 Agency review.

(a) *General.* The Agency will review all requests as expeditiously as possible, making every attempt to respond to requests prior to the time when the proposed use is needed. The Agency will review the application and other available data necessary to make a determination with respect to all of the following:

(1) Whether an emergency condition exists or will exist;

(2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s) from the requirement of a tolerance for any pesticide residues resulting from the authorized use, identifying the level of permissible residues in or on food or feed resulting from the proposed use;

(3) The anticipated benefits to be derived from the proposed use; and

(4) The potential risks to human health, endangered or threatened species, beneficial organisms, and the environment from the proposed use.

(b) *Criteria for approval.* The Administrator may authorize a specific, public health, or quarantine exemption, based on the information available to the Agency, after:

(1) He determines that:

(i) An emergency condition exists;

(ii) The use of the pesticide under the exemption will not cause unreasonable adverse effects on the environment;

(iii) Registration of the pesticide use for which the exemption is requested has not been suspended under section 6(c) of the Act or cancelled following a notice under section 6(b) of the Act,

unless the use is authorized in accordance with the provisions of §§ 164.130 through 164.133 of this chapter;

(2) Giving due consideration to:

(i) Whether the pesticide is reasonably likely to be used in compliance with the requirements imposed by the Agency under the exemption; and

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.28 Duration of exemption.

(a) *Specific or public health exemptions.* EPA shall allow use of a pesticide under a specific or public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.

(b) *Quarantine exemption.* EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed necessary but in no case for longer than 3 years. Quarantine exemptions may be renewed. Interim reports containing the information specified in § 166.32(b) to the extent available shall be filed annually.

§ 166.30 Notice of Agency decision.

(a) *Notification of applicants.* The Agency shall notify an applicant of its decision to approve or deny an application request for an emergency exemption in a timely manner.

(1) *Incomplete applications.* The Agency may discontinue the processing of any application that does not address all of the requirements of § 166.20 until such time the additional information is submitted by the applicant.

(2) *Complete applications*—(i) *Denials.* The Agency shall provide the specific reasons and rationale for denying the exemption request. If the denial is based on a specific information gap, the decision shall be reconsidered in a timely manner when the information gap is filled.

(ii) *Approvals.* The Agency *shall* provide the specific terms and conditions under which the exempted pesticide may be used.

(b) *Federal Register publication.* (1) At least quarterly, the Administrator shall issue a notice in the FEDERAL REGISTER announcing all approvals of specific, quarantine, and public health exemptions. The notice shall contain all of the following:

(i) The name of the applicant;

(ii) The pesticide authorized for use;

(iii) The crop or site to be treated; and

(iv) The name, address, and telephone number of a person in the Agency who can provide further information.

(2) In addition, if EPA has issued a Notice of Receipt of an application for an exemption, it will issue a notice of its final decision and the reasons for that decision.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.

(a) *Unexpected adverse effects information.* Any unexpected adverse effects resulting from the use of a pesticide under a specific, quarantine, or public health exemption must be immediately reported to the Agency.

(b) *Interim and final reports.* A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:

(1) Total acreage, amount of commodity or other unit treated and the total quantity of the pesticide used;

(2) A discussion of the effectiveness of the pesticide in dealing with the emergency condition;

(3) A description of any unexpected adverse effects which resulted from use of the pesticide under the exemption;

(4) The results of any monitoring required and/or carried out under the exemption;

(5) A discussion of any enforcement actions taken in connection with the exemption;

(6) Method(s) of disposition of a food crop, if required to be destroyed under an exemption; and

(7) Any other information requested by the Administrator.

(c) *Records.* Records for all treatments involving the first food use of a pesticide will be maintained by the agency to which the emergency exemption was granted for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency these records shall be made available to the Administrator. Records will include all of the following:

(1) Locations where the pesticide was applied;

(2) Dates of application (range); and

(3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.34 EPA review of information obtained in connection with emergency exemptions.

EPA shall review information submitted in connection with emergency exemptions and, when applicable, use it in connection with other regulatory decisions under the Act.

§ 166.35 Revocation or modification of exemptions.

(a) *Grounds.* The Administrator may revoke or modify the terms or conditions of a specific, quarantine, or public health exemption if he determines one of the following:

(1) An emergency no longer exists;

(2) Use of the pesticide under the exemption may cause unreasonable adverse effects on the environment;

(3) The pesticide authorized under the exemption is not effective at controlling the pest or conditions causing the emergency; or

(4) The terms and conditions established by the exemption and these regulations are not being complied with.

(b) *Implementation.* The revocation or modification becomes effective as soon as the Administrator notifies the State or Federal agency which submitted the application. Upon notification, the applicant is required immediately to take all necessary steps to assure that further use complies with the terms and conditions of any modification or, if the exemption has been revoked, to stop further use.

Subpart C—Crisis Exemptions

§ 166.40 Authorization.

The head of a Federal or State agency, the Governor of a State, or their official designee, may issue a crisis exemption in situations involving an unpredictable emergency situation when:

(a) An unpredictable emergency condition exists;

(b) The time element with respect to the application of the pesticide is critical, and there is not sufficient time either to request a specific, quarantine, or public health exemption or, if such a request has been submitted, for EPA to complete review of the request; and

(c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other objection.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.41 Limitations.

The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

(a) EPA has informed the head of the Federal or State agency, the Governor, or their official designee, not to issue such an exemption;

(b) The pesticide use has been suspended under section 6(c) of the Act;

(c) The pesticide use has been cancelled following a notice issued under section 6(b) of the Act;

(d) The pesticide contains a new chemical; or

(e) The application proposes the first food use of a pesticide.

§ 166.43 Notice to EPA and registrants or basic manufacturers.

(a) *Timing of notice.* (1) The State or Federal Agency issuing the crisis exemption must notify the Administrator in advance of utilization of the crisis provisions.

(2) The State or Federal agency issuing the crisis exemption shall notify the registrant(s) or, if appropriate, the basic manufacturer(s) of the pesticide(s) being used under the crisis exemption at the same time notice is given to EPA or as soon thereafter as possible.

(b) *Contents of notice.* Information required to be provided in notices shall include all of the following:

(1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use;

(2) The site on which the pesticide is to be used or is being used;

(3) The use pattern;

(4) The date on which the pesticide use is to begin and the date when the use will end;

(5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;

(6) Earliest anticipated harvest date of the treated commodity;

(7) Description of the emergency situation; and

(8) Any other pertinent information available at the time.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.45 Duration of crisis exemption.

A crisis exemption may be authorized for:

(a) Only as long as is necessary to control the pest or conditions causing the emergency; and

(b) No longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

§ 166.49 Public notice of crisis exemptions.

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the FEDERAL REGISTER announcing issuance of crisis exemptions. The notice shall contain all of the following:

(1) The name of the applicant;

(2) The pesticide authorized for use;

(3) The crop or site to be treated; and

(4) The name, address, and telephone number of a person in the Agency who can provide further information.

(b) *Annual reports.* Annually, the Agency shall issue a notice in the FEDERAL REGISTER that shall summarize:

(1) The number of crisis exemptions declared; and

(2) The number of crisis exemptions revoked.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.50 Reporting and recordkeeping requirements for crisis exemption.

(a) *Adverse effects information.* Any adverse effects resulting from the use of a pesticide under a crisis exemption must be immediately reported to the Agency.

(b) *Final reports.* (1) A report summarizing the results of treatment under a crisis exemption will be required to be submitted to the Agency within 3 months following the last date of treatment. If a specific, quarantine, or public health exemption has been approved while the crisis exemption is in effect, however, the crisis exemption report may be incorporated into the specific, quarantine, or public health exemption final report required under § 166.32(b) and submitted at the time it is due.

(2) Information to be included in the crisis exemption report includes the same information as required in § 166.32(b) and an explanation as to why there was a need to utilize the crisis provisions.

(c) *Records.* Records will be maintained for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency, these records shall be made available to the Administrator. Records will include all of the following:

(1) Location where the pesticide was applied;

(2) Dates of application (range); and

(3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993]

§ 166.53 EPA review of crisis exemption and revocation of authority.

(a) *Review.* When a crisis exemption is about to be or has already been declared by a State or Federal agency, EPA will undertake an expedited review of the pesticide to determine if use of the pesticide may result in such unreasonable health or environmental risks that the crisis authority should not be exercised or the crisis exemption should be revoked.

(b) *Revocation*—(1) *Individual crisis exemptions.* A crisis exemption for the use of a specific pesticide may be revoked if the Administrator determines that:

(i) There are insufficient data to determine the risks posed from the use;

(ii) Such action is necessary to protect man or the environment; or

(iii) The State or Federal agency is not complying with the requirements of this subpart C.

(2) *State or Federal agency authority.* The Administrator may revoke the authority of a State or Federal agency to issue crisis exemptions for any pesticide if he determines that:

(i) Such action is necessary to protect man or the environment; or

(ii) The State or Federal agency is not complying with the requirements of this subpart C.

(c) *Reason for revocation.* The Agency shall provide the specific reasons for revoking an agency's authority to issue a crisis exemption and for revoking an issued crisis exemption.

PART 167—REGISTRATION OF PESTICIDE AND ACTIVE INGREDIENT PRODUCING ESTABLISHMENTS, SUBMISSION OF PESTICIDE REPORTS

Subpart A—General Provisions

Sec.
167.3 Definitions.

Subpart B—Registration Requirements

167.20 Establishments requiring registration.

Subparts C–D [Reserved]

Subpart E—Recordkeeping and Reporting Requirements

167.85 Reporting requirements.
167.90 Where to obtain and submit forms.

AUTHORITY: 7 U.S.C. 136 (e) and (w).

SOURCE: 53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 167.3 Definitions.

Terms used in this part shall have the meanings set forth for such terms in the Federal Insecticide, Fungicide, and Rodenticide Act. In addition, when used in this part, the following terms shall have the meanings stated below:

Act means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

Amount of pesticidal product means quantity, expressed in weight or volume of the product, and is to be reported in pounds for solid or semi-solid pesticides and active ingredients or gallons for liquid pesticides and active ingredients, or number of individual retail units for devices.

Current production [sales or distribution] means amount of planned production in the calendar year in which the pesticides report is submitted, including new pesticidal products not previously sold or distributed.

Custom blender means any establishment which provides the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when: (1) The blend is prepared to the order of

the customer and is not held in inventory by the blender; (2) the blend is to be used on the customer's property (including leased or rented property); (3) the pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend; (4) the blend is prepared from registered pesticides; (b) the blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of mixture; and (6) no other pesticide production activity is performed at the establishment.

Device means any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act.

Establishment means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

Past year means the calendar year immediately prior to that in which the report is submitted.

Pesticidal product means a pesticide, active ingredient, or device.

Pesticidal product report means information showing the types and amounts of pesticidal products which were: (1) Produced in the past calendar year; (2) produced in the current calendar year; and, (3) sold or distributed in the past calendar year. For active ingredients, the pesticidal product report must include information on the types and amounts of an active ingredient for which there is actual or constructive knowledge of its use or intended use as a pesticide. This pesticidal product report also pertains to those products produced for export only which must also be reported. A positive or a negative annual report is required in order to maintain registration for the establishment.

Produce means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the Act, any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

Producer means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

Sold or distributed means the aggregate amount of a pesticidal product released for shipment by the establishment in which the pesticidal product was produced.

Type of pesticidal product refers to each individual product as identified by: the product name; EPA Registration Number (or EPA File Symbol, if any, for planned products, or Experimental Permit Number, if the pesticide is produced under an Experimental Use Permit); active ingredients; production type (technical, formulation, repackaging, etc.); and, market for which the product was produced (domestic, foreign, etc.). In cases where a pesticide is not registered, registration is not applied for, or the pesticide is not produced under an Experimental Use Permit, the term shall also include the chemical formulation.

Subpart B—Registration Requirements

§ 167.20 Establishments requiring registration.

(a) *Who must register.* (1) Any establishment where a pesticidal product is produced must be registered with the Agency. This requirement does not apply to custom blenders as defined in this part.

(2) Any establishment where a substance is produced must be registered with the Agency if the producer intends the substance to be used as an active ingredient of a pesticide, or has actual or constructive knowledge that the substance will be used by any person as an active ingredient of a pesticide.

(3) Any domestic establishment producing a pesticidal product for export, or any unregistered pesticide, or any foreign establishment producing a pesticidal product for import into the United States must be registered. Also, any establishment, either foreign or

domestic, which produces a pesticidal product for use under an Experimental Use Permit, FIFRA section 18 Emergency Exemption or section 24(c) Special Local Needs registration, must be registered.

(b) *Information required.* An applicant for establishment registration must submit the following information:

(1) Name and address of the company.

(2) The type of ownership (individual, partnership, cooperative association, corporation, or any organized group of persons whether incorporated or not).

(3) The name and address of each producing establishment for which registration is sought.

(c) *When to apply.* An application for establishment registration must be submitted, and an establishment registration number must be assigned by the Agency, before any production may occur at an establishment. In the case of an establishment which has not previously been required to be registered and is not currently registered, the producer must apply for establishment registration by submitting an application within 180 days after the effective date of this regulation.

(d) *Assignment of establishment registration number.* The Agency will return incomplete or inaccurately completed applications to the applicant. If the application is complete and accurate, the Agency will register the establishment and assign a registration number to the establishment. The establishment registration number will be entered on the application, and a copy of the application will be returned to the applicant.

(e) *Amendment.* If at any time after the first report there is a change in the information required to be submitted under paragraph (b) of this section, that new information must be reported to EPA, in writing on letterhead stationery or on forms supplied by the Agency, within 30 days after such change occurs.

(f) *Duration of registration.* Establishment registration will remain effective provided pesticide reports are submitted annually pursuant to the requirements of this part. Failure to submit a report may result in termination of establishment registration, civil and/or criminal penalty assessments.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 58 FR 34203, June 23, 1993]

Subparts C–D [Reserved]

Subpart E—Recordkeeping and Reporting Requirements

§ 167.85 Reporting requirements.

(a) *Who must report.* Each producer operating an establishment must submit the reports required by this section concerning any pesticide, active ingredient, or device produced at each establishment. Custom blenders are not required to report production to the Agency.

(b) *Information required.* The pesticide report shall include the following: (1) Name and address of the establishment; (2) amount of each pesticidal product: (i) Produced during the past year; (ii) sold or distributed during the past year; (iii) estimated to be produced during the current year. The report shall only include those pesticidal products actually produced at the reporting establishment. Reports submitted by foreign-producing establishments shall cover only those pesticidal products exported to the United States.

(c) *How to report.* The reports required by this section must be made on forms supplied by the Agency. It is the ultimate responsibility of companies to obtain, complete, and submit the form each year.

(d) *When to report.* A producer operating an establishment must submit an initial report no later than 30 days after the first registration of each establishment the producer operates. Thereafter, the producer must submit an annual report on or before March 1 of each year, even if the producer has produced no pesticidal product for that reporting year.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 58 FR 34203, June 23, 1993]

§ 167.90 Where to obtain and submit forms.

(a) *Where to obtain forms.* Any person may obtain blank forms for the applications and reports required by this part from any EPA Regional Office, or from the address listed in paragraph (b) of this section.

(b) *Where to submit applications and reports.* Each producer operating an establishment, with the exception of those establishments not found at the same location as their company headquarters, must submit applications and reports required by this part to the EPA Regional Office which serves the area where the establishment is located. The list of Regional Office addresses is found in 40 CFR 1.7. Applications and reports for those establishments not found at the same location as their company headquarters to be submitted by the company headquarters to the Regional Office having jurisdiction over the State in which the company headquarters is located. A foreign producer who exports any pesticide product, device, or active ingredient to the United States must submit all applications and reports to:

U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Office of Compliance, Agriculture and Ecosystems Division (2225A), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460, ATTN: FIFRA Foreign Establishment Registration Contact.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 62 FR 49620, Sept. 23, 1997; 65 FR 4577, Jan. 31, 2000]

PART 168—STATEMENTS OF ENFORCEMENT POLICIES AND INTERPRETATIONS

Subpart A—General Provisions [Reserved]

Subpart B—Advertising

Sec.
168.22 Advertising of unregistered pesticides, unregistered uses of registered pesticides and FIFRA section 24(c) registrations.

Subpart C [Reserved]

Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

168.65 Pesticide export label and labeling requirements.
168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.
168.85 Other export requirements.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 54 FR 1125, Jan. 11, 1989, unless otherwise noted.

Subpart A—General Provisions [Reserved]

Subpart B—Advertising

§ 168.22 Advertising of unregistered pesticides, unregistered uses of registered pesticides and FIFRA section 24(c) registrations.

(a) FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to ''offer for sale'' any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

(b) EPA regards it as unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to place or sponsor advertisements which recommend or suggest the purchase or use of:

(1) Any pesticide for a use authorized under a FIFRA section 5 experimental use permit (EUP).

(2) Any pesticide for a use authorized under a FIFRA section 18 emergency exemption, except for advertisements that:

(i) Are placed in media which address primarily persons in the geographical area to which the exemption applies.

(ii) State the name and address of one or more retail dealers who stock the pesticide.

(iii) Contain a prominent notice of the limitations on use under the section 18 emergency exemption.

(3) Any pesticide for any use authorized only by a FIFRA section 24(c) special local need registration, unless the advertisement contains a prominent notice of the limitations on use under the section 24(c) registrations.

(4) Any unregistered pesticide for any use unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section.

(5) A registered pesticide product for an unregistered use, unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section. However, as a matter of policy, the Agency will not regard as unlawful the advertisement of uses permitted by FIFRA section 2(ee) provided the product is not an antimicrobial pesticide targeted against human pathogens (see 51 FR 19174; May 28, 1986).

(c) For purposes of paragraph (b) of this section, a ''prominent notice of the limitations on use'' is one which sets forth the limitations on use in a manner reasonably likely to be understood by persons to whom the advertisement is addressed. For printed advertising, this criterion will be met by a legend in 6-point or larger type.

Subpart C [Reserved]

Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

SOURCE: 58 FR 9085, Feb. 18, 1993, unless otherwise noted.

§ 168.65 Pesticide export label and labeling requirements.

(a) *General.* This section describes how EPA interprets and will enforce the requirements of FIFRA section 17(a)(1). Every exported pesticide, device, and active ingredient used in producing a pesticide (see § 152.3 of this chapter for the definition of ''active ingredient'' and ''pesticide'') must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1). This requirement applies to all such pesticides, devices, or active ingredients, regardless of whether the export is for commercial or research use. In the case of unregistered pesticides, including research substances which are being exported for testing, the labeling requirements of this section continue to apply independently of whether the exporter must submit a purchaser acknowledgement statement under FIFRA section 17(a)(2) as described at § 168.75 of this chapter. In addition, information which will satisfy FIFRA section 2(q)(1)(E), (G), and (H) and section 2(q)(2)(A) and (D) must appear in English and in the appropriate foreign languages, on the label or labeling as described in paragraph (b)(4) of this section. The required label and labeling statements may be met through either immediate container labels, accompanying supplemental labeling as described in paragraph (c) of this section, or a combination of the two.

(b) *Specific requirements.* The labels and labeling of any exported pesticides, devices, and active ingredients used in producing pesticides must meet the requirements regarding label and labeling content, correct representation, and understandability as stated in this paragraph.

(1) *Label contents.* The term *label* means the written, printed, or graphic matter on or attached to the immediate container of the pesticide, device, or active ingredient used in producing a pesticide. In the case that the immediate container is enclosed in an outer container or wrapper through which the label cannot be read, the label must also be on such outer container or wrapper. Except as provided in paragraph (c) of this section, the immediate container of the pesticide, device, or active ingredient used in producing a pesticide must bear a conspicuous and readable label which includes:

(i) *EPA pesticide producing establishment number.* The producing establishment registration number must be present but may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in § 156.10(f) of this chapter.

(ii) *Warning or caution statements.* Warning or caution statements must appear on the label and must be adequate for the protection of persons handling the pesticide, device, or active ingredients including warnings regarding general toxicological hazards

and environmental, physical, or chemical hazards. Warning and caution statements must appear in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country (for example, where a statement calls for a gas mask meeting the specifications of the National Institute of Occupational Safety and Health), an equivalent caution must be substituted.

(iii) *The statement ''Not Registered for Use in the United States of America.''* The labels of all pesticides, devices, and active ingredients which are not registered for use in the United States under FIFRA section 3 must prominently display the following statement: ''Not Registered for Use in the United States of America.'' The statement must appear in English and in appropriate foreign languages, as described in paragraph (b)(4) of this section. It is permissible to append explanatory text which qualifies the statement by pointing out the reasons for the unregistered status. Examples of possible additional statements are ''Not Registered for Use on...'', ''No Longer Registered for Use...'', or ''Not Registered...because...'' Such additions must not be misleading or misrepresent the registration status of the pesticide. The statement ''Not Registered For Use in the United States of America'' must also be present.

(A) A pesticide is considered registered for the purposes of the section 17(a)(1) requirement only when:

(*1*) A label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(*2*) The formula of the exported product is the same as the formula of the U.S. registered product (within certified limits). In addition, a change in the color or fragrance of the export product will not affect the product's registration status, as long as the following conditions are met:

(*i*) The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, which can be obtained at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).)

(*ii*) The change in fragrance must result only from the addition of a chemical included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the chemical must not be a List 1 inert.

(*iii*) The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See ''Food Fragrances in Pesticide Formulations,'' EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975, which can be obtained at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).)

(*iv*) Any differences in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(*3*) No statements which appear on any of the product labels or labeling add new uses or claims or in any way contradict the approved FIFRA section 3 labeling. However, certain minor changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter.

(iv) *The ingredient statement.* The ingredient statement must appear on the label in English and in appropriate foreign languages (as described in paragraph (b)(4) of this section). If the English language description of the ingredients is easily identifiable and likely to be understood by the ordinary individual, the foreign language ingredient statement need not be included

on the label. In the case of pesticide products, devices and active ingredients shipped solely for research and development purposes, it is permissible to use coded identification of ingredients on the label in order to protect confidentiality, in accordance with the requirements of §§168.75(c) and 168.85(a).

(v) *Identity of parties.* The name and address of the producer, registrant (if any), or the person for whom the pesticide was produced, must appear on the label.

(vi) *Weight or measure.* The net weight must appear on the label in either English or metric units.

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active ingredient is highly toxic to humans, the skull and crossbones, the word ''Poison,'' and a first aid statement must appear on the label. The word ''Poison'' and the first aid statement shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see §156.62 of this chapter.

(2) *Use classification statement.* In addition to the label contents described in paragraph (b)(1) of this section, the labeling must include a use classification statement, if a use classification has been assigned under a FIFRA section 3 registration. The use classification shall accurately describe the use classification applicable to the U.S. registered use of the pesticide, device or active ingredient (e.g., ''Restricted Use Pesticide''). Summary statements describing the use classification, e.g., ''For retail sale to and use only by Certified Applicators...'', or explaining what such terms mean are not required, but may be included if such statements do not result in false representation of the U.S. regulatory status of the pesticide. The use classification information may appear on the product label or on the labeling accompanying the pesticide product during shipment.

(3) *Misrepresentation.* The labeling shall not make false or misleading representations or represent the product as an imitation of other products.

(4) *Understandability.* The required statements must be expressed in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. To satisfy this section, certain information described in paragraph (b)(4)(i) of this section, which appears on the labeling of all exported pesticide products, devices and active ingredients must appear in English, in an acceptable language of the country of import as defined in paragraph (b)(4)(ii) of this section, and in an acceptable language of the country of final destination, if known or reasonably ascertainable by the exporter. When there are several official languages or dialects in a country, the language which is predominately spoken or written, or a language in which official government business is conducted, will be acceptable.

(i) *Information required to be multilingual.* The following labeling information must be multilingual:

(A) The warning and caution statements.

(B) Where required, the statement ''Not Registered for Use in the United States of America.''

(C) The ingredient statement.

(D) Where required in accordance with paragraph (b)(1)(vii) of this section, the word ''Poison'' and the statement of practical treatment in case of poisoning.

(ii) *Acceptable languages.* In all cases, English must be one of the languages used on the label or labeling. In addition, either the language which is used to conduct official government business, or the predominantly spoken or written language of the country of import must appear on the labeling. In each case where a country of final destination is known, the language which is used to conduct official government business or which is predominantly spoken in that country, if different from the language of the country of import, shall also appear on the labeling. In any case where English is predominantly spoken or written or is the language used to conduct official government business in a country, no other language need be included to meet the multiple language requirement of this paragraph.

(c) *Supplemental labeling.* A pesticide, device or active ingredient intended for export will not be considered in violation of the labeling requirements of FIFRA when the label and/or labeling requirements stated in paragraph (b) of this section are met by supplemental labeling. Supplemental labeling must be attached to the immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment to meet export label requirements. Supplemental labeling must meet all of the label requirements in paragraph (b) of this section which are not met by the immediate product labels. Supplemental labeling will satisfy the labeling requirements of FIFRA only if the following conditions are met:

(1) *Applicability.* The use of supplemental labeling applies to any situation where the labeling requirements specified in this section are not met fully on the product label which is attached to the immediate product container. Any required label or labeling statement not met on the immediate container may be met through supplemental labeling.

(2) *Labeling contents and relation to shipment.* If supplemental labeling is used to meet any of the labeling requirements of FIFRA section 17(a)(1), it must meet all of the requirements in paragraph (b) of this section which are not met by the label on the immediate product container. Thus, the supplemental labeling, together with the immediate product container label will meet all of the requirements of paragraph (b) of this section. Where used, supplemental labeling must be attached to or accompany the product shipping container of the pesticide, device, or active ingredient used in producing a pesticide at all times when shipped or held for shipment in the United States.

[58 FR 9085, Feb. 18, 1993, as amended at 69 FR 23117, Apr. 28, 2004; 69 FR 39864, July 1, 2004; 71 FR 35546, June 21, 2006, 73 FR 75598, Dec. 12, 2008]

§ 168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.

This section describes how EPA interprets and will enforce requirements of FIFRA section 17(a)(2). Section 17(a)(2) provides that any person exporting a pesticide other than a pesticide registered for use under FIFRA section 3 or sold under FIFRA section 6(a)(1), shall obtain a statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. Section 17(a)(2) requires that a copy of the statement be transmitted to an appropriate official of the government of the importing country.

(a) *Products subject to the requirement.* EPA will not consider an exporter of an unregistered pesticide to be in violation of FIFRA section 17(a)(2) if, prior to export of the pesticide, the exporter submits to EPA a statement signed by the foreign purchaser which affirms that the purchaser is aware that the pesticide is not registered for use in the United States and cannot be sold for use in the United States. The exporter must also include with the submission of the purchaser acknowledgement statement to EPA, a certification signed by the exporter affirming that the export did not occur until the statement signed by the foreign purchaser was obtained by the exporter. Except as provided in paragraph (b) of this section, all pesticide products produced for export which cannot be sold for use in the United States in the form that they are produced for export, are considered to be unregistered pesticides. This includes pesticides which are of a different formulation, including composition (except for variation within certified limits), or type of formulation, and pesticides which are packaged for use patterns for which they are not registered, which may be evidenced by package type or label use statements. This also includes unregistered products which are under development as pesticidal products and which are being exported for research testing.

(b) *Exceptions.* Under the specific circumstances discussed below, EPA will

not treat a registered product which has been modified slightly for export purposes, as unregistered for the purposes of the purchaser acknowledgement statement requirement. Any changes to the registered product for export purposes must be documented in accordance with the record-keeping requirements at § 169.2 of this chapter and this policy.

(1) *Labeling on immediate product.* EPA will not treat as unregistered for the purposes of section 17(a)(2), a registered pesticide product which cannot be sold or distributed for use in the United States because its immediate product container does not bear a label approved under a FIFRA section 3 registration, but which could be sold or distributed in the United States with the approved label attached to the immediate product container, provided that the label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) *Packaging.* (i) Certain changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter and this policy. These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), as described in § 168.75 of this chapter including the requirement for a purchaser acknowledgement statement.

(ii) If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of nonmandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See § 152.46(b)).

(3) *Labeling statements.* The following statements which appear on any of the product labels or labeling will not affect the status of the product, provided that they do not contradict the approved FIFRA section 3 labeling:

(i) It is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement ''restricted use pesticide'' may be expanded to read: ''Restricted in the United States of America to use by certified applicators'' or ''Restricted Use Pesticide. In The United States this product is restricted to use by applicators determined by each state to be competent in pesticide application and the human health and environmental consequences of misuse.'' If the explanatory language falsely represents or is misleading regarding the U.S. use classification, the product will be considered misbranded. In addition, a use classification can only be listed if one has been assigned pursuant to the U.S. registration.

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and

greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop' indoor use' and forestry use. Adding new uses to the label which change the use pattern, such as changes from nonfood to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

(4) *Composition*. EPA will not treat a registered product as unregistered for the purposes of the purchaser acknowledgement statement requirement under the following specific circumstances:

(i) The formula of the exported product is within certified limits of the formula of the U.S. registered product.

(ii) An exporter, who is also the manufacturer of a U.S. registered pesticide, may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing the product to be treated as ''unregistered'' and triggering the requirement to obtain a purchaser acknowledgement statement as a condition for export. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4-a list of inert ingredients posing minimal hazard or risk-if the inert ingredients were generally regarded as innocuous. The provisions of this paragraph do not apply to those pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to § 158.400 or § 161.640 of this chapter, as applicable. Any differences in formula or composition caused by adding a List 4 inert must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(iii) A change in the color or fragrance of the export product will not affect the product's registration status as long as the following conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products. The change in fragrance must result only from the addition of a chemical included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the chemical must not be a List 1 inert. The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See ''Food Fragrances in Pesticide Formulations,'' EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.) Any difference in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(5) *Research and development products.* An unregistered pesticide product exported only for research and development purposes is subject to the notification requirements of this section, unless its use fits within the criteria described in this paragraph.

(i) An unregistered pesticide product exported solely for research and development purposes will not be considered to be in violation of the notification requirements if the export of the research and development product:

(A) Would not involve land uses of more than 10 acres (4.05 hectares), or be used on or affect food or feed crops which are intended for consumption.

(B) Would not involve aquatic uses of more than 1 acre (0.405 hectares), or any aquatic uses which involve water used for irrigation, drinking or recreation, or be used on or affect plants or animals taken for food or feed from such waters.

(C) Would not involve tests on animals intended for food or feed.

(ii) Shipments to different purchasers, to different countries of final destination, or which occur more than a calendar year apart will be evaluated separately. When determining whether

total shipments exceed the criteria described in this paragraph, EPA will evaluate the total amount of shipments by a single exporter during a calendar year for use in a particular country.

(iii) An exporter bears the burden of demonstrating that the product meets these criteria before the research product is shipped. This may be met by documenting before the product is shipped and maintaining records for the time period required by §169.2(h) of this chapter from the date of the last shipment relevant to such records. The records to be maintained consist of:

(A) The identity of the purchaser and country of intended use of the research product.

(B) The amount shipped.

(C) The intended research use by the purchaser, including the type of application site, rate of application, and measures taken for protection of humans from direct or dietary exposure.

(c) *Procedures.* An exporter of an unregistered pesticide product must submit a purchaser acknowledgement statement to EPA containing the information stated in paragraph (c)(1) of this section, and a statement signed by the exporter certifying that the exportation did not occur until the signed acknowledgement statement had been obtained from the purchaser. If the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter. These statements shall be submitted in accordance with one of the two options for submission described in paragraph (c)(2) of this section.

(1) *Contents of the purchaser acknowledgement statements.* The purchaser acknowledgement statement must include the following information in a format that is clearly understandable:

(i) Name, address, and EPA identification number, if applicable, of the exporter.

(ii) Name and address of the foreign purchaser.

(iii) Identity of the product and the active ingredient(s), including:

(A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.

(B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgement statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser acknowledgement statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, *i.e.*, where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

(2) *Reporting options.* At the discretion of the exporter, the requirements of paragraph (c)(1) of this section may be met on a per-shipment or annual basis, as stated in paragraphs (c)(2)(i) and (c)(2)(ii) of this section. If the procedures in paragraph (c)(2)(ii) of this section are not followed, EPA will consider paragraph (c)(2)(i) of this section, requiring pershipment purchaser acknowledgement statements, to be applicable in full. Where paragraph (c)(2)(i) of this section is applicable, each shipment which does not meet the requirements of that paragraph will be considered to be a separate violation of FIFRA.

(i) *Per-shipment purchaser acknowledgment statement.* Unless the exporter chooses to follow the procedures described in paragraph (c)(2)(ii) of this

section for the annual reporting procedures, the exporter must obtain and submit to EPA, a signed purchaser acknowledgement statement prior to each shipment of an unregistered pesticide according to the following procedures:

(A) Prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgment statement.

(B) The exporter must obtain, prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgment statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b), Attention: Purchaser Acknowledgement Statement.

(ii) *Annual reporting procedures.* Unless the exporter chooses to follow the per-shipment reporting option described in paragraph (c)(2)(i) of this section, the exporter must follow the procedures for annual summary reporting which include the requirement of a purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide product to a particular purchaser, and an annual summary of shipments to that purchaser. The annual summary reporting procedures are as follows:

(A) Prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated purchaser acknowledgement statement.

(B) The exporter must obtain, prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received, indicating that this statement is for the first shipment to a particular purchaser in a specific country for that calendar year, and that the exporter will meet all the purchaser acknowledgement statement requirements as described in this paragraph (c)(2)(ii) of this section. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b), Attention: Purchaser Acknowledgement Statement.

(E) The exporter, who has chosen to comply with the requirements of this paragraph instead of providing per-shipment purchaser acknowledgement statements in accordance with paragraph (c)(2)(i) of this section, must submit an annual summary report to EPA. An annual summary report is required for each unregistered pesticide exported within the preceding calendar year. The report must be in writing, signed by the exporter, and include the following information:

(*1*) Name, address, and EPA identification number if applicable, of the exporter.

(*2*) Name and address of the foreign purchaser, and the date the purchaser acknowledgement statement, submitted to EPA during the previous calendar year, was signed by the purchaser.

(*3*) The identity of the product and the active ingredients, including: the Chemical Abstract Services (CAS) registry number for each active ingredient, the chemical nomenclature for each active ingredient used by the International Union of Pure and Applied Chemists (IUPAC), and other known chemical or common names, or if the export involves a research product, the code name or identification number that can be used by EPA to identify the product from the exporter's records.

(*4*) The dates of each shipment of the pesticide exported to the foreign purchaser during that calendar year.

(*5*) If known, or reasonably ascertainable, the country or countries of final destination of the export shipments, *i.e.*, where the exported pesticide was intended to be used, if different from the foreign purchaser's address.

(F) The exporter shall submit the annual summary no later than March 1st of the following calendar year. The annual summary shall be sent to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b), Attention: Annual Summary of Exports.

(iii) *Confidentiality claims.* Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as ''FIFRA Confidential Business Information.'' Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

(3) *Recordkeeping.* Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by §169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgement statement be kept, as stated at §169.2(h)(3) of this chapter, the following records must be maintained:

(i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.

(ii) Copies of signed purchaser acknowledgement statements obtained according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.

(iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.

(d) *Agency transmission of purchaser acknowledgement statements.* EPA will transmit a copy of each purchaser acknowledgement statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

[58 FR 9085, Feb. 18, 1993, as amended at 69 FR 23117, Apr. 28, 2004; 71 FR 35546, June 21, 2006; 72 FR 61029, Oct. 26, 2007]

§ 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

(a) *Recordkeeping and inspection.* Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at § 168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by § 169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled ''Not Registered for Use in the United States of America'' must be reported as unregistered production regardless of whether a purchaser acknowledgement statement is required.

PART 169—BOOKS AND RECORDS OF PESTICIDE PRODUCTION AND DISTRIBUTION

Sec.
169.1 Definitions.
169.2 Maintenance of records.
169.3 Inspection.

AUTHORITY: 7 U.S.C. 136f and 136w.

SOURCE: 45 FR 54338, Aug. 15, 1980, unless otherwise noted.

§ 169.1 Definitions.

Terms used in this part shall have the meanings set forth for such terms in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, as used in this part, the following terms shall have the meanings set forth below:

(a) *Amount of pesticide or active ingredient.* The term ''amount of pesticide or active ingredient'' means the weight or volume of the pesticide or active ingredient used in producing a pesticide expressed as weight for solid or semi-solid products and as weight or volume of liquid products.

(b) *Batch.* The term ''batch'' means a quantity of a pesticide product or active ingredient used in producing a pesticide made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.

(c) *Device.* The term ''device'' means any device or class of device as defined by the Act and determined by the Administrator to be subject to the provisions of the Act.

(d) *Inability*. The term ''inability'' means the incapacity of any person to maintain, furnish or permit access to any records under this Act and regulations, where such incapacity arises out of causes beyond the control and without the fault or negligence of such person. Such causes may include, but are not restricted to acts of God or of the public enemy, fires, floods, epidemics, quarantine restrictions, strikes, and unusually severe weather, but in every case, the failure must be beyond the control and without the fault or negligence of said person.

(e) *Producer*. The term ''producer'' means the person, as defined by the Act, who produces or imports any pesticide or device or active ingredient used in producing a pesticide.

§ 169.2 Maintenance of records.

All producers of pesticides, devices, or active ingredients used in producing pesticides subject to this Act, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, shall maintain the following records:

(a) Records showing the product name, EPA Registration Number, Experimental Permit Number if the pesticide is produced under an Experimental Use Permit, amounts per batch and batch identification (numbers, letters, etc.) of all pesticides produced. In cases where the product is an active ingredient used in producing a pesticide or where the product is a pesticide which is not registered, is not the subject of an application for registration, or is not produced under an Experimental Use Permit, the records shall also show the complete formula. The batch identification shall appear on all production control records. These records shall be retained for a period of two (2) years.

(b) Records showing the brand names and quantities of devices produced. These records shall be retained for a period of two (2) years.

(c) Records showing the following information regarding the receipt, by the producer, of all pesticides, devices, and active ingredients used in producing pesticides:

(1) Brand name of the pesticide or device, or common or chemical name of the pesticide active ingredient;

(2) Name and address of shipper;

(3) Name of delivering carrier;

(4) Date received; and

(5) Quantities received.

These records are not intended to cover receipt of pesticides used for in-plant maintenance, extermination, or sanitation programs, etc. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for the purposes of this section. These records shall be retained for a period of two (2) years.

(d) Records showing the following information regarding the shipment of all pesticides, devices, and active ingredients used in producing pesticides:

(1) Brand name of pesticide or device, or the common or chemical name of the pesticide active ingredient;

(2) Name and address of consignee;

(3) Where the pesticide is produced pursuant to an experimental use permit (FIFRA section 5), a special exemption (section 18), or a special local need (section 24), the information required under these sections and any regulations promulgated thereto regarding the distribution of such pesticides;

(4) Name of originating carrier;

(5) Date shipped or delivered for shipment; and

(6) Quantities shipped or delivered for shipment.

Such records are required regardless of whether any shipment or receipt of shipment is between plants owned or otherwise controlled by the same person. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for purposes of this section. These records shall be retained for a period of two (2) years.

(e) Inventory records with respect to the types and amounts of pesticides or pesticide active ingredients, or quantities of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

(f) Copies of all domestic advertising of the restricted uses of any pesticide registered for restricted use which the producer caused to have prepared, including any radio or television scripts for all such pesticides. These records shall be retained for a period of two (2) years.

(g) Copies of all guarantees given pursuant to section 12(a)(2)(C) of the Act. These records shall be retained for a period of one (1) year after expiration of the guarantee.

(h) In the case of all pesticides, devices, and active ingredients used in producing pesticides intended solely for export to any foreign country:

(1) Copies of the specification or directions of the foreign purchaser for the production of such pesticides, devices, or pesticide active ingredients;

(2) Copies of labels or labeling required to comply with section 17(a)(1) of the Act; and

(3) For any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of the Act, copies of a statement signed by the foreign purchaser of the pesticide acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act.

These records shall be retained for a period of 2 years after expiration of the contract.

(i) Records on the method of disposal (burial, incineration, etc.) date or dates of disposal, location of the disposal sites, and the types and amounts of pesticides or pesticide active ingredients disposed of by the producer or his contractor. With regard to the disposal of containers accumulated during production, the Agency will consider satisfactory a statement, attested to by a responsible firm official, describing in general terms the method and location of disposal, e.g., all containers are taken periodically to a certain site. Records of deviations from normal practice must be maintained. In addition, any records on the disposal of pesticides or pesticide active ingredients and/or containers specified pursuant to section 19 of the Act and any regulations promulgated thereto shall also be maintained. The above requirements apply to those products bearing label instructions for disposal and to any other products specified under any regulations promulgated pursuant to section 19. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance. Notwithstanding these record keeping requirements, whenever any producer of pesticides or pesticide active ingredients is complying with a rule promulgated under the authority of the Resource Conservation and Recovery Act of 1976 (RCRA) (Pub. L. 94–580, 90 Stat. 2795, October 21, 1976), for the handling or disposal of hazardous wastes, as defined by RCRA or any regulations promulgated thereunder, such producer will no longer be required to maintain records in accordance with this subsection.

(j) Records of any tests conducted on human beings whether performed by the producer himself or authorized and/or paid for by the producer. Such records shall include: The names and addresses of subjects tested, dates of tests, types of tests, written consent of subjects to test, and all information and instructions given to the subjects regarding the nature and purpose of the tests and of any physical and mental health consequences which were reasonably foreseen therefrom, and any adverse effects of the test on the subjects, including any such effects coming to the attention of the producer after completion of the tests. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance.

(k) Records containing research data relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof, whether in the possession of the producer or in the possession of the independent testing facility or laboratory (if any) which performed such tests on behalf of the

producer. These records shall be retained as long as the registration is valid and the producer is in business.

[45 FR 54338, Aug. 15, 1980, as amended at 58 FR 9090, Feb. 18, 1993]

§ 169.3 Inspection.

(a) *Producers.* Any producer of any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and to copy all records required to be maintained by this part, including records in the possession of an independent testing facility or laboratory which performed tests on behalf of the producer. Such inspection will be conducted in accordance with procedures detailed in section 8(b) of the Act.

(b) Distributors, carriers, dealers, etc. Any distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act, shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and copy all records showing the delivery or holding of such pesticide, device, or active ingredient used in producing a pesticide, including the quantity, the date of shipment and receipt, and the name and address of the consignor and consignee, and any guarantee received pursuant to section 12(b)(1) of the Act.

(c) *Confidentiality.* Any record which is subject to the regulations under this part, and which may be confidential, shall be treated in accordance with the provisions of section 10 of the Act. The availability to the public of information provided to, or otherwise obtained by, the Administrator under this part shall be governed by part 2 of this chapter.

(d) *Inability.* (1) In the event of the inability of any person to produce records containing the information required to be maintained, furnished for inspection, or given access to, all other records and information regarding the same shall be provided.

(2) Where no such inability exists and any such person fails to give access to and permit copying of such records as required, such failure shall be deemed a refusal to keep records required or a refusal to allow the inspection of any such records or both.

PART 170—WORKER PROTECTION STANDARD

Subpart A—General Provisions

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AUTHORITY: 7 U.S.C. 136w.

SOURCE: 57 FR 38151, Aug. 21, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 170.1 Scope and purpose.

This part contains a standard designed to reduce the risks of illness or injury resulting from workers' and handlers' occupational exposures to pesticides used in the production of agricultural plants on farms or in nurseries, greenhouses, and forests and also from the accidental exposure of workers and other persons to such pesticides. It requires workplace practices designed to reduce or eliminate exposure to pesticides and establishes procedures for responding to exposure-related emergencies.

§ 170.3 Definitions.

Terms used in this part have the same meanings they have in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, the following terms, when used in this part, shall have the following meanings:

Agricultural employer means any person who hires or contracts for the services of workers, for any type of compensation, to perform activities related to the production of agricultural plants, or any person who is an owner of or is responsible for the management or condition of an agricultural establishment that uses such workers.

Agricultural establishment means any farm, forest, nursery, or greenhouse.

Agricultural plant means any plant grown or maintained for commercial or research purposes and includes, but is not limited to, food, feed, and fiber plants; trees; turfgrass; flowers, shrubs; ornamentals; and seedlings.

Chemigation means the application of pesticides through irrigation systems.

Commercial pesticide handling establishment means any establishment, other than an agricultural establishment, that:

(1) Employs any person, including a self-employed person, to apply on an agricultural establishment, pesticides used in the production of agricultural plants.

(2) Employs any person, including a self-employed person, to perform on an agricultural establishment, tasks as a crop advisor.

Crop advisor means any person who is assessing pest numbers or damage, pesticide distribution, or the status or requirements of agricultural plants. The term does not include any person who is performing hand labor tasks.

Early entry means entry by a worker into a treated area on the agricultural establishment after a pesticide application is complete, but before any restricted-entry interval for the pesticide has expired.

Farm means any operation, other than a nursery or forest, engaged in the outdoor production of agricultural plants.

Forest means any operation engaged in the outdoor production of any agricultural plant to produce wood fiber or timber products.

Fumigant means any pesticide product that is a vapor or gas, or forms a vapor or gas on application, and whose method of pesticidal action is through the gaseous state.

Greenhouse means any operation engaged in the production of agricultural plants inside any structure or space that is enclosed with nonporous covering and that is of sufficient size to permit worker entry. This term includes, but is not limited to, polyhouses, mushroom houses, rhubarb houses, and similar structures. It does not include such structures as malls, atriums, conservatories, arboretums, or office buildings where agricultural plants are present primarily for aesthetic or climatic modification.

Hand labor means any agricultural activity performed by hand or with hand tools that causes a worker to have substantial contact with surfaces (such as plants, plant parts, or soil) that may contain pesticide residues. These activities include, but are not limited to, harvesting, detasseling, thinning, weeding, topping, planting, sucker removal, pruning, disbudding, roguing, and packing produce into containers in the field. Hand labor does not include operating, moving, or repairing irrigation or watering equipment or performing the tasks of crop advisors.

Handler means any person, including a self-employed person:

(1) Who is employed for any type of compensation by an agricultural establishment or commercial pesticide handling establishment to which subpart C of this part applies and who is:

(i) Mixing, loading, transferring, or applying pesticides.

(ii) Disposing of pesticides or pesticide containers.

(iii) Handling opened containers of pesticides.

(iv) Acting as a flagger.

(v) Cleaning, adjusting, handling, or repairing the parts of mixing, loading, or application equipment that may contain pesticide residues.

(vi) Assisting with the application of pesticides.

(vii) Entering a greenhouse or other enclosed area after the application and before the inhalation exposure level listed in the labeling has been reached or one of the ventilation criteria established by this part (§ 170.110(c)(3)) or in the labeling has been met:

(A) To operate ventilation equipment.

(B) To adjust or remove coverings used in fumigation.

(C) To monitor air levels.

(viii) Entering a treated area outdoors after application of any soil fumigant to adjust or remove soil coverings such as tarpaulins.

(ix) Performing tasks as a crop advisor:

(A) During any pesticide application.

(B) Before the inhalation exposure level listed in the labeling has been reached or one of the ventilation criteria established by this part (§ 170.110(c)(3)) or in the labeling has been met.

(C) During any restricted-entry interval.

(2) The term does not include any person who is only handling pesticide containers that have been emptied or cleaned according to pesticide product labeling instructions or, in the absence of such instructions, have been subjected to triple-rinsing or its equivalent.

Handler employer means any person who is self-employed as a handler or who employs any handler, for any type of compensation.

Immediate family includes only spouse, children, stepchildren, foster children, parents, stepparents, foster parents, brothers, and sisters.

Nursery means any operation engaged in the outdoor production of any agricultural plant to produce cut flowers and ferns or plants that will be used in their entirety in another location. Such plants include, but are not limited to, flowering and foliage plants or trees; tree seedlings; live Christmas trees; vegetable, fruit, and ornamental transplants; and turfgrass produced for sod.

Owner means any person who has a present possessory interest (fee, leasehold, rental, or other) in an agricultural establishment covered by this part. A person who has both leased such agricultural establishment to another person and granted that same person the right and full authority to manage and govern the use of such agricultural establishment is not an owner for purposes of this part.

Restricted-entry interval means the time after the end of a pesticide application during which entry into the treated area is restricted.

Treated area means any area to which a pesticide is being directed or has been directed.

Worker means any person, including a self-employed person, who is employed for any type of compensation and who is performing activities relating to the production of agricultural plants on an agricultural establishment to which subpart B of this part applies. While persons employed by a commercial pesticide handling establishment are performing tasks as crop advisors, they are not workers covered by the requirements of subpart B of this part.

§ 170.7 General duties and prohibited actions.

(a) *General duties.* The agricultural employer or the handler employer, as appropriate, shall:

(1) Assure that each worker subject to subpart B of this part or each handler subject to subpart C of this part receives the protections required by this part.

(2) Assure that any pesticide to which subpart C of this part applies is used in a manner consistent with the labeling of the pesticide, including the requirements of this part.

(3) Provide, to each person who supervises any worker or handler, information and directions sufficient to assure that each worker or handler receives the protections required by this part. Such information and directions shall specify which persons are responsible for actions required to comply with this part.

(4) Require each person who supervises any worker or handler to assure compliance by the worker or handler with the provisions of this part and to assure that the worker or handler receives the protections required by this part.

(b) *Prohibited actions.* The agricultural employer or the handler employer shall not take any retaliatory action for attempts to comply with this part or any action having the effect of preventing or discouraging any worker or handler from complying or attempting to comply with any requirement of this part.

§ 170.9 Violations of this part.

(a) Under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) (FIFRA) section 12(a)(2)(G) it is unlawful for any person ''to use any registered pesticide in a manner inconsistent with its labeling.'' When this part is referenced on a label, users must comply with all of its requirements except those that are inconsistent with product-specific instructions on the labeling. For the purposes of this part, EPA interprets the term ''use'' to include:

(1) Preapplication activities, including, but not limited to:

(i) Arranging for the application of the pesticide;

(ii) Mixing and loading the pesticide; and

(iii) Making necessary preparations for the application of the pesticide, including responsibilities related to worker notification, training of handlers, decontamination, use and care of personal protective equipment, emergency information, and heat stress management.

(2) Application of the pesticide.

(3) Post-application activities necessary to reduce the risks of illness and injury resulting from handlers' and workers' occupational exposures to pesticide residues during the restricted-entry interval plus 30 days. These activities include, but are not limited to, responsibilities related to worker training, notification, and decontamination.

(4) Other pesticide-related activities, including, but not limited to, providing emergency assistance, transporting or storing pesticides that have been opened, and disposing of excess pesticides, spray mix, equipment wash waters, pesticide containers, and other pesticide-containing materials.

(b) A person who has a duty under this part, as referenced on the pesticide product label, and who fails to perform that duty, violates FIFRA section 12(a)(2)(G) and is subject to a civil penalty under section 14. A person who knowingly violates section 12(a)(2)(G) is subject to section 14 criminal sanctions.

(c) FIFRA section 14(b)(4) provides that a person is liable for a penalty under FIFRA if another person employed by or acting for that person violates any provision of FIFRA. The term ''acting for'' includes both employment and contractual relationships.

(d) The requirements of this part, including the decontamination requirements, shall not, for the purposes of section 653(b)(1) of title 29 of the U.S. Code, be deemed to be the exercise of statutory authority to prescribe or enforce standards or regulations affecting the general sanitary hazards addressed by the OSHA Field Sanitation Standard, 29 CFR 1928.110, or other agricultural, nonpesticide hazards.

Subpart B—Standard for Workers

§ 170.102 Applicability of this subpart.

Except as provided by §§ 170.103 and 170.104, this subpart applies when any pesticide product is used on an agricultural establishment in the production of agricultural plants.

[60 FR 21952, May 3, 1995]

§ 170.103 Exceptions.

Exceptions. This subpart does not apply when any pesticide is applied on an agricultural establishment in the following circumstances:

(a) For mosquito abatement, Mediterranean fruit fly eradication, or similar wide-area public pest control programs sponsored by governmental entities;

(b) On livestock or other animals, or in or about animal premises;

(c) On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses;

(d) On plants that are in ornamental gardens, parks, and public or private lawns and grounds that are intended only for aesthetic purposes or climatic modification;

(e) By injection directly into agricultural plants. Direct injection does not include ''hack and squirt,'' ''frill and spray,'' chemigation, soil-incorporation, or soil-injection;

(f) In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other noncrop areas, and pasture and rangeland use;

(g) For control of vertebrate pests;

(h) As attractants or repellents in traps;

(i) On the harvested portions of agricultural plants or on harvested timber; and

(j) For research uses of unregistered pesticides.

[57 FR 38151, Aug. 21, 1992. Redesignated at 60 FR 21952, May 3, 1995]

§ 170.104 Exemptions.

The workers listed in this section are exempt from the specified provisions of this subpart.

(a) *Owners of agricultural establishments.* (1) The owner of an agricultural establishment is not required to provide to himself or members of his immediate family who are performing tasks related to the production of agricultural plants on their own agricultural establishment the protections of:

(i) Section 170.112(c)(5) through (9).

(ii) Section 170.112(c)(5) through (9) as referenced in §§ 170.112(d)(2)(iii) and 170.112(e).

(iii) Section 170.120.

(iv) Section 170.122.

(v) Section 170.130.

(vi) Section 170.135.

(vii) Section 170.150.

(viii) Section 170.160.

(2) The owner of the agricultural establishment must provide the protections listed in paragraph (a)(1)(i) through (viii) of this section to other workers and other persons who are not members of his immediate family.

(b) *Crop advisors.* (1) Provided that the conditions of paragraph (b)(2) of this section are met, a person who is certified or licensed as a crop advisor by a program acknowledged as appropriate in writing by EPA or a State or Tribal lead agency for pesticide enforcement, and persons performing crop advising tasks under such qualified crop advisor's direct supervision, are exempt from the provisions of:

(i) Section 170.150.

(ii) Section 170.160.

A person is under the direct supervision of a crop advisor when the crop advisor exerts the supervisory controls set out in paragraphs (b)(2)(iii) and (iv) of this section. Direct supervision does not require that the crop advisor be physically present at all times, but the crop advisor must be readily accessible to the employees at all times.

(2) Conditions of exemption. (i) The certification or licensing program requires pesticide safety training that includes, at least, all the information in § 170.230(c)(4).

(ii) Applies only when performing crop advising tasks in the treated area.

(iii) The crop advisor must make specific determinations regarding the appropriate personal protective equipment, appropriate decontamination supplies, and how to conduct the tasks safely. The crop advisor must convey this information to each person under his direct supervision in a language that the person understands.

(iv) Before entering a treated area, the certified or licensed crop advisor must inform, through an established practice of communication, each person under his direct supervision of the pesticide product and active ingredient(s) applied, method of application, time of application, the restricted

entry interval, which tasks to undertake, and how to contact the crop advisor.

[60 FR 21952, May 3, 1995, as amended at 73 FR 75598, Dec. 12, 2008]

§ 170.110 Restrictions associated with pesticide applications.

(a) *Farms and forests.* During the application of any pesticide on a farm or in a forest, the agricultural employer shall not allow or direct any person, other than an appropriately trained and equipped handler, to enter or to remain in the treated area.

(b) *Nurseries.* In a nursery, during any pesticide application described in column A of Table 1 of this paragraph, the agricultural employer shall not allow or direct any person, other than an appropriately trained and equipped handler, to enter or to remain in the area specified in column B of Table 1 of this paragraph. After the application is completed, until the end of any restricted-entry interval, the entry-restricted area is the treated area.

TABLE 1—ENTRY-RESTRICTED AREAS IN NURSERIES DURING PESTICIDE APPLICATIONS

A. During Application of a Pesticide:	B. Workers are Prohibited in:
(1)(a) Applied: (i) Aerially, or (ii) In an upward direction, or (iii) Using a spray pressure greater than 150 psi, or (b) Applied as a: (i) Fumigant, or (ii) Smoke, or (iii) Mist, or (iv) Fog, or (v) Aerosol.	Treated area plus 100 feet in all directions on the nursery
(2)(a) Applied downward using: (i) A height of greater than 12 inches from the planting medium, or (ii) A fine spray, or (iii) A spray pressure greater than 40 psi and less than 150 psi. (b) Not as in 1 or 2(a) above but for which a respiratory protection device is required for application by the product labeling.	Treated are plus 25 feet in all directions on the nursery
(3) Applied otherwise.	Treated area

(c) *Greenhouses.* (1) When a pesticide application described in column A of Table 2 under paragraph (c)(4) of this section takes place in a greenhouse, the agricultural employer shall not allow or direct any person, other than an appropriately trained and equipped handler, to enter or to remain in the area specified in column B of Table 2 until the time specified in column C of Table 2 has expired.

(2) After the time specified in column C of Table 2 under paragraph (c)(4) of this section has expired, until the expiration of any restricted-entry interval, the agricultural employer shall not allow or direct any worker to enter or to remain in the treated area as specified in column D of Table 2 under paragraph (c)(4) of this section, except as provided in § 170.112.

(3) When column C of Table 2 under paragraph (c)(4) of this section specifies that ventilation criteria must be met, ventilation shall continue until the air concentration is measured to be equal to or less than the inhalation exposure level the labeling requires to be achieved. If no inhalation exposure level is listed on the labeling, ventilation shall continue until after:

(i) Ten air exchanges are completed; or

(ii) Two hours of ventilation using fans or other mechanical ventilating systems; or

(iii) Four hours of ventilation using vents, windows or other passive ventilation; or

(iv) Eleven hours with no ventilation followed by 1 hour of mechanical ventilation; or

(v) Eleven hours with no ventilation followed by 2 hours of passive ventilation; or

(vi) Twenty-four hours with no ventilation.

(4) The following Table 2 applies to paragraphs (c) (1), (2), and (3) of this section.

TABLE 2—GREENHOUSE ENTRY RESTRICTIONS ASSOCIATED WITH PESTICIDE APPLICATIONS

A. When a Pesticide is Applied:	B. Workers are Prohibited in:	C. Until:	D. After the Expiration of Time in Column C Until the Restricted-Entry Interval Expires, the Entry-Restricted Area is:
(1) As a fumigant	Entire greenhouse plus any adjacent structure that cannot be sealed off from the treated area	The ventilation criteria of paragraph (c)(3) of this section are met	No entry restrictions after criteria in column C are met
(2) As a (i) Smoke, or (ii) Mist, or (iii) Fog, or (iv) Aerosol	Entire enclosed area	The ventilation criteria of paragraph (c)(3) of this section are met	Entire enclosed area is the treated area
(3) Not in 1 or 2 above, and for which a respiratory protection device is required for application by the product labeling	Entire enclosed area	The ventilation criteria of paragraph (c)(3) of this section are met	Treated area
(4) Not in 1, 2, or 3 above, and: (i) From a height of greater than 12 in. from the planting medium, or (ii) As a fine spray, or (iii) Using a spray pressure greater than 40 psi	Treated area plus 25 feet in all directions in the enclosed area	Application is complete	Treated area
(5) Otherwise	Treated area	Application is complete	Treated area

§ 170.112 Entry restrictions.

(a) *General restrictions.* (1) After the application of any pesticide on an agricultural establishment, the agricultural employer shall not allow or direct any worker to enter or to remain in the treated area before the restricted-entry interval specified on the pesticide labeling has expired, except as provided in this section.

(2) Entry-restricted areas in greenhouses are specified in column D in table 2 under § 170.110(c)(4).

(3) When two or more pesticides are applied at the same time, the restricted-entry interval shall be the longest of the applicable intervals.

(4) The agricultural employer shall assure that any worker who enters a treated area under a restricted-entry interval as permitted by paragraphs (c), (d), and (e) of this section uses the personal protective equipment specified in the product labeling for early-entry workers and follows any other requirements on the pesticide labeling regarding early entry.

(b) *Exception for activities with no contact.* A worker may enter a treated area during a restricted-entry interval if the agricultural employer assures that both of the following are met:

(1) The worker will have no contact with anything that has been treated with the pesticide to which the restricted-entry interval applies, including, but not limited to, soil, water, air, or surfaces of plants; and

(2) No such entry is allowed until any inhalation exposure level listed in the labeling has been reached or any ventilation criteria established by § 170.110(c)(3) or in the labeling have been met.

(c) *Exception for short-term activities.* A worker may enter a treated area during a restricted-entry interval for short-term activities if the agricultural employer assures that the following requirements are met:

(1) No hand labor activity is performed.

(2) The time in treated areas under a restricted-entry interval for any worker does not exceed 1 hour in any 24-hour period.

(3) No such entry is allowed for the first 4 hours following the end of the application, and no such entry is allowed thereafter until any inhalation exposure level listed in the labeling has been reached or any ventilation criteria established by § 170.110(c)(3) or in the labeling have been met.

(4) The personal protective equipment specified on the product labeling for early entry is provided to the worker. Such personal protective equipment shall conform to the following standards:

(i) Personal protective equipment (PPE) means devices and apparel that are worn to protect the body from contact with pesticides or pesticide residues, including, but not limited to, coveralls, chemical-resistant suits, chemical-resistant gloves, chemical-resistant footwear, respiratory protection devices, chemical-resistant aprons, chemical-resistant headgear, and protective eyewear.

(ii) Long-sleeved shirts, short-sleeved shirts, long pants, short pants, shoes, socks, and other items of work clothing are not considered personal protective equipment for the purposes of this section and are not subject to the requirements of this section, although pesticide labeling may require that such work clothing be worn during some activities.

(iii) When ''chemical-resistant'' personal protective equipment is specified by the product labeling, it shall be made of material that allows no measurable movement of the pesticide being used through the material during use.

(iv) When ''waterproof'' personal protective equipment is specified by the product labeling, it shall be made of material that allows no measurable movement of water or aqueous solutions through the material during use.

(v) When a ''chemical-resistant suit'' is specified by the product labeling, it shall be a loose-fitting, one- or two-piece, chemical-resistant garment that covers, at a minimum, the entire body except head, hands, and feet.

(vi) When ''coveralls'' are specified by the product labeling, they shall be a loose-fitting, one- or two-piece garment, such as a cotton or cotton and polyester coverall, that covers, at a minimum, the entire body except head, hands, and feet. The pesticide product labeling may specify that the coveralls be worn over a layer of clothing. If a chemical-resistant suit is substituted for coveralls, it need not be worn over a layer of clothing.

(vii)(A) Gloves shall be of the type specified on the pesticide product labeling. Gloves made of leather, cotton, or other absorbent materials must not be worn for early-entry activities, unless gloves made of these materials are listed as acceptable for such use on the product labeling. If chemical-resistant gloves with sufficient durability and suppleness are not obtainable, leather gloves may be worn on top of chemical-resistant gloves. However, once leather gloves have been worn for this use, they shall not be worn thereafter for any other purpose, and they shall only be worn over chemical-resistant gloves.

(B) Separable glove liners may be worn beneath chemical-resistant gloves, unless the pesticide product labeling specifically prohibits their use. Separable glove liners are defined as separate glove-like hand coverings made of lightweight material, with or without fingers. Work gloves made from lightweight cotton or poly-type material are considered to be glove liners if worn beneath chemical-resistant gloves. Separable glove liners may not extend outside the chemical-resistant gloves under which they are worn. Chemical-resistant gloves with non-separable absorbent lining materials are prohibited.

(C) If used, separable glove liners must be discarded immediately after a total of no more than 10 hours of use or within 24 hours of when first put on, whichever comes first. The liners must be replaced immediately if directly contacted by pesticide. Used glove liners shall not be reused. Contaminated

liners must be disposed of in accordance with any Federal, State, or local regulations.

(viii) When ''chemical-resistant footwear'' is specified by the product labeling, it shall be one of the following types of footwear: chemical-resistant shoes, chemical-resistant boots, or chemical-resistant shoe coverings worn over shoes or boots. If chemical-resistant footwear with sufficient durability and a tread appropriate for wear in rough terrain is not obtainable for workers, then leather boots may be worn in such terrain.

(ix) When ''protective eyewear'' is specified by the product labeling, it shall be one of the following types of eyewear: goggles; face shield; safety glasses with front, brow, and temple protection; or a full-face respirator.

(x) When ''chemical-resistant headgear'' is specified by the product labeling, it shall be either a chemical-resistant hood or a chemical-resistant hat with a wide brim.

(5) The agricultural employer shall assure that the worker, before entering the treated area, either has read the product labeling or has been informed, in a manner that the worker can understand, of all labeling requirements related to human hazards or precautions, first aid, symptoms of poisoning, personal protective equipment specified for early entry, and any other labeling requirements related to safe use.

(6) The agricultural employer shall assure that:

(i) Workers wear the personal protective equipment correctly for its intended purpose and use personal protective equipment according to manufacturer's instructions.

(ii) Before each day of use, all personal protective equipment is inspected for leaks, holes, tears, or worn places, and any damaged equipment is repaired or discarded.

(iii) Personal protective equipment that cannot be cleaned properly is disposed of in accordance with any applicable Federal, State, and local regulations.

(iv) All personal protective equipment is cleaned according to manufacturer's instructions or pesticide product labeling instructions before each day of reuse. In the absence of any such instructions, it shall be washed thoroughly in detergent and hot water.

(v) Before being stored, all clean personal protective equipment is dried thoroughly or is put in a well-ventilated place to dry.

(vi) Personal protective equipment contaminated with pesticides is kept separately and washed separately from any other clothing or laundry.

(vii) Any person who cleans or launders personal protective equipment is informed that such equipment may be contaminated with pesticides, of the potentially harmful effects of exposure to pesticides, and of the correct way(s) to handle and clean personal protective equipment and to protect themselves when handling equipment contaminated with pesticides.

(viii) All clean personal protective equipment is stored separately from personal clothing and apart from pesticide-contaminated areas.

(ix) Each worker is instructed how to put on, use, and remove the personal protective equipment and is informed about the importance of washing thoroughly after removing personal protective equipment.

(x) Each worker is instructed in the prevention, recognition, and first aid treatment of heat-related illness.

(xi) Workers have a clean place(s) away from pesticide-storage and pesticide-use areas for storing personal clothing not in use; putting on personal protective equipment at the start of any exposure period; and removing personal protective equipment at the end of any exposure period.

(7) When personal protective equipment is required by the labeling of any pesticide for early entry, the agricultural employer shall assure that no worker is allowed or directed to perform the early-entry activity without implementing, when appropriate, measures to prevent heat-related illness.

(8) During any early-entry activity, the agricultural employer shall provide a decontamination site in accordance with § 170.150.

(9) The agricultural employer shall not allow or direct any worker to wear

home or to take home personal protective equipment contaminated with pesticides.

(d) *Exception for an agricultural emergency.* (1) An ''agricultural emergency'' means a sudden occurrence or set of circumstances which the agricultural employer could not have anticipated and over which the agricultural employer has no control, and which requires entry into a treated area during a restricted-entry interval, when no alternative practices would prevent or mitigate a substantial economic loss. A substantial economic loss means a loss in profitability greater than that which would be expected based on the experience and fluctuations of crop yields in previous years. Only losses caused by the agricultural emergency specific to the affected site and geographic area are considered. The contribution of mismanagement cannot be considered in determining the loss.

(2) A worker may enter a treated area under a restricted-entry interval in an agricultural emergency to perform tasks, including hand labor tasks, necessary to mitigate the effects of the agricultural emergency, if the agricultural employer assures that all the following criteria are met:

(i) A State, Tribal, or Federal Agency having jurisdiction declares the existence of circumstances that could cause an agricultural emergency on that agricultural establishment.

(ii) The agricultural employer determines the agricultural establishment is subject to the circumstances declared under paragraph (d)(2)(i) of this section that result in an agricultural emergency meeting the criteria of paragraph (d)(1) of this section.

(iii) The requirements of paragraphs (c) (3) through (9) of this section are met.

(e) *Exception requiring Agency approval.* The Agency may, in accordance with paragraphs (e) (1) through (3) of this section, grant an exception from the requirements of this section. An exception may be withdrawn in accordance with paragraph (e)(6) of this section.

(1) *Exception requiring agency approval.* A request for an exception must be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b) and must be accompanied by two copies of the following information:

(i) The name, address, and telephone number of the submitter.

(ii) The time period for which the exception is requested.

(iii) A description of the crop(s) and specific crop production task(s) for which the exception is requested. Such a description must include an explanation as to the necessity of applying pesticides of a type and at a frequency such that the restricted-entry interval would interfere with necessary and time-sensitive hand labor tasks for the period for which the exception is sought.

(iv) A description of the geographic area for which the exception is requested. If the exception request is for a limited geographic area, the explanation must include a description as to why the circumstances of exposure or economic impact resulting from the prohibition of routine hand labor tasks during the restricted-entry interval are unique to the geographic area named in the exception.

(v) An explanation as to why, for each requested crop-task combination, alternative practices would not be technically or financially viable. Such alternative practices might include: rescheduling the pesticide application or hand labor activity; using a non-chemical pest control alternative; using an alternative to the hand labor tasks, such as machine cultivation; or substituting a pesticide with a shorter restricted-entry interval. This information should include estimates or data on per acre revenue and cost of production for the crop and area for which the exception is requested. These estimates or data should include: the situation prior to implementation of this final rule, the situation after implementation of this final rule if the exception is not granted, the situation after implementation of this final rule if the exception is granted, and specific information on individual factors which cause differences in revenues and costs among the three situations.

(vi) A description or documentation of the safety and feasibility of such an exception, including, but not limited

to, the feasibility of performing the necessary hand labor activity while wearing the personal protective equipment required for early entry for the pesticide(s) expected to be applied, the means of mitigating heat-related illness concerns, the period of time required daily per worker to perform the hand labor activity, any suggested methods of reducing the worker's exposure, and any other mitigating factors, such as the availability of running water for routine and emergency decontamination and mechanical devices that would reduce the workers' contact with the treated surfaces. The information should include the costs associated with early-entry, such as decontamination facilities, special information and training for the workers, heat stress avoidance procedures, and provision, inspection, cleaning, and maintenance of personal protective equipment. EPA will not grant exceptions where the costs of early entry equal or exceed the expected loss in value of crop yield or quality.

(2) *Notice of receipt.* (i) When a request for an exception is submitted to the Agency along with all of the information required in paragraph (e)(1) of this section, the Agency shall issue a notice in the FEDERAL REGISTER stating that an exception is being considered, describing the nature of the exception, and allowing at least 30 days for interested parties to comment.

(ii) If a request for an exception is submitted to the Agency without all of the information required in paragraph (e)(1) of this section, the Agency shall return the request to the submitter.

(3) *Exception decision.* EPA will publish in the FEDERAL REGISTER its decision whether to grant the request for exception. EPA will base its decision on whether the benefits of the exception outweigh the costs, including the value of the health risks attributable to the exception. If the exception is granted, the notice will state the nature of and reasons for the exception.

(4) *Presumptive denial.* (i) Except as provided in paragraph (e)(4)(ii) of this section, persons requesting an exception may assume that the exception has been denied if EPA has not issued its decision whether to grant the exception within 9 months from the comment-closure date specified in the FEDERAL REGISTER notice in which the Agency announced, in accordance with paragraph (e)(2) of this section, that it would consider the exception.

(ii) Persons requesting an exception may not assume that the request has been denied as provided by paragraph (e)(4)(i) of this section if the Agency has taken action to extend its review period for a specified time interval due to the complexity of the exception request or to the number of exception requests concurrently under Agency review. EPA shall state the reason(s) for the delay in issuing a decision on the exception request. A notice of such an action may be published in the FEDERAL REGISTER or persons who requested the exception may be directly notified of the action.

(5) *Agricultural employer duties.* When a worker enters a treated area during a restricted-entry interval under an exception granted under paragraph (e) of this section, the agricultural employer shall assure that the requirements of paragraphs (c) (3) through (9) of this section are met, unless the notice granting the exception specifically indicates otherwise.

(6) *Withdrawing an exception.* An exception may be withdrawn by the Agency at any time if the Agency receives poisoning information or other data that indicate that the health risks imposed by this early-entry exception are unacceptable or if the Agency receives other information that indicates that the exception is no longer necessary or prudent. If the Agency determines that an exception should be withdrawn, it will publish a notice in the FEDERAL REGISTER, stating the basis for its determination. Affected parties would then have 30 days to request a hearing on the Agency's determination. The exception, however, would be discontinued as of the date specified by EPA in the notice, which may include any of the 30-day period and the time required for any subsequent hearing process. Thereafter the Agency will decide whether to withdraw the exception and will publish a notice in the FEDERAL REGISTER stating its decision.

(7) *List of exceptions granted by EPA.* The following administrative exceptions from the requirements of this section have been granted by EPA. Each exception listed in paragraph (e)(7) of this section contains a reference to the FEDERAL REGISTER notice in which EPA has granted the exception and the effective dates of the exception. The terms and conditions of the exception appear in the referenced FEDERAL REGISTER notice.

(i) Exception to perform irrigation tasks under specified conditions published in the FEDERAL REGISTER of May 3, 1995.

(ii) Exceptions to perform limited contact tasks under specified conditions published in the FEDERAL REGISTER of May 3, 1995.

[57 FR 38151, Aug. 21, 1992, as amended at 59 FR 30264, June 10, 1994; 60 FR 21954, May 3, 1995; 62 FR 52003, Oct. 3, 1997; 69 FR 53346, Sept. 1, 2004; 71 FR 35546, June 21, 2006; 73 FR 75598, Dec. 12, 2008]

§ 170.120 Notice of applications.

(a) *Notification to workers of pesticide applications in greenhouses.* The agricultural employer shall notify workers of any pesticide application in the greenhouse in accordance with this paragraph.

(1) All pesticide applications shall be posted in accordance with paragraph (c) of this section.

(2) If the pesticide product labeling has a statement requiring both the posting of treated areas and oral notification to workers, the agricultural employer shall also provide oral notification of the application to the worker in accordance with paragraph (d) of this section.

(3) Notice need not be given to a worker if the agricultural employer can assure that one of the following is met:

(i) From the start of the application until the end of the application and during any restricted-entry interval, the worker will not enter, work in, remain in, or pass through the greenhouse; or

(ii) The worker applied (or supervised the application of) the pesticide for which the notice is intended and is aware of all information required by paragraphs (d)(1) through (3) of this section.

(b) *Notification to workers on farms, in nurseries, or in forests of pesticide applications.* The agricultural employer shall notify workers of any pesticide application on the farm or in the nursery or forest in accordance with this paragraph.

(1) If the pesticide product labeling has a statement requiring both the posting of treated areas and oral notification to workers, the agricultural employer shall post signs in accordance with paragraph (c) of this section and shall provide oral notification of the application to the worker in accordance with paragraph (d) of this section.

(2) For any pesticide other than those for which the labeling requires both posting and oral notification of applications, the agricultural employer shall give notice of the application to the worker either by the posting of warning signs in accordance with paragraph (c) of this section or orally in accordance with paragraph (d) of this section, and shall inform the workers as to which method of notification is in effect.

(3) Notice need not be given to a worker if the agricultural employer can assure that one of the following is met:

(i) From the start of the application until the end of the application and during any restricted-entry interval, the worker will not enter, work in, remain in, or pass through on foot the treated area or any area within 1/4 mile of the treated area; or

(ii) The worker applied (or supervised the application of) the pesticide for which the notice is intended and is aware of all information required by (d)(1) through (3) of this section.

(c) *Posted warning signs.* The agricultural employer shall post warning signs in accordance with the following criteria:

(1) The warning sign shall have a background color that contrasts with red. The words ''DANGER'' and ''PELIGRO,'' plus ''PESTICIDES'' and ''PESTICIDAS,'' shall be at the top of the sign, and the words ''KEEP OUT'' and ''NO ENTRE'' shall be at the bottom of the sign. Letters for all words

must be clearly legible. A circle containing an upraised hand on the left and a stern face on the right must be near the center of the sign. The inside of the circle must be red, except that the hand and a large portion of the face must be in a shade that contrasts with red. The length of the hand must be at least twice the height of the smallest letters. The length of the face must be only slightly smaller than the hand. Additional information such as the name of the pesticide and the date of application may appear on the warning sign if it does not detract from the appearance of the sign or change the meaning of the required information. A black-and-white example of a warning sign meeting these requirements, other than the size requirements, follows:

(2) The standard sign shall be at least 14 inches by 16 inches with letters at least 1 inch in height. Farms and forests shall use the standard size sign unless a smaller sign is necessary because the treated area is too small to accommodate a sign of this size. In nurseries and greenhouses, the agricultural employer may, at any time, use a sign smaller than the standard size sign. Whenever a small sign is used on any establishment, there are specific posting distances depending on the size of the lettering and symbol on the sign. If a sign is used with DANGER and PELIGRO in letters at least ⅞ inch in height and the remaining letters at least ½ inch in height and a red circle

at least 3 inches in diameter containing an upraised hand and a stern face, the signs shall be no further than 50 feet apart. If a sign is used with DANGER and PELIGRO in letters at least 7/16 inch in height and the remaining letters at least ¼ inch in height and a red circle at least 1½ inches in diameter containing an upraised hand and a stern face, the signs shall be no further than 25 feet apart. A sign with DANGER and PELIGRO in letters less than 7/16 inch in height or with any words in letters less than ¼ inch in height or a red circle smaller than 1½ inches in diameter containing an upraised hand and a stern face will not satisfy the requirements of the rule. All signs must meet the requirements of paragraph (c)(1) of this section.

(3) The employer may replace the Spanish portion of the warning sign with a non-English language read by the largest group of workers who do not read English. The replacement sign must be in the same format as the original sign and be visible and legible.

(4) On farms and in forests and nurseries, the signs shall be visible from all usual points of worker entry to the treated area, including at least each access road, each border with any labor camp adjacent to the treated area, and each footpath and other walking route that enters the treated area. When there are no usual points of worker entry, signs shall be posted in the corners of the treated area or in any other location affording maximum visibility.

(5) In greenhouses, the signs shall be posted so they are visible from all usual points of worker entry to the treated area including each aisle or other walking route that enters the treated area. When there are no usual points of worker entry to the treated area, signs shall be posted in the corners of the treated area or in any other location affording maximum visibility.

(6) The signs shall:

(i) Be posted no sooner than 24 hours before the scheduled application of the pesticide.

(ii) Remain posted throughout the application and any restricted-entry interval.

(iii) Be removed within 3 days after the end of the application and any restricted-entry interval and before agricultural-worker entry is permitted, other than entry permitted by § 170.112.

(7) The signs shall remain visible and legible during the time they are posted.

(8) When several contiguous areas are to be treated with pesticides on a rotating or sequential basis, the entire area may be posted. Worker entry, other than entry permitted by § 170.112, is prohibited for the entire area while the signs are posted.

(d) *Oral warnings.* The agricultural employer shall provide oral warnings to workers in a manner that the worker can understand. If a worker will be on the premises during the application, the warning shall be given before the application takes place. Otherwise, the warning shall be given at the beginning of the worker's first work period during which the application is taking place or the restricted-entry interval for the pesticide is in effect. The warning shall consist of:

(1) The location and description of the treated area.

(2) The time during which entry is restricted.

(3) Instructions not to enter the treated area until the restricted-entry interval has expired.

[57 FR 38151, Aug. 21, 1992, as amended at 61 FR 33207, June 26, 1996]

§ 170.122 Providing specific information about applications.

When workers are on an agricultural establishment and, within the last 30 days, a pesticide covered by this subpart has been applied on the establishment or a restricted-entry interval has been in effect, the agricultural employer shall display, in accordance with this section, specific information about the pesticide.

(a) *Location, accessibility, and legibility.* The information shall be displayed in the location specified for the pesticide safety poster in § 170.135(d) and shall be accessible and legible, as specified in § 170.135 (e) and (f).

(b) *Timing.* (1) If warning signs are posted for the treated area before an application, the specific application information for that application shall be posted at the same time or earlier.

(2) The information shall be posted before the application takes place, if workers will be on the establishment

during application. Otherwise, the information shall be posted at the beginning of any worker's first work period.

(3) The information shall continue to be displayed for at least 30 days after the end of the restricted-entry interval (or, if there is no restricted-entry interval, for at least 30 days after the end of the application) or at least until workers are no longer on the establishment, whichever is earlier.

(c) *Required information.* The information shall include:

(1) The location and description of the treated area.

(2) The product name, EPA registration number, and active ingredient(s) of the pesticide.

(3) The time and date the pesticide is to be applied.

(4) The restricted-entry interval for the pesticide.

§ 170.124 Notice of applications to handler employers.

Whenever handlers who are employed by a commercial pesticide handling establishment will be performing pesticide handling tasks on an agricultural establishment, the agricultural employer shall provide to the handler employer, or assure that the handler employer is aware of, the following information concerning any areas on the agricultural establishment that the handler may be in (or may walk within 1/4 mile of) and that may be treated with a pesticide or that may be under a restricted-entry interval while the handler will be on the agricultural establishment:

(a) Specific location and description of any such areas; and

(b) Restrictions on entering those areas.

§ 170.130 Pesticide safety training for workers.

(a) *General requirement*—(1) *Agricultural employer assurance.* The agricultural employer shall assure that each worker, required by this section to be trained, has been trained according to this section during the last 5 years, counting from the end of the month in which the training was completed.

(2) *Requirement for workers performing early-entry activities.* Before a worker enters a treated area on the agricultural establishment during a restricted-entry interval to perform early-entry activities permitted by § 170.112 and contacts anything that has been treated with the pesticide to which the restricted-entry interval applies, including but not limited to, soil, water, or surfaces of plants, the agricultural employer shall assure that the worker has been trained.

(3) *Requirements for other agricultural workers*—(i) *Information before entry.* Except as provided in paragraph (a)(2) of this section, before a worker enters any areas on the agricultural establishment where, within the last 30 days a pesticide to which this subpart applies has been applied or the restricted-entry interval for such pesticide has been in effect, the agricultural employer shall assure that the worker has been provided the pesticide safety information specified in paragraph (c) of this section, in a manner that agricultural workers can understand, such as by providing written materials or oral communication or by other means. The agricultural employer must be able to verify compliance with this requirement.

(ii) *Training before the 6th day of entry.* Except as provided in paragraph (a)(2) of this section, before the 6th day that a worker enters any areas on the agricultural establishment where, within the last 30 days a pesticide to which this subpart applies has been applied or a restricted-entry interval for such pesticide has been in effect, the agricultural employer shall assure that the worker has been trained.

(b) *Exceptions.* The following persons need not be trained under this section:

(1) A worker who is currently certified as an applicator of restricted-use pesticides under part 171 of this chapter.

(2) A worker who satisfies the training requirements of part 171 of this chapter.

(3) A worker who satisfies the handler training requirements of § 170.230(c).

(4) A worker who is certified or licensed as a crop advisor by a program acknowledged as appropriate in writing by EPA or a State or Tribal lead agency for pesticide enforcement, provided

that a requirement for such certification or licensing is pesticide safety training that includes all the information set out in § 170.230(c)(4).

(c) *Pesticide safety information.* The pesticide safety information required by paragraph (a)(3)(i) shall be presented to workers in a manner that the workers can understand. At a minimum, the following information shall be provided:

(1) Pesticides may be on or in plants, soil, irrigation water, or drifting from nearby applications.

(2) Prevent pesticides from entering your body by:

(i) Following directions and/or signs about keeping out of treated or restricted areas.

(ii) Washing before eating, drinking, using chewing gum or tobacco, or using the toilet.

(iii) Wearing work clothing that protects the body from pesticide residues.

(iv) Washing/showering with soap and water, shampoo hair, and put on clean clothes after work.

(v) Washing work clothes separately from other clothes before wearing them again.

(vi) Washing immediately in the nearest clean water if pesticides are spilled or sprayed on the body. As soon as possible, shower, shampoo, and change into clean clothes.

(3) Further training will be provided within 5 days.

(d) *Training programs.* (1) General pesticide safety information shall be presented to workers either orally from written materials or audiovisually. The information must be presented in a manner that the workers can understand (such as through a translator) using nontechnical terms. The presenter also shall respond to workers' questions.

(2) The person who conducts the training shall meet at least one of the following criteria:

(i) Be currently certified as an applicator of restricted-use pesticides under part 171 of this chapter; or

(ii) Be currently designated as a trainer of certified applicators or pesticide handlers by a State, Federal, or Tribal agency having jurisdiction; or

(iii) Have completed a pesticide safety train-the-trainer program approved by a State, Federal, or Tribal agency having jurisdiction; or

(iv) Satisfy the training requirements in part 171 of this chapter or in § 170.230(c).

(3) Any person who issues an EPA-approved Worker Protection Standard worker training certificate must assure that the worker who receives the training certificate has been trained in accordance with paragraph (d)(4) of this section.

(4) The training materials shall convey, at a minimum, the following information:

(i) Where and in what form pesticides may be encountered during work activities.

(ii) Hazards of pesticides resulting from toxicity and exposure, including acute and chronic effects, delayed effects, and sensitization.

(iii) Routes through which pesticides can enter the body.

(iv) Signs and symptoms of common types of pesticide poisoning.

(v) Emergency first aid for pesticide injuries or poisonings.

(vi) How to obtain emergency medical care.

(vii) Routine and emergency decontamination procedures, including emergency eyeflushing techniques.

(viii) Hazards from chemigation and drift.

(ix) Hazards from pesticide residues on clothing.

(x) Warnings about taking pesticides or pesticide containers home.

(xi) Requirements of this subpart designed to reduce the risks of illness or injury resulting from workers' occupational exposure to pesticides, including application and entry restrictions, the design of the warning sign, posting of warning signs, oral warnings, the availability of specific information about applications, and the protection against retaliatory acts.

(e) *Verification of training.* (1) Except as provided in paragraph (e)(2) of this section, if the agricultural employer assures that a worker possesses an EPA-approved Worker Protection Standard worker training certificate, then the requirements of paragraph (a) and (c) of this section will have been met.

(2) If the agricultural employer is aware or has reason to know that an EPA-approved Worker Protection Standard worker training certificate has not been issued in accordance with this section, or has not been issued to the worker bearing the certificate, or the training was completed more than 5 years before the beginning of the current month, a worker's possession of that certificate does not meet the requirements of paragraph (a) of this section.

[57 FR 38151, Aug. 21, 1992, as amended at 60 FR 21947, 21952, May 3, 1995; 73 FR 75598, Dec. 12, 2008]

§ 170.135 Posted pesticide safety information.

(a) *Requirement.* When workers are on an agricultural establishment and, within the last 30 days, a pesticide covered by this subpart has been applied on the establishment or a restricted-entry interval has been in effect, the agricultural employer shall display, in accordance with this section, pesticide safety information.

(b) *Pesticide safety poster.* A safety poster must be displayed that conveys, at a minimum, the following basic pesticide safety concepts:

(1) Help keep pesticides from entering your body. At a minimum, the following points shall be conveyed:

(i) Avoid getting on your skin or into your body any pesticides that may be on plants and soil, in irrigation water, or drifting from nearby applications.

(ii) Wash before eating, drinking, using chewing gum or tobacco, or using the toilet.

(iii) Wear work clothing that protects the body from pesticide residues (long-sleeved shirts, long pants, shoes and socks, and a hat or scarf).

(iv) Wash/shower with soap and water, shampoo hair, and put on clean clothes after work.

(v) Wash work clothes separately from other clothes before wearing them again.

(vi) Wash immediately in the nearest clean water if pesticides are spilled or sprayed on the body. As soon as possible, shower, shampoo, and change into clean clothes.

(vii) Follow directions about keeping out of treated or restricted areas.

(2) There are Federal rules to protect workers and handlers, including a requirement for safety training.

(c) *Emergency medical care information.* (1) The name, address, and telephone number of the nearest emergency medical care facility shall be on the safety poster or displayed close to the safety poster.

(2) The agricultural employer shall inform workers promptly of any change to the information on emergency medical care facilities.

(d) *Location.* (1) The information shall be displayed in a central location on the farm or in the nursery or greenhouse where it can be readily seen and read by workers.

(2) The information shall be displayed in a location in or near the forest in a place where it can be readily seen and read by workers and where workers are likely to congregate or pass by, such as at a decontamination site or an equipment storage site.

(e) *Accessibility.* Workers shall be informed of the location of the information and shall be allowed access to it.

(f) *Legibility.* The information shall remain legible during the time it is posted.

§ 170.150 Decontamination.

(a)(1) *Requirement.* The agricultural employer must provide decontamination supplies for workers in accordance with this section whenever:

(i) Any worker on the agricultural establishment is performing an activity in the area where a pesticide was applied or a restricted-entry interval (REI) was in effect within the last 30 days, and;

(ii) The worker contacts anything that has been treated with the pesticide, including, but not limited to soil, water, plants, plant surfaces, and plant parts.

(2) *Exception.* The 30–day time period established in paragraph (a)(1)(i) of this section shall not apply if the only pesticides used in the treated area are products with an REI of 4 hours or less on the label (but not a product without an REI on the label). When workers are in such treated areas, the agricultural employer shall provide decontamination supplies for not less than 7 days

following the expiration of any applicable REI.

(b) *General conditions.* (1) The agricultural employer shall provide workers with enough water for routine washing and emergency eyeflushing. At all times when the water is available to workers, the employer shall assure that it is of a quality and temperature that will not cause illness or injury when it contacts the skin or eyes or if it is swallowed.

(2) When water stored in a tank is to be used for mixing pesticides, it shall not be used for decontamination or eyeflushing, unless the tank is equipped with properly functioning valves or other mechanisms that prevent movement of pesticides into the tank.

(3) The agricultural employer shall provide soap and single-use towels in quantities sufficient to meet worker's needs.

(4) To provide for emergency eyeflushing, the agricultural employer shall assure that at least 1 pint of water is immediately available to each worker who is performing early-entry activities permitted by § 170.112 and for which the pesticide labeling requires protective eyewear. The eyeflush water shall be carried by the early-entry worker, or shall be on the vehicle the early-entry worker is using, or shall be otherwise immediately accessible.

(c) *Location.* (1) The decontamination supplies shall be located together and be reasonably accessible to and not more than 1/4 mile from where workers are working.

(2) For worker activities performed more than 1/4 mile from the nearest place of vehicular access:

(i) The soap, single-use towels, and water may be at the nearest place of vehicular access.

(ii) The agricultural employer may permit workers to use clean water from springs, streams, lakes, or other sources for decontamination at the remote work site, if such water is more accessible than the water located at the nearest place of vehicular access.

(3) The decontamination supplies shall not be maintained in an area being treated with pesticides.

(4) The decontamination supplies shall not be maintained in an area that is under a restricted-entry interval, unless the workers for whom the supplies are provided are performing early-entry activities permitted by § 170.112 and involving contact with treated surfaces and the decontamination supplies would otherwise not be reasonably accessible to those workers.

(d) *Decontamination after early-entry activities.* At the end of any exposure period for workers engaged in early-entry activities permitted by § 170.112 and involving contact with anything that has been treated with the pesticide to which the restricted-entry interval applies, including, but not limited to, soil, water, air, or surfaces of plants, the agricultural employer shall provide, at the site where the workers remove personal protective equipment, soap, clean towels, and a sufficient amount of water so that the workers may wash thoroughly.

[57 FR 38151, Aug. 21, 1992, as amended at 61 FR 33212, June 26, 1996]

§ 170.160 Emergency assistance.

If there is reason to believe that a person who is or has been employed on an agricultural establishment to perform tasks related to the production of agricultural plants has been poisoned or injured by exposure to pesticides used on the agricultural establishment, including, but not limited to, exposures from application, splash, spill, drift, or pesticide residues, the agricultural employer shall:

(a) Make available to that person prompt transportation from the agricultural establishment, including any labor camp on the agricultural establishment, to an appropriate emergency medical facility.

(b) Provide to that person or to treating medical personnel, promptly upon request, any obtainable information on:

(1) Product name, EPA registration number, and active ingredients of any product to which that person might have been exposed.

(2) Antidote, first aid, and other medical information from the product labeling.

(3) The circumstances of application or use of the pesticide on the agricultural establishment.

(4) The circumstances of exposure of that person to the pesticide.

Subpart C—Standard for Pesticide Handlers

§ 170.202 Applicability of this subpart.

Except as provided by §§ 170.203 and 170.204, this subpart applies when any pesticide is handled for use on an agricultural establishment.

[60 FR 21952, May 3, 1995]

§ 170.203 Exceptions.

Exceptions. This subpart does not apply when any pesticide is handled for use on an agricultural establishment in the following circumstances:

(a) For mosquito abatement, Mediterranean fruit fly eradication, or similar wide-area public pest control programs sponsored by governmental entities.

(b) On livestock or other animals, or in or about animal premises.

(c) On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses.

(d) On plants that are in ornamental gardens, parks, and public or private lawns and grounds and that are intended only for aesthetic purposes or climatic modification.

(e) In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other noncrop areas, and pasture and rangeland use.

(f) For control of vertebrate pests.

(g) As attractants or repellents in traps.

(h) On the harvested portions of agricultural plants or on harvested timber.

(i) For research uses of unregistered pesticides.

[57 FR 38151, Aug. 21, 1992. Redesignated at 60 FR 21952, May 3, 1995]

§ 170.204 Exemptions.

The handlers listed in this section are exempt from the specified provisions of this subpart.

(a) *Owners of agricultural establishments.* (1) The owner of an agricultural establishment is not required to provide to himself or members of his immediate family who are performing handling tasks on their own agricultural establishment the protections of:

(i) Section 170.210(b) and (c).

(ii) Section 170.222.

(iii) Section 170.230.

(iv) Section 170.232.

(v) Section 170.234.

(vi) Section 170.235.

(vii) Section 170.240(e) through (g).

(viii) Section 170.250.

(ix) Section 170.260.

(2) The owner of the agricultural establishment must provide the protections listed in paragraphs (a)(1) (i) through (ix) of this section to other handlers and other persons who are not members of his immediate family.

(b) *Crop advisors.* (1) Provided that the conditions of paragraph (b)(2) of this section are met, a person who is certified or licensed as a crop advisor by a program acknowledged as appropriate in writing by EPA or a State or Tribal lead agency for pesticide enforcement, and persons performing crop advising tasks under such qualified crop advisor's direct supervision, are exempt from the provisions of:

(i) Section 170.232.

(ii) Section 170.240.

(iii) Section 170.250.

(iv) Section 170.260.

A person is under the direct supervision of a crop advisor when the crop advisor exerts the supervisory controls set out in paragraphs (b)(2)(iv) and (v) of this section. Direct supervision does not require that the crop advisor be physically present at all times, but the crop advisor must be readily accessible to the employees at all times.

(2) Conditions of exemption. (i) The certification or licensing program requires pesticide safety training that includes, at least, all the information in § 170.230(c)(4).

(ii) No entry into the treated area occurs until after application ends.

(iii) Applies only when performing crop advising tasks in the treated area.

(iv) The crop advisor must make specific determinations regarding the appropriate PPE, appropriate decontamination supplies, and how to conduct the tasks safely. The crop advisor must convey this information to each

person under his direct supervision in a language that the person understands.

(v) Before entering a treated area, the certified or licensed crop advisor must inform, through an established practice of communication, each person under his direct supervision of the pesticide products and active ingredient(s) applied, method of application, time of application, the restricted entry interval, which tasks to undertake, and how to contact the crop advisor.

[60 FR 21953, May 3, 1995, as amended at 73 FR 75599, Dec. 12, 2008]

§ 170.210 Restrictions during applications.

(a) *Contact with workers and other persons.* The handler employer and the handler shall assure that no pesticide is applied so as to contact, either directly or through drift, any worker or other person, other than an appropriately trained and equipped handler.

(b) *Handlers handling highly toxic pesticides.* The handler employer shall assure that any handler who is performing any handling activity with a product that has the skull and crossbones symbol on the front panel of the label is monitored visually or by voice communication at least every 2 hours.

(c) *Fumigant applications in greenhouses.* The handler employer shall assure:

(1) That any handler who handles a fumigant in a greenhouse, including a handler who enters the greenhouse before the acceptable inhalation exposure level or ventilation criteria have been met to monitor air levels or to initiate ventilation, maintains continuous visual or voice contact with another handler.

(2) That the other handler has immediate access to the personal protective equipment required by the fumigant labeling for handlers in the event entry into the fumigated greenhouse becomes necessary for rescue.

§ 170.222 Providing specific information about applications.

When handlers (except those employed by a commercial pesticide handling establishment) are on an agricultural establishment and, within the last 30 days, a pesticide covered by this subpart has been applied on the establishment or a restricted-entry interval has been in effect, the handler employer shall display, in accordance with this section, specific information about the pesticide.

(a) *Location, accessibility, and legibility.* The information shall be displayed in the same location specified for the pesticide safety poster in § 170.235(d) of this part and shall be accessible and legible, as specified in § 170.235(e) and (f) of this part.

(b) *Timing.* (1) If warning signs are posted for the treated area before an application, the specific application information for that application shall be posted at the same time or earlier.

(2) The information shall be posted before the application takes place, if handlers (except those employed by a commercial pesticide handling establishment) will be on the establishment during application. Otherwise, the information shall be posted at the beginning of any such handler's first work period.

(3) The information shall continue to be displayed for at least 30 days after the end of the restricted-entry interval (or, if there is no restricted-entry interval, for at least 30 days after the end of the application) or at least until the handlers are no longer on the establishment, whichever is earlier.

(c) *Required information.* The information shall include:

(1) The location and description of the treated area.

(2) The product name, EPA registration number, and active ingredient(s) of the pesticide.

(3) The time and date the pesticide is to be applied.

(4) The restricted-entry interval for the pesticide.

§ 170.224 Notice of applications to agricultural employers.

Before the application of any pesticide on or in an agricultural establishment, the handler employer shall provide the following information to any agricultural employer for the establishment or shall assure that any agricultural employer is aware of:

(a) Specific location and description of the treated area.

(b) Time and date of application.

(c) Product name, EPA registration number, and active ingredient(s).

(d) Restricted-entry interval.

(e) Whether posting and oral notification are required.

(f) Any other product-specific requirements on the product labeling concerning protection of workers or other persons during or after application.

§ 170.230 Pesticide safety training for handlers.

(a) *Requirement.* Before any handler performs any handling task, the handler employer shall assure that the handler has been trained in accordance with this section during the last 5 years, counting from the end of the month in which the training was completed.

(b) *Exceptions.* The following persons need not be trained under this section:

(1) A handler who is currently certified as an applicator of restricted-use pesticides under part 171 of this chapter.

(2) A handler who satisfies the training requirements of part 171 of this chapter.

(3) A handler who is certified or licensed as a crop advisor by a program acknowledged as appropriate in writing by EPA or a State or Tribal lead agency for pesticide enforcement, provided that a requirement for such certification or licensing is pesticide safety training that includes all the information set out in § 170.230(c)(4).

(c) *Training programs.* (1) General pesticide safety information shall be presented to handlers either orally from written materials or audiovisually. The information must be presented in a manner that the handlers can understand (such as through a translator). The presenter also shall respond to handlers' questions.

(2) The person who conducts the training shall meet at least one of the following criteria:

(i) Be currently certified as an applicator of restricted-use pesticides under part 171 of this chapter; or

(ii) Be currently designated as a trainer of certified applicators or pesticide handlers by a State, Federal, or Tribal agency having jurisdiction; or

(iii) Have completed a pesticide safety train-the-trainer program approved by a State, Federal, or Tribal agency having jurisdiction.

(3) Any person who issues an EPA-approved Worker Protection Standard handler training certificate must assure that the handler who receives the training certificate has been trained in accordance with paragraph (c)(4) of this section.

(4) The pesticide safety training materials must convey, at a minimum, the following information:

(i) Format and meaning of information contained on pesticide labels and in labeling, including safety information such as precautionary statements about human health hazards.

(ii) Hazards of pesticides resulting from toxicity and exposure, including acute and chronic effects, delayed effects, and sensitization.

(iii) Routes by which pesticides can enter the body.

(iv) Signs and symptoms of common types of pesticide poisoning.

(v) Emergency first aid for pesticide injuries or poisonings.

(vi) How to obtain emergency medical care.

(vii) Routine and emergency decontamination procedures.

(viii) Need for and appropriate use of personal protective equipment.

(ix) Prevention, recognition, and first aid treatment of heat-related illness.

(x) Safety requirements for handling, transporting, storing, and disposing of pesticides, including general procedures for spill cleanup.

(xi) Environmental concerns such as drift, runoff, and wildlife hazards.

(xii) Warnings about taking pesticides or pesticide containers home.

(xiii) Requirements of this subpart that must be followed by handler employers for the protection of handlers and other persons, including the prohibition against applying pesticides in a manner that will cause contact with workers or other persons, the requirement to use personal protective equipment, the provisions for training and decontamination, and the protection against retaliatory acts.

(d) *Verification of training.* (1) Except as provided in paragraph (d)(2) of this section, if the handler employer

assures that a handler possesses an EPA-approved Worker Protection Standard handler training certificate, then the requirements of paragraph (a) of this section will have been met.

(2) If the handler employer is aware or has reason to know that an EPA-approved Worker Protection Standard handler training certificate has not been issued in accordance with this section, or has not been issued to the handler bearing the certificate, or the handler training was completed more than 5 years before the beginning of the current month, a handler's possession of that certificate does not meet the requirements of paragraph (a) of this section.

[57 FR 38151, Aug. 21, 1992, as amended at 60 FR 21953, May 3, 1995]

§ 170.232 Knowledge of labeling and site-specific information.

(a) *Knowledge of labeling information.* (1) The handler employer shall assure that before the handler performs any handling activity, the handler either has read the product labeling or has been informed in a manner the handler can understand of all labeling requirements related to safe use of the pesticide, such as signal words, human hazard precautions, personal protective equipment requirements, first aid instructions, environmental precautions, and any additional precautions pertaining to the handling activity to be performed.

(2) The handler employer shall assure that the handler has access to the product labeling information during handling activities.

(b) *Knowledge of site-specific information.* Whenever a handler who is employed by a commercial pesticide handling establishment will be performing pesticide handling tasks on an agricultural establishment, the handler employer shall assure that the handler is aware of the following information concerning any areas on the agricultural establishment that the handler may be in (or may walk within 1/4 mile of) and that may be treated with a pesticide or that may be under a restricted-entry interval while the handler will be on the agricultural establishment:

(1) Specific location and description of any such areas; and

(2) Restrictions on entering those areas.

§ 170.234 Safe operation of equipment.

(a) The handler employer shall assure that before the handler uses any equipment for mixing, loading, transferring, or applying pesticides, the handler is instructed in the safe operation of such equipment, including, when relevant, chemigation safety requirements and drift avoidance.

(b) The handler employer shall assure that, before each day of use, equipment used for mixing, loading, transferring, or applying pesticides is inspected for leaks, clogging, and worn or damaged parts, and any damaged equipment is repaired or is replaced.

(c) Before allowing any person to repair, clean, or adjust equipment that has been used to mix, load, transfer, or apply pesticides, the handler employer shall assure that pesticide residues have been removed from the equipment, unless the person doing the cleaning, repairing, or adjusting is a handler employed by the agricultural or commercial pesticide handling establishment. If pesticide residue removal is not feasible, the handler employer shall assure that the person who repairs, cleans, or adjusts such equipment is informed:

(1) That such equipment may be contaminated with pesticides.

(2) Of the potentially harmful effects of exposure to pesticides.

(3) Of the correct way to handle such equipment.

§ 170.235 Posted pesticide safety information.

(a) *Requirement.* When handlers (except those employed by a commercial pesticide handling establishment) are on an agricultural establishment and, within the last 30 days, a pesticide covered by this subpart has been applied on the establishment or a restricted-entry interval has been in effect, the handler employer shall display, in accordance with this section, pesticide safety information.

(b) *Pesticide safety poster.* A safety poster must be displayed that conveys,

at a minimum, the following basic pesticide safety concepts:

(1) Help keep pesticides from entering your body. At a minimum, the following points shall be conveyed:

(i) Avoid getting on your skin or into your body any pesticides that may be on plants and soil, in irrigation water, or drifting from nearby applications.

(ii) Wash before eating, drinking, using chewing gum or tobacco, or using the toilet.

(iii) Wear work clothing that protects the body from pesticide residues (long-sleeved shirts, long pants, shoes and socks, and a hat or scarf).

(iv) Wash/shower with soap and water, shampoo hair, and put on clean clothes after work.

(v) Wash work clothes separately from other clothes before wearing them again.

(vi) Wash immediately in the nearest clean water if pesticides are spilled or sprayed on the body. As soon as possible, shower, shampoo, and change into clean clothes.

(vii) Follow directions about keeping out of treated or restricted areas.

(2) There are Federal rules to protect workers and handlers including a requirement for safety training.

(c) *Emergency medical care information.* (1) The name, address, and telephone number of the nearest emergency medical care facility shall be on the safety poster or displayed close to the safety poster.

(2) The handler employer shall inform handlers promptly of any change to the information on emergency medical care facilities.

(d) *Location.* (1) The information shall be displayed in a central location on the farm or in the nursery or greenhouse where it can be readily seen and read by handlers.

(2) The information shall be displayed in a location in or near the forest in a place where it can be readily seen and read by handlers and where handlers are likely to congregate or pass by, such as at a decontamination site or an equipment storage site.

(e) *Accessibility.* Handlers shall be informed of the location of the information and shall be allowed access to it.

(f) *Legibility.* The information shall remain legible during the time it is posted.

§ 170.240 Personal protective equipment.

(a) *Requirement.* Any person who performs tasks as a pesticide handler shall use the clothing and personal protective equipment specified on the labeling for use of the product.

(b) *Definition.* (1) Personal protective equipment (PPE) means devices and apparel that are worn to protect the body from contact with pesticides or pesticide residues, including, but not limited to, coveralls, chemical-resistant suits, chemical-resistant gloves, chemical-resistant footwear, respiratory protection devices, chemical-resistant aprons, chemical-resistant headgear, and protective eyewear.

(2) Long-sleeved shirts, short-sleeved shirts, long pants, short pants, shoes, socks, and other items of work clothing are not considered personal protective equipment for the purposes of this section and are not subject to the requirements of this section, although pesticide labeling may require that such work clothing be worn during some activities.

(c) *Provision.* When personal protective equipment is specified by the labeling of any pesticide for any handling activity, the handler employer shall provide the appropriate personal protective equipment in clean and operating condition to the handler.

(1) When ''chemical-resistant'' personal protective equipment is specified by the product labeling, it shall be made of material that allows no measurable movement of the pesticide being used through the material during use.

(2) When ''waterproof'' personal protective equipment is specified by the product labeling, it shall be made of material that allows no measurable movement of water or aqueous solutions through the material during use.

(3) When a ''chemical-resistant suit'' is specified by the product labeling, it shall be a loose-fitting, one- or two-piece chemical-resistant garment that covers, at a minimum, the entire body except head, hands, and feet.

(4) When ''coveralls'' are specified by the product labeling, they shall be a

loose-fitting, one- or two-piece garment, such as a cotton or cotton and polyester coverall, that covers, at a minimum, the entire body except head, hands, and feet. The pesticide product labeling may specify that the coveralls be worn over another layer of clothing.

(5)(i) Gloves shall be of the type specified on the pesticide product labeling. Gloves made of leather, cotton, or other absorbent materials may not be worn while mixing, loading, applying, or otherwise handling pesticides, unless gloves made of these materials are listed as acceptable for such use on the product labeling.

(ii) Separable glove liners may be worn beneath chemical-resistant gloves, unless the pesticide product labeling specifically prohibits their use. Separable glove liners are defined as separate glove-like hand coverings, made of lightweight material, with or without fingers. Work gloves made from lightweight cotton or poly-type material are considered to be glove liners if worn beneath chemical-resistant gloves. Separable glove liners may not extend outside the chemical-resistant gloves under which they are worn. Chemical-resistant gloves with non-separable absorbent lining materials are prohibited.

(iii) If used, separable glove liners must be discarded immediately after a total of no more than 10 hours of use or within 24 hours of when first put on, whichever comes first. The liners must be replaced immediately if directly contacted by pesticide. Used glove liners shall not be reused. Contaminated liners must be disposed of in accordance with any Federal, State, or local regulations.

(6) When ''chemical-resistant footwear'' is specified by the product labeling, one of the following types of footwear must be worn:

(i) Chemical-resistant shoes.

(ii) Chemical-resistant boots.

(iii) Chemical-resistant shoe coverings worn over shoes or boots.

(7) When ''protective eyewear'' is specified by the product labeling, one of the following types of eyewear must be worn:

(i) Goggles.

(ii) Face shield.

(iii) Safety glasses with front, brow, and temple protection.

(iv) Full-face respirator.

(8) When a ''chemical-resistant apron'' is specified by the product labeling, an apron that covers the front of the body from mid-chest to the knees shall be worn.

(9) When a respirator is specified by the product labeling, it shall be appropriate for the pesticide product used and for the activity to be performed. The handler employer shall assure that the respirator fits correctly.

(10) When ''chemical-resistant headgear'' is specified by the product labeling, it shall be either a chemical resistant hood or a chemical-resistant hat with a wide brim.

(d) *Exceptions to personal protective equipment specified on product labeling*—(1) *Body protection.* (i) A chemical-resistant suit may be substituted for ''coveralls,'' and any requirement for an additional layer of clothing beneath is waived.

(ii) A chemical-resistant suit may be substituted for ''coveralls'' and a chemical-resistant apron.

(2) *Boots.* If chemical-resistant footwear with sufficient durability and a tread appropriate for wear in rough terrain is not obtainable, then leather boots may be worn in such terrain.

(3) *Gloves.* If chemical-resistant gloves with sufficient durability and suppleness are not obtainable, then during handling activities with roses or other plants with sharp thorns, leather gloves may be worn over chemical-resistant glove liners. However, once leather gloves are worn for this use, thereafter they shall be worn only with chemical-resistant liners and they shall not be worn for any other use.

(4) *Closed systems.* If handling tasks are performed using properly functioning systems that enclose the pesticide to prevent it from contacting handlers or other persons, and if such systems are used and are maintained in accordance with that manufacturer's written operating instructions, exceptions to labeling-specified personal protective equipment for the handling activity are permitted as provided in paragraphs (d)(4)(i) and (ii) of this section.

(i) Persons using a closed system to mix or load pesticides with a signal word of DANGER or WARNING may substitute a long-sleeved shirt, long pants, shoes, socks, chemical-resistant apron, and any protective gloves specified on the labeling for handlers for the labeling-specified personal protective equipment.

(ii) Persons using a closed system to mix or load pesticides other than those in paragraph (d)(4)(i) of this section or to perform other handling tasks may substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified personal protective equipment.

(iii) Persons using a closed system that operates under pressure shall wear protective eyewear.

(iv) Persons using a closed system shall have all labeling-specified personal protective equipment immediately available for use in an emergency.

(5) *Enclosed cabs.* If handling tasks are performed from inside a cab that has a nonporous barrier which totally surrounds the occupants of the cab and prevents contact with pesticides outside of the cab, exceptions to personal protective equipment specified on the product labeling for that handling activity are permitted as provided in paragraphs (d)(5) (i) through (iv) of this section.

(i) Persons occupying an enclosed cab may substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified personal protective equipment. If a respiratory protection device is specified on the pesticide product labeling for the handling activity, it must be worn.

(ii) Persons occupying an enclosed cab that has a properly functioning ventilation system which is used and maintained in accordance with the manufacturer's written operating instructions and which is declared in writing by the manufacturer or by a governmental agency to provide respiratory protection equivalent to or greater than a dust/mist filtering respirator may substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified personal protective equipment. If a respiratory protection device other than a dust/mist-filtering respirator is specified on the pesticide product labeling, it must be worn.

(iii) Persons occupying an enclosed cab that has a properly functioning ventilation system which is used and maintained in accordance with the manufacturer's written operating instructions and which is declared in writing by the manufacturer or by a governmental agency to provide respiratory protection equivalent to or greater than the vapor- or gas-removing respirator specified on pesticide product labeling may substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified personal protective equipment. If an air-supplying respirator or a self-contained breathing apparatus (SCBA) is specified on the pesticide product labeling, it must be worn.

(iv) Persons occupying an enclosed cab shall have all labeling-specified personal protective equipment immediately available and stored in a chemical-resistant container, such as a plastic bag. They shall wear such personal protective equipment if it is necessary to exit the cab and contact pesticide-treated surfaces in the treated area. Once personal protective equipment is worn in the treated area, it must be removed before reentering the cab.

(6) *Aerial application*—(i) *Use of gloves.* The wearing of chemical-resistant gloves when entering or leaving an aircraft used to apply pesticides is optional, unless such gloves are required on the pesticide product labeling. If gloves are brought into the cockpit of an aircraft that has been used to apply pesticides, the gloves shall be kept in an enclosed container to prevent contamination of the inside of the cockpit.

(ii) *Open cockpit.* Persons occupying an open cockpit shall use the personal protective equipment specified in the product labeling for use during application, except that chemical-resistant footwear need not be worn. A helmet may be substituted for chemical-resistant headgear. A visor may be substituted for protective eyewear.

(iii) *Enclosed cockpit.* Persons occupying an enclosed cockpit may substitute a long-sleeved shirt, long pants, shoes, and socks for labeling-specified personal protective equipment.

(7) *Crop advisors.* Crop advisors entering treated areas while a restricted-entry interval is in effect may wear the personal protective equipment specified on the pesticide labeling for early-entry activities instead of the personal protective equipment specified on the pesticide labeling for handling activities, provided:

(i) Application has been completed for at least 4 hours.

(ii) Any inhalation exposure level listed in the labeling has been reached or any ventilation criteria established by §170.110(c)(3) or in the labeling have been met.

(e) *Use of personal protective equipment.* (1) The handler employer shall assure that personal protective equipment is used correctly for its intended purpose and is used according to the manufacturer's instructions.

(2) The handler employer shall assure that, before each day of use, all personal protective equipment is inspected for leaks, holes, tears, or worn places, and any damaged equipment is repaired or discarded.

(f) *Cleaning and maintenance.* (1) The handler employer shall assure that all personal protective equipment is cleaned according to the manufacturer's instructions or pesticide product labeling instructions before each day of reuse. In the absence of any such instructions, it shall be washed thoroughly in detergent and hot water.

(2) If any personal protective equipment cannot be cleaned properly, the handler employer shall dispose of the personal protective equipment in accordance with any applicable Federal, State, and local regulations. Coveralls or other absorbent materials that have been drenched or heavily contaminated with an undiluted pesticide that has the signal word DANGER or WARNING on the label shall be not be reused.

(3) The handler employer shall assure that contaminated personal protective equipment is kept separately and washed separately from any other clothing or laundry.

(4) The handler employer shall assure that all clean personal protective equipment shall be either dried thoroughly before being stored or shall be put in a well ventilated place to dry.

(5) The handler employer shall assure that all personal protective equipment is stored separately from personal clothing and apart from pesticide-contaminated areas.

(6) The handler employer shall assure that when dust/mist filtering respirators are used, the filters shall be replaced:

(i) When breathing resistance becomes excessive.

(ii) When the filter element has physical damage or tears.

(iii) According to manufacturer's recommendations or pesticide product labeling, whichever is more frequent.

(iv) In the absence of any other instructions or indications of service life, at the end of each day's work period.

(7) The handler employer shall assure that when gas- or vapor-removing respirators are used, the gas- or vapor-removing canisters or cartridges shall be replaced:

(i) At the first indication of odor, taste, or irritation.

(ii) According to manufacturer's recommendations or pesticide product labeling, whichever is more frequent.

(iii) In the absence of any other instructions or indications of service life, at the end of each day's work period.

(8) The handler employer shall inform any person who cleans or launders personal protective equipment:

(i) That such equipment may be contaminated with pesticides.

(ii) Of the potentially harmful effects of exposure to pesticides.

(iii) Of the correct way(s) to clean personal protective equipment and to protect themselves when handling such equipment.

(9) The handler employer shall assure that handlers have a clean place(s) away from pesticide storage and pesticide use areas where they may:

(i) Store personal clothing not in use.

(ii) Put on personal protective equipment at the start of any exposure period.

(iii) Remove personal protective equipment at the end of any exposure period.

(10) The handler employer shall not allow or direct any handler to wear home or to take home personal protective equipment contaminated with pesticides.

(g) *Heat-related illness.* When the use of personal protective equipment is specified by the labeling of any pesticide for the handling activity, the handler employer shall assure that no handler is allowed or directed to perform the handling activity unless appropriate measures are taken, if necessary, to prevent heat-related illness.

[57 FR 38151, Aug. 21, 1992, as amended at 69 FR 53346, Sept. 1, 2004]

§ 170.250 Decontamination.

(a) *Requirement.* During any handling activity, the handler employer shall provide for handlers, in accordance with this section, decontamination supplies for washing off pesticides and pesticide residues.

(b) *General conditions.* (1) The handler employer shall provide handlers with enough water for routine washing, for emergency eyeflushing, and for washing the entire body in case of an emergency. At all times when the water is available to handlers, the handler employer shall assure that it is of a quality and temperature that will not cause illness or injury when it contacts the skin or eyes or if it is swallowed.

(2) When water stored in a tank is to be used for mixing pesticides, it shall not be used for decontamination or eye flushing, unless the tank is equipped with properly functioning valves or other mechanisms that prevent movement of pesticides into the tank.

(3) The handler employer shall provide soap and single-use towels in quantities sufficient to meet handlers' needs.

(4) The handler employer shall provide one clean change of clothing, such as coveralls, for use in an emergency.

(c) *Location.* The decontamination supplies shall be located together and be reasonably accessible to and not more than ¼ mile from each handler during the handling activity.

(1) *Exception for mixing sites.* For mixing activities, decontamination supplies shall be at the mixing site.

(2) *Exception for pilots.* Decontamination supplies for a pilot who is applying pesticides aerially shall be in the airplaine or at the aircraft loading site.

(3) *Exception for handling pesticides in remote areas.* When handling activities are performed more than 1/4 mile from the nearest place of vehicular access:

(i) The soap, single-use towels, clean change of clothing, and water may be at the nearest place of vehicular access.

(ii) The handler employer may permit handlers to use clean water from springs, streams, lakes, or other sources for decontamination at the remote work site, if such water is more accessible than the water located at the nearest place of vehicular access.

(4) *Decontamination supplies in treated areas.* The decontamination supplies shall not be in an area being treated with pesticides or in an area under a restricted-entry interval, unless:

(i) The decontamination supplies are in the area where the handler is performing handling activities;

(ii) The soap, single-use towels, and clean change of clothing are in enclosed containers; and

(iii) The water is running tap water or is enclosed in a container.

(d) *Emergency eyeflushing.* To provide for emergency eyeflushing, the handler employer shall assure that at least 1 pint of water is immediately available to each handler who is performing tasks for which the pesticide labeling requires protective eyewear. The eyeflush water shall be carried by the handler, or shall be on the vehicle or aircraft the handler is using, or shall be otherwise immediately accessible.

(e) *Decontamination after handling activities.* At the end of any exposure period, the handler employer shall provide at the site where handlers remove personal protective equipment, soap, clean towels, and a sufficient amount of water so that the handlers may wash thoroughly.

[57 FR 38151, Aug. 21, 1992, as amended at 61 FR 33213, June 26, 1996]

§ 170.260 Emergency assistance.

If there is reason to believe that a person who is or has been employed by an agricultural establishment or commercial pesticide handling establishment to perform pesticide handling tasks has been poisoned or injured by exposure to pesticides as a result of that employment, including, but not limited to, exposures from handling tasks or from application, splash, spill,

drift, or pesticide residues, the handler employer shall:

(a) Make available to that person prompt transportation from the place of employment or the handling site to an appropriate emergency medical facility.

(b) Provide to that person or to treating medical personnel, promptly upon request, any obtainable information on:

(1) Product name, EPA registration number, and active ingredients of any product to which that person might have been exposed.

(2) Antidote, first aid, and other medical information from the product labeling.

(3) The circumstances of handling of the pesticide.

(4) The circumstances of exposure of that person to the pesticide.

PART 171—CERTIFICATION OF PESTICIDE APPLICATORS

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AUTHORITY: 7 U.S.C. 136i and 136w.

SOURCE: 39 FR 36449, Oct. 9, 1974, unless otherwise noted.

§ 171.1 General.

This section deals with the certification of applicators of restricted use pesticides.

§ 171.2 Definitions.

(a) Terms used in this subpart have the same meaning as in the Act. In addition, the following definitions are applicable to all aspects of the certification of pesticide applicator program in this part:

(1) The term *accident* means an unexpected, undesirable event, caused by the use or presence of a pesticide, that adversely affects man or the environment.

(2) The term *Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973), and other legislation supplementary thereto and amendatory thereof.

(3) The term *Administrator* means the Administrator of the Environmental Protection Agency, or any office or employee of the Agency to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(4) The term *Agency,* unless otherwise specified, means the United States Environmental Protection Agency.

(5) The term *agricultural commodity* means any plant, or part thereof, or animal, or animal product, produced by a person (including farmers, ranchers, vineyardists, plant propagators, Christmas tree growers, aquaculturists, floriculturists, orchardists, foresters, or other comparable persons) primarily for sale, consumption, propagation, or other use by man or animals.

(6) The term *calibration of equipment* means measurement of dispersal or output of application equipment and adjustment of such equipment to control the rate of dispersal, and droplet or particle size of a pesticide dispersed by the equipment.

(7) The term *certification* means the recognition by a certifying agency that a person is competent and thus authorized to use or supervise the use of restricted use pesticides.

(8) The term *certified applicator* means any individual who is certified to use or supervise the use of any restricted use pesticides covered by his certification.

(9) The term *commercial applicator* means a certified applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which

is classified for restricted use for any purpose or on any property other than as provided by the definition of ''private applicator.''

(10) The term *compatibility* means that property of a pesticide which permits its use with other chemicals without undesirable results being caused by the combination.

(11) The term *competent* means properly qualified to perform functions associated with pesticide application, the degree of capability required being directly related to the nature of the activity and the associated responsibility.

(12) The term *common exposure route* means a likely way (oral, dermal, respiratory) by which a pesticide may reach and/or enter an organism.

(13) The term *environment* means water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among them.

(14) The term *forest* means a concentration of trees and related vegetation in non-urban areas sparsely inhabited by and infrequently used by humans; characterized by natural terrain and drainage patterns.

(15) The term *hazard* means a probability that a given pesticide will have an adverse effect on man or the environment in a given situation, the relative likelihood of danger or ill effect being dependent on a number of interrelated factors present at any given time.

(16) The term *host* means any plant or animal on or in which another lives for nourishment, development, or protection.

(17) The term *non-target organism* means a plant or animal other than the one against which the pesticide is applied.

(18) The term *ornamental* means trees, shrubs, and other plantings in and around habitations generally, but not necessarily located in urban and suburban areas, including residences, parks, streets, retail outlets, industrial and institutional buildings.

(19) The term *practical knowledge* means the possession of pertinent facts and comprehension together with the ability to use them in dealing with specific problems and situations.

(20) The term *private applicator* means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(21) The term *protective equipment* means clothing or any other materials or devices that shield against unintended exposure to pesticides.

(22) The term *regulated pest* means a specific organism considered by a State or Federal agency to be a pest requiring regulatory restrictions, regulations, or control procedures in order to protect the host, man and/or his environment.

(23) The term *restricted use pesticide* means a pesticide that is classified for restricted use under the provisions of section 3(d)(1)(C) of the Act.

(24) The term *standard* means the measure of knowledge and ability which must be demonstrated as a requirement for certification.

(25) The term *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(26) The term *susceptibility* means the degree to which an organism is affected by a pesticide at a particular level of exposure.

(27) The term *toxicity* means the property of a pesticide to cause any adverse physiological effects.

(28) The term *under the direct supervision of* means the act or process whereby the application of a pesticide is made by a competent person acting under the instructions and control of a certified applicator who is responsible for the actions of that person and who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(b) *Limited.* The following definitions apply only to dealers, dealerships and transactions in States or on Indian Reservations where EPA conducts a Federal Pesticide Applicator Certification Program.

(1) The term *restricted use pesticide retail dealer* means any person who makes available for use any restricted use pesticide, or who offers to make available for use any such pesticide.

(2) The term *make available for use* means to distribute, sell, ship, deliver for shipment, or receive and (having so received) deliver, to any person. However, the term excludes transactions solely between persons who are pesticide producers, registrants, wholesalers, or retail sellers, acting only in those capacities.

(3) The term *dealership* means any site owned or operated by a restricted use pesticide retail dealer where any restricted use pesticide is made available for use, or where the dealer offers to make available for use any such pesticide.

(4) The term *uncertified person* means any person who is not holding a currently valid certification document indicating that he is certified under section 11 of FIFRA in the category of the restricted use pesticide made available for use.

(5) The term *principal place of business* means the principal location, either residence or office, in the State in which an individual, partnership, or corporation applies pesticides.

[39 FR 36449, Oct. 9, 1974, as amended at 48 FR 53974, Nov. 1983; 73 FR 75599, Dec. 12, 2008]

§ 171.3 Categorization of commercial applicators of pesticides.

(a) *Procedure.* Categories of applicators (other than private) using or supervising the use of restricted use pesticides are identified below. State systems of applicator identification shall adopt these categories as needed, along with such appropriate subcategories as are necessary to meet the particular requirements of the State.

(b) *Categories*—(1) *Agricultural pest control*—(i) *Plant.* This category includes commercial applicators using or supervising the use of restricted use pesticides in production of agricultural crops, including without limiting the foregoing, tobacco, peanuts, cotton, feed grains, soybeans and forage; vegetables; small fruits; tree fruits and nuts; as well as on grasslands and noncrop agricultural lands.

(ii) *Animal.* This category includes commercial applicators using or supervising the use of restricted use pesticides on animals, including without limiting the foregoing, beef cattle, dairy cattle, swine, sheep, horses, goats, poultry, and livestock, and to places on or in which animals are confined.

Doctors of Veterinary Medicine engaged in the business of applying pesticides for hire, publicly holding themselves out as pesticide applicators, or engaged in large-scale use of pesticides are included in this category.

(2) *Forest pest control.* This category includes commercial applicators using or supervising the use of restricted use pesticides in forests, forest nurseries, and forest seed producing areas.

(3) *Ornamental and turf pest control.* This category includes commercial applicators using or supervising the use of restricted use pesticides to control pests in the maintenance and production of ornamental trees, shrubs, flowers, and turf.

(4) *Seed treatment.* This category includes commercial applicators using or supervising the use of restricted use pesticides on seeds.

(5) *Aquatic pest control.* This category includes commercial applicators using or supervising the use of any restricted use pesticide purposefully applied to standing or running water, excluding applicators engaged in public health related activities included in category 8 below.

(6) *Right-of-way pest control.* This category includes commercial applicators using or supervising the use of restricted use pesticides in the maintenance of public roads, electric powerlines, pipelines, railway rights-of-way or other similar areas.

(7) *Industrial, institutional, structural and health related pest control.* This category includes commercial applicators using or supervising the use of restricted use pesticides in, on, or around food handling establishments, human dwellings, institutions, such as schools and hospitals, industrial establishments, including warehouses and grain elevators, and any other structures and adjacent areas, public or private; and for the protection of stored, processed, or manufactured products.

(8) *Public health pest control.* This category includes State, Federal or other governmental employees using or supervising the use of restricted use pesticides in public health programs for the management and control of pests having medical and public health importance.

(9) *Regulatory pest control.* This category includes State, Federal or other governmental employees who use or supervise the use of restricted use pesticides in the control of regulated pests.

(10) *Demonstration and research pest control.* This category includes: (i) individuals who demonstrate to the public the proper use and techniques of application of restricted use pesticides or supervise such demonstration, and (ii) persons conducting field research with pesticides, and in doing so, use or supervise the use of restricted use pesticides. Included in the first group are such persons as extension specialists and county agents, commercial representatives demonstrating pesticide products, and those individuals demonstrating methods used in public programs. The second group includes: State, Federal, commercial and other persons conducting field research on or utilizing restricted use pesticides.

(c) *Other categories and subcategories.* Any State submitting a plan pursuant to this section for the certification of applicators, as provided for below, may designate such subcategories within the above 10 categories as it deems necessary. In addition, a State may delete a category not needed or may request the Administrator's approval of additional major categories.

§ 171.4 Standards for certification of commercial applicators.

(a) *Determination of competency.* Competence in the use and handling of pesticides shall be determined on the basis of written examinations, and, as appropriate, performance testing, based upon standards set forth below and which are approved by the Administrator. Such examination and testing shall include the general standards applicable to all categories (§ 171.4(b)) and the additional standards specifically identified for each category or subcategory (if any) in which an applicator is to be classified (§ 171.4(c)). State standards must conform and be at least equal to those prescribed herein. In developing the details of standards at the State level and in structuring examinations, it is important to recognize and reflect the extent of competency appropriate and necessary to a particular category.

(b) *General standards for all categories of certified commercial applicators.* (1) All commercial applicators shall demonstrate practical knowledge of the principles and practices of pest control and safe use of pesticides. Testing shall be based on examples of problems and situations appropriate to the particular category or subcategory of the applicator's certification and the following areas of competency:

(i) *Label & labeling comprehension.* (*a*) The general format and terminology of pesticide labels and labeling;

(*b*) The understanding of instructions, warnings, terms, symbols, and other information commonly appearing on pesticide labels;

(*c*) Classification of the product, general or restricted; and

(*d*) Necessity for use consistent with the label.

(ii) *Safety.* Factors including:

(*a*) Pesticide toxicity and hazard to man and common exposure routes;

(*b*) Common types and causes of pesticide accidents;

(*c*) Precautions necessary to guard against injury to applicators and other individuals in or near treated areas;

(*d*) Need for and use of protective clothing and equipment;

(*e*) Symptoms of pesticide poisoning;

(*f*) First aid and other procedures to be followed in case of a pesticide accident; and

(*g*) Proper identification, storage, transport, handling, mixing procedures and disposal methods for pesticides and used pesticide containers, including precautions to be taken to prevent children from having access to pesticides and pesticide containers.

(iii) *Environment.* The potential environmental consequences of the use and misuse of pesticides as may be influenced by such factors as:

(*a*) Weather and other climatic conditions;

(*b*) Types of terrain, soil or other substrate;

(*c*) Presence of fish, wildlife and other non-target organisms; and

(*d*) Drainage patterns.

(iv) *Pests.* Factors such as: (*a*) Common features of pest organisms and characteristics of damage needed for pest recognition;

(*b*) Recognition of relevant pests; and

(*c*) Pest development and biology as it may be relevant to problem identification and control.

(v) *Pesticides.* Factors such as:

(*a*) Types of pesticides;

(*b*) Types of formulations;

(*c*) Compatibility, synergism, persistence and animal and plant toxicity of the formulations;

(*d*) Hazards and residues associated with use;

(*e*) Factors which influence effectiveness or lead to such problems as resistance to pesticides; and

(*f*) Dilution procedures.

(vi) *Equipment.* Factors including: (*a*) Types of equipment and advantages and limitations of each type; and

(*b*) Uses, maintenance and calibration.

(vii) *Application techniques.* Factors including:

(*a*) Methods of procedure used to apply various formulations of pesticides, solutions, and gases, together with a knowledge of which technique of application to use in a given situation;

(*b*) Relationship of discharge and placement of pesticides to proper use, unnecessary use, and misuse; and

(*c*) Prevention of drift and pesticide loss into the environment.

(viii) *Laws and regulations.* Applicable State and Federal laws and regulations.

(c) *Specific standards of competency for each category of commercial applicators.* Some of the factors referenced in paragraph (b) of this section are of particular importance because of the different types of activities carried out by applicators in each category. Such factors must be especially stressed and specifically reflected in State certification standards, as appropriate. For example, practical knowledge of drift problems should be required of agricultural applicators but not of seed treatment applicators. The latter, however, should be particularly knowledgeable of the hazards of the misuse of treated seed and the necessary precautionary techniques. Many applicators in § 171.3(b) (8), (9), and (10) will have had considerable formal education, training and experience in preparation for their positions. Their competency with respect to the use and handling of pesticides will have been determined by examining boards of their professional scientific societies utilizing standards which equal or exceed those prescribed herein. Such standards should be consulted by States in developing their State standards for certification of such applicators under these regulations. Commercial applicators in each category shall be particularly qualified with respect to the practical knowledge standards elaborated below:

(1) *Agricultural pest control*—(i) *Plant.* Applicators must demonstrate practical knowledge of crops grown and the specific pests of those crops on which they may be using restricted use pesticides. The importance of such competency is amplified by the extensive areas involved, the quantities of pesticides needed, and the ultimate use of many commodities as food and feed. Practical knowledge is required concerning soil and water problems, preharvest intervals, re-entry intervals, phytotoxicity, and potential for environmental contamination, non-target injury and community problems resulting from the use of restricted use pesticides in agricultural areas.

(ii) *Animal.* Applicators applying pesticides directly to animals must demonstrate practical knowledge of such animals and their associated pests. A practical knowledge is also required concerning specific pesticide toxicity and residue potential, since host animals will frequently be used for food. Further, the applicator must know the relative hazards associated with such factors as formulation, application techniques, age of animals, stress and extent of treatment.

(2) *Forest pest control.* Applicators shall demonstrate practical knowledge of types of forests, forest nurseries, and seed production in their State and the pests involved. They should possess practical knowledge of the cyclic occurrence of certain pests and specific population dynamics as a basis for programming pesticide applications. A

practical knowledge is required of the relative biotic agents and their vulnerability to the pesticides to be applied. Because forest stands may be large and frequently include natural aquatic habitats and harbor wildlife, the consequences of pesticide use may be difficult to assess. The applicator must therefore demonstrate practical knowledge of control methods which will minimize the possibility of secondary problems such is unintended effects on wildlife. Proper use of specialized equipment must be demonstrated, especially as it may relate to meteorological factors and adjacent land use.

(3) *Ornamental and turf pest control.* Applicators shall demonstrate practical knowledge of pesticide problems associated with the production and maintenance of ornamental trees, shrubs, plantings, and turf, including cognizance of potential phytotoxicity due to a wide variety of plant material, drift, and persistence beyond the intended period of pest control. Because of the frequent proximity of human habitations to application activities, applicators in this category must demonstrate practical knowledge of application methods which will minimize or prevent hazards to humans, pets, and other domestic animals.

(4) *Seed-treatment.* Applicators shall demonstrate practical knowledge of types of seeds that require chemical protection against pests and factors such as seed coloration, carriers, and surface active agents which influence pesticide binding and may affect germination. They must demonstrate practical knowledge of hazards associated with handling, sorting and mixing, and misuse of treated seed such as introduction of treated seed into food and feed channels, as well as proper disposal of unused treated seeds.

(5) *Aquatic pest control.* Applicators shall demonstrate practical knowledge of the secondary effects which can be caused by improper application rates, incorrect formulations, and faulty application of restricted use pesticides used in this category. They shall demonstrate practical knowledge of various water use situations and the potential of downstream effects. Further, they must have practical knowledge concerning potential pesticide effects on plants, fish, birds, beneficial insects and other organisms which may be present in aquatic environments. These applicators shall demonstrate practical knowledge of the principles of limited area application.

(6) *Right-of-way pest control.* Applicators shall demonstrate practical knowledge of a wide variety of environments, since rights-of-way can traverse many different terrains, including waterways. They shall demonstrate practical knowledge of problems on runoff, drift, and excessive foliage destruction and ability to recognize target organisms. They shall also demonstrate practical knowledge of the nature of herbicides and the need for containment of these pesticides within the right-of-way area, and the impact of their application activities in the adjacent areas and communities.

(7) *Industrial, institutional, structural and health related pest control.* Applicators must demonstrate a practical knowledge of a wide variety of pests, including their life cycles, types of formulations appropriate for their control, and methods of application that avoid contamination of food, damage and contamination of habitat, and exposure of people and pets. Since human exposure, including babies, children, pregnant women, and elderly people, is frequently a potential problem, applicators must demonstrate practical knowledge of the specific factors which may lead to a hazardous condition, including continuous exposure in the various situations encountered in this category. Because health related pest control may involve outdoor applications, applicators must also demonstrate practical knowledge of environmental conditions, particularly related to this activity.

(8) *Public health pest control.* Applicators shall demonstrate practical knowledge of vector-disease transmission as it relates to and influences application programs. A wide variety of pests is involved, and it is essential that they be known and recognized, and appropriate life cycles and habitats be understood as a basis for control strategy. These applicators shall have practical knowledge of a great variety of environments ranging from streams to those conditions found in buildings.

They should also have practical knowledge of the importance and employment of such non-chemical control methods as sanitation, waste disposal, and drainage.

(9) *Regulatory pest control.* Applicators shall demonstrate practical knowledge of regulated pests, applicable laws relating to quarantine and other regulation of pests, and the potential impact on the environment of restricted use pesticides used in suppression and eradication programs. They shall demonstrate knowledge of factors influencing introduction, spread, and population dynamics of relevant pests. Their knowledge shall extend beyond that required by their immediate duties, since their services are frequently required in other areas of the country where emergency measures are invoked to control regulated pests and where individual judgments must be made in new situations.

(10) *Demonstration and research pest control.* Persons demonstrating the safe and effective use of pesticides to other applicators and the public will be expected to meet comprehensive standards reflecting a broad spectrum of pesticide uses. Many different pest problems situations will be encountered in the course of activities associated with demonstration, and practical knowledge of problems, pests, and population levels occurring in each demonstration situation is required. Further, they should demonstrate an understanding of a pesticide-organism interactions and the importance of integrating pesticide use with other control methods. In general, it would be expected that applicators doing demonstration pest control work possess a practical knowledge of all of the standards detailed in § 171.4(b). In addition, they shall meet the specific standards required for paragraphs (c) (1) through (7) of this section as may be applicable to their particular activity.

Persons conducting field research or method improvement work with restricted use pesticides should be expected to know the general standards detailed in 171.4(b). In addition, they shall be expected to know the specific standards required for paragraphs (c) (1) through (9) of this section, applicable to their particular activity, or alternatively, to meet the more inclusive requirements listed under ''Demonstration.''

(d) *Special standards.* This space reserved for possible issuance of Special Standards.

(e) *The above standards do not apply to the following persons for purposes of these regulations.* (1) Persons conducting laboratory type research involving restricted use pesticides; and

(2) Doctors of Medicine and Doctors of Veterinary Medicine applying pesticides as drugs or medication during the course of their normal practice.

§ 171.5 Standards for certification of private applicators.

(a) Competence in the use and handling of pesticides by a private applicator will be determined by procedures set forth below. State standards must conform and be at least equal to those prescribed herein. As a minimum requirement for certification, a private applicator must show that he possesses a practical knowledge of the pest problems and pest control practices associated with his agricultural operations; proper storage, use, handling and disposal of the pesticides and containers; and his related legal responsibility. This practical knowledge includes ability to:

(1) Recognize common pests to be controlled and damage caused by them.

(2) Read and understand the label and labeling information—including the common name of pesticides he applied; pest(s) to be controlled, timing and methods of application; safety precautions; any pre-harvest or re-entry restrictions; and any specific disposal procedures.

(3) Apply pesticides in accordance with label instructions and warnings, including the ability to prepare the proper concentration of pesticide to be used under particular circumstances taking into account such factors as area to be covered, speed at which application equipment will be driven, and the quantity dispersed in a given period of operation.

(4) Recognize local environmental situations that must be considered during application to avoid contamination.

(5) Recognize poisoning symptoms and procedures to follow in case of a pesticide accident.

(b) Such competence of each private applicator shall be verified by the responsible State agency through the administration of a private applicator certification system which ensures that the private applicator is competent, based upon the standards set forth above, to use the restricted use pesticides under limitations of applicable State and Federal laws and regulations. A certification system shall employ a written or oral testing procedure, or such other equivalent system as may be approved as part of a State plan.

(1) In any case where a person, at the time of testing for certification, is unable to read a label, the responsible State agency may employ a testing procedure, previously approved by the Administrator, which can adequately assess the competence of such person with regard to all of the above standards. Certification must be related and limited to the use and handling of each individual pesticide for which he desires certification at any time. Therefore, the applicator will be authorized to use only the pesticide(s) for which he has demonstrated competence. A specific procedure is required for § 171.5(a)(2) relating to label comprehension, with testing designed to assure his knowledge of the following:

(i) Understanding of the label and labeling information including those items indicated in that subsection.

(ii) Sources of advice and guidance necessary for the safe and proper use of each pesticide related to his certification.

(2) [Reserved]

§ 171.6 Standards for supervision of noncertified applicators by certified private and commercial applicators.

(a) Certified applicators whose activities indicate a supervisory role must demonstrate a practical knowledge of Federal and State supervisory requirements, including labeling, regarding the application of restricted use pesticides by noncertified applicators.

The availability of the certified applicator must be directly related to the hazard of the situation. In many situations, where the certified applicator is not required to be physically present, ''direct supervision'' shall include verifiable instruction to the competent person, as follows: (1) Detailed guidance for applying the pesticide properly, and (2) provisions for contacting the certified applicator in the event he is needed. In other situations, and as required by the label, the actual physical presence of a certified applicator may be required when application is made by a noncertified applicator.

(b) [Reserved]

§ 171.7 Submission and approval of State plans for certification of commercial and private applicators of restricted use pesticides.

If any State, at any time, desires to certify applicators of restricted use pesticides, the Governor of that State shall submit a State plan for that purpose. The Administrator shall approve the plan submitted by any State, or any modification thereof, if the plan in his judgment—

(a) Designates a State agency as the agency responsible for administering the plan throughout the State. Since several other agencies or organizations may also be involved in administering portions of the State plan, all of these shall be identified in the State plan, particularly any other agencies or organizations responsible for certifying applicators and suspending or revoking certification. In the extent that more than one governmental agency will be responsible for performing certain functions under the State plans, the plans shall identify which functions are to be performed by which agency and indicate how the program will be coordinated by the lead agency to ensure consistency of programs within the State. The lead agency will serve as the central contact point for the Environmental Protection Agency in carrying out the certification program. The numbers and job titles of the responsible officials of the lead agency and cooperating units shall be included.

(b) Contains satisfactory assurances that such lead agency has or will have the legal authority and qualified personnel necessary to carry out the plan:

(1) Satisfactory assurances that the lead agency or other cooperating agencies have the legal authority necessary to carry out the plans should be in the form of an opinion of the Attorney General or the legal counsel of the lead agency. In addition:

(i) The lead agency should submit a copy of each appropriate State law and regulation.

(ii) In those States where any requisite legal authorities are pending enactment and/or promulgation, the Governor (or Chief Executive) may request that a State plan be approved contingent upon the enactment and/or promulgation of such authorities. Plans approved on a contingency basis will be subject to such reasonable terms and conditions, concerning the duration of the contingency approval and other matters, as the Administrator may impose. During the period of the contingency approval, the State will have an approved certification program and may proceed to certify applicators, who will then be permitted to use or supervise the use of pesticides classified for restricted use under FIFRA, as amended.

(iii) The State plan should indicate by citations to specific laws (whether enacted or pending enactment) and/or regulations (whether promulgated or pending promulgation) that the State has legal authorities as follows:

(A) Provisions for and listing of the acts which constitute grounds for denying, suspending, and revoking certification of applicators, and for assessing criminal and/or civil penalties. Such grounds should include, at a minimum, misuse of a pesticide and falsification of any records required to be maintained by the certified applicator.

(B) Provisions for reviewing an applicator's certification to determine whether suspension or revocation of the certification is appropriate in the event of criminal conviction under section 14(b) of the amended FIFRA, a final order imposing civil penalty under section 14(a) of the amended FIFRA, or conclusion of a State enforcement action.

(C) Provisions for right-of-entry by consent or warrant by appropriate State officials at reasonable times for sampling, inspection, and observation purposes.

(D) Provisions making it unlawful for persons other than certified applicators or persons working under their direct supervision to use restricted use pesticides.

(E) Provisions requiring certified commercial applicators to keep and maintain for the period of at least two years routine operational records containing information on kinds, amounts, uses, dates, and places of application of restricted use pesticides; and for ensuring that such records will be available to appropriate State officials.

(2) Satisfactory assurances that the lead agency and any cooperating organizations have qualified personnel necessary to carry out the plan will be demonstrated by including the numbers, job titles and job functions of persons so employed.

(c) Gives satisfactory assurances that the State will devote adequate funds to the administration of the plan.

(d) Provides that the State agency will make reports to the Administrator in a manner and containing information that the Administrator may from time to time require, including:

(1) An annual report to be submitted by the lead agency, at a time to be specified by the State, to include the following information:

(i) Total number of applicators, private and commercial, by category, currently certified; and number of applicators, private and commercial, by category, certified during the last reporting period.

(ii) Any changes in commercial applicator subcategories.

(iii) A summary of enforcement activities related to use of restricted use pesticides during the last reporting period.

(iv) Any significant proposed changes in required standards of competency.

(v) Proposed changes in plans and procedures for enforcement activities related to use of restricted use pesticides for the next reporting period.

(vi) Any other proposed changes from the State plan that would significantly affect the State certification program.

(2) Other reports as may be required by the Administrator shall be submitted from time to time to meet specific needs.

(e) Contains satisfactory assurances that the State standards for the certification of applicators of pesticides conform to those standards prescribed by the Administrator under §§171.1 through 171.6. Such assurances should consist of:

(1) A detailed description of the State's plan for certifying applicators and a discussion of any special situations, problems, and needs together with an explanation of how the State intends to handle them. The State plan should include the following elements as a minimum:

(i) For commercial applicators:

(A) A list and description of categories and subcategories to be used in the State, such categories to be consistent with those defined in §171.3.

(B) An estimate of the number of commercial applicators by category expected to be certified by the State.

(C) The standards of competency elaborated by the State. These shall conform and be at least equal to those prescribed in §171.4 for the various categories of applicators utilized by the State. The standards shall also cover each of the points listed in the general standards in §171.4(b) and the points covered in the appropriate specific standards set forth in §171.4(c).

(D) For each category and subcategory listed under §171.7(e)(1)(i)(A), either submission of examinations or a description of the types and contents of examinations (e.g., multiple choice, true-false) and submission of sample examination questions; and a description of any performance testing used to determine competency of applicators.

(ii) For private applicators:

(A) An estimate of the number of private applicators expected to be certified by the State.

(B) The standards of competency elaborated by the State. These shall conform and be at least equal to those prescribed in §171.5(a), including the five requirements listed in §171.5(a) (1) through (5).

(C) Types and contents of examinations and/or submission of detailed description of methods other than examination used to determine competency of private applicators.

(D) A description of any special procedure of testing that a State develops to determine the competency of a private applicator who is unable to read the label as prescribed in §171.5(b)(1).

(2) A provision for issuance by the State of appropriate credentials or documents verifying certification of applicators.

(3) If appropriate, a description of any existing State licensing, certification or authorization programs for private applicators or for one or more categories of commercial applicators may be included. If these programs are determined by EPA to meet standards of competency prescribed by §§171.1 through 171.6, States may certify applicators so licensed, certified or authorized without any additional demonstration of competency provided:

(i) The commercial applicators who were licensed, certified, or authorized have demonstrated their competency based on written examinations and, as appropriate, performance testing, conforming to the standards set forth in §171.4, and

(ii) The private applicators who were licensed, certified, or authorized have demonstrated their competency by written or oral testing procedures or other acceptable equivalent system, conforming to the standards set forth in §171.5.

(4) A statement that the State accepts Federal employees qualified under the Government Agency Plan (GAP) as fully meeting the requirements for certification by that State; or a description of any additional requirements these employees must meet to apply restricted use pesticides in that State. Any such additional requirements shall be consistent with and shall not exceed standards established for other comparable applicators in that State.

(i) Until such time as the GAP has been fully developed and approved by EPA, this statement (§171.7(e)(4)) is not required. However, within 60 days after final approval of the GAP, the State should forward such a statement for inclusion in its State plan.

(5) A description of any cooperative agreements a State has made with any

Indian Governing Body to certify or assist in the certification of applicators not subject to State jurisdiction. (§ 171.10).

(6) A description of any arrangements that a State has made or plans to make relating to reciprocity with other States or jurisdictions for the acceptance of certified applicators from those States or jurisdictions. However, those arrangements should meet these conditions:

(i) The State according reciprocity should provide for issuance of an appropriate document verifying certification based upon the certifying document issued by the other States or jurisdictions.

(ii) The State according reciprocity should have enforcement procedures that cover out-of-State applicators determined to be competent and certified within the State or jurisdiction.

(iii) The detailed State or jurisdiction standards of competency, for each category identified in the reciprocity arrangement should be sufficiently comparable to justify waiving an additional determination of competency by the State granting reciprocity.

(f) In responding to the preceding requirements, a State may describe in its State plan other regulatory activities implemented under State laws or regulations which will contribute to the desired control of the use of restricted use pesticides by certified applicators. Such other regulatory activities, if described, will be considered by the Administrator in evaluating whether or not a State's certified applicator program satisfies the requirements of § 171.7 (a) through (e).

[40 FR 11702, Mar. 12, 1975]

§ 171.8 Maintenance of State plans.

(a) Any State certification program approved under § 171.7 shall be maintained in accordance with the State plan approved under that section. Accordingly, the State plan should include:

(1) Provisions to assure that certified applicators comply with standards for the use of restricted use pesticides and carry out their responsibility to provide adequate supervision of noncertified applicators.

(2) Provisions to ensure that certified applicators continue to meet the requirements of changing technology and to assure a continuing level of competency and ability to use pesticides safely and properly.

(b) An approved State plan and the certification program carried out under such plan may not be substantially modified without the prior approval of the Administrator. A proposed change may be submitted for approval at any time but all applicable requirements prescribed by these Regulations must be satisfied for the modification to be eligible for approval by the Administrator.

(c) Whenever the Administrator determines that a State is not administering the certification program in accordance with the State plan approved under § 171.7, he shall so notify the State and provide for a hearing at the request of the State and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of the plan.

[40 FR 11704, Mar. 12, 1975]

§ 171.9 Submission and approval of Government Agency Plan.

This section is included to provide for certain Federal employees including those whose duties may require them to use or supervise the use of restricted use pesticides in a number of States.

(a) Sections 171.1 through 171.8 will, with the necessary changes, apply to the Government Agency Plan (GAP) for determining and attesting to the competency of Federal employees to use or supervise the use of restricted use pesticides.

(b) Federal employees qualified under the GAP shall:

(1) Be prepared to present the Federal form issued to them attesting to their competency to appropriate State officials.

(2) Fulfill any additional requirements States may have enumerated in their State plans as provided for under § 171.7(e)(4).

(c) The employing Federal agency shall ensure that certified employees using or supervising the use of restricted use pesticides within a Federal

facility are subject to the same or equivalent provisions prescribed under § 171.7(b)(1)(iii) (A)–(E).

[40 FR 11704, Mar. 12, 1975]

§ 171.10 Certification of applicators on Indian Reservations.

This section applies to applicators on Indian Reservations.

(a) On Indian Reservations[1] not subject to State jurisdiction the appropriate Indian Governing Body[2] may choose to utilize the State certification program, with the concurrence of the State, or develop its own plan for certifying private and commercial applicators to use or supervise the use of restricted use pesticides.

(1) If the Indian Governing Body decides to utilize the State certification program, it should enter into a cooperative agreement with the State. This agreement should include matters concerning funding and proper authority for enforcement purposes. Such agreement and any amendments thereto shall be incorporated in the State plan, and forwarded to the Administrator for approval or disapproval.

(2) If the Indian Governing Body decides to develop its own certification plan, it shall be based on either Federal standards (§§ 171.1 through 171.8) or State standards for certification which have been accepted by EPA. Such a plan shall be submitted through the United States Department of the Interior to the EPA Administrator for approval.

(b) On Indian Reservations where the State has assumed jurisdiction under other Federal laws, anyone using or supervising the use of restricted use pesticides shall be certified under the appropriate State certification plan.

(c) Non-Indians applying restricted use pesticides on Indian Reservations not subject to State jurisdiction shall be certified either under a State certification plan accepted by the Indian Governing Body or under the Indian Reservation certification plan.

(d) Nothing in this section is intended either to confer or deny jurisdiction to the States over Indian Reservations not already conferred or denied under other laws or treaties.

[40 FR 11704, Mar. 12, 1975]

§ 171.11 Federal certification of pesticide applicators in States or on Indian Reservations where there is no approved State or Tribal certification plan in effect.

(a) *Applicability.* This section applies to persons in any State and on any Indian Reservation where, because there is no approved State or Tribal certification plan in effect, the Administrator implements an EPA plan for the Federal certification of applicators of restricted use pesticides.

(b) *Certification requirement.* In any State or on any Indian Reservation where this section is applicable, any person who uses or supervises the use of any pesticide classified for restricted use must be certified in accordance with this section. However, a competent person who is not certified may use a restricted use pesticide under the direct supervision of a certified applicator for uses authorized by the certified applicator's certification. Private applicator certification shall authorize only those uses, or the supervision of those uses, described in § 171.2(t). Commercial applicator certification shall authorize only those uses, or the supervision of those uses, included within the specific category(ies) or subcategory(ies), described in § 171.3(b) or an applicable Federal plan, in which the applicator is certified.

(c) *Certification of commercial applicators*—(1) *Categories for Commercial Applicators.* Categories referred to in this section are the same as those listed in § 171.3(b). Determination of competency in each category shall conform to the requirements of § 171.4(a).

(2) *Subcategories.* The Administrator may adopt subcategories as he or she deems necessary, consonant with the needs of the individual State or Reservation.

[1] The term *Indian Reservation* means any federally-recognized reservation established by Treaty, Agreement, Executive Order, or Act of Congress.

[2] The term *Indian Governing Body* means the governing body of any tribe, band, or group of Indians subject to the jurisdiction of the United States and recognized by the United States as possessing power of self-government.

(3) *Standards for certification.* The standards of competency for certification of commercial applicators under this section are the same as those listed in § 171.4 (b) and (c) and § 171.6.

(4) *Certification procedure.* An individual who desires to be certified or recertified under this paragraph shall complete the EPA certification form and submit the form to the appropriate EPA Regional Office. In order to be initially certified as a commercial applicator under this paragraph, an individual must take and pass written examinations approved by the Administrator and administered by the Administrator or any other party approved by him or her. A general examination will be given, based on the general standards found in § 171.4(b) and the standards for supervision found in § 171.6. In addition, specific category and subcategory examinations will be given, based on the appropriate category or subcategory standards found in § 171.4(c) and the applicable Federal plan. The Administrator will notify the individual in writing of the results of the examinations within 45 days unless special circumstances justify a longer time period. The Administrator will issue to each person who has passed a general examination and one or more category or subcategory examinations a commercial applicator certificate covering each category and subcategory in which he or she has qualified. A commercial applicator certificate is valid for a period of three years from the date of issuance, unless earlier suspended or revoked by the Administrator (two years from the date of issuance, in the case of certificates issued prior to [effective date of amended rule]), and is valid within the State or Indian Reservation named on the certificate.

(5) *Re-examination.* Individuals failing to pass the required certification examination(s) may be re-examined after notification of failure. An individual seeking re-examination need take only the examination(s) which he or she originally failed.

(6) *Renewal of commercial applicator certification.* A certified commercial applicator may qualify for recertification by taking and passing written examinations as specified in paragraph (c)(4) of this section, or by successfully completing any available training program approved for this purpose by the Administrator. Recertification procedures must be completed by the certified commercial applicator during the twelve month period preceding the expiration date of his or her certificate.

(7) *Recordkeeping requirements.* (i) Each self-employed certified commercial applicator, each firm employing a certified commercial applicator, and each person who contracts with a certified commercial applicator (or his or her employer) to have a restricted use pesticide applied on property owned or operated by another person shall keep and maintain at their principal place of business true and accurate records of the use of restricted use pesticides, providing the following information:

(A) Name and address of the person for whom the pesticide was applied;

(B) Location of the pesticide application;

(C) Target pest(s);

(D) Specific crop or commodity, as appropriate, and site, to which the pesticide was applied;

(E) Year, month, day, and time of application;

(F) Trade name and EPA registration number of the pesticide applied;

(G) Amount of the pesticide applied and percentage of active ingredient per unit of the pesticide used; and

(H) Type and amount of the pesticide disposed of, method of disposal, date(s) of disposal, and location of the disposal site.

(ii) *Availability of required records.* Each certified commercial applicator shall keep all records required under this paragraph current and shall make such records available for inspection and copying by representatives of EPA for a period of at least two years from the date of use of the pesticide.

(d) *Certification of private applicators*—(1) *Certification procedures.* An individual who desires to be certified or recertified under this paragraph shall complete the EPA certification form and submit the form to the appropriate EPA Regional Office. In order to be certified or recertified as a private applicator to use restricted use pesticides, an individual must be determined competent with respect to the

use and handling of pesticide. Standards for such determination are the same as those listed in §§ 171.5 and 171.6. The Administrator will offer one or more of the following certification options, including at least one option which does not require the applicator to take an examination—

(i) *Approved training course.* The individual may successfully complete an approved training course. Approved training courses may include courses sponsored by EPA, State cooperative extension services, State vocational agricultural courses, or private educational groups. Each training course for certification must be approved for that purpose by the Administrator and include, at a minimum, coverage of the private applicator standards listed in §§ 171.5 and 171.6, and a demonstration that the individual has successfully completed the training course. Subject to the approval of the Administrator, this demonstration may be accomplished by completion of a no pass/no fail written questionnaire or a workbook, receipt of a passing grade in an approved course offered by an educational institution, or any other equivalent procedure.

(ii) *Written examination.* The individual may pass a written examination approved by the Administrator and administered by the Administrator or any other party approved by him or her.

(iii) *Self-study program.* The individual may successfully complete a self-study learning program approved by the Administrator and administered by the Administrator or any other party approved by him or her.

(iv) *Non-reader certification.* Non-readers may be certified for specific use(s) of a single product by successfully completing an approved training course as specified in (d)(1) (i) of this section, or by passing an oral examination approved by the Administrator and administered by the Administrator or any other party approved by him or her. Such training or testing shall incorporate a specific procedure relating to label comprehension, as described in § 171.5(b)(1).

(2) *Issuance of certificates.* The Administrator will issue a private applicator certificate to each individual who successfully completes any available certification option. Individuals who, for any reason, fail to complete successfully a certification option may attempt to complete the same option or, if available, an alternative option. A private applicator certificate is valid for a period of four years from the date of issuance (three years from the date of issuance, in the case of certificates issued before [effective date of amended rule]), unless earlier suspended or revoked by the Administrator, and is valid within the State or Indian Reservation named on the certificate.

(3) *Renewal of private applicator certification.* A certified private applicator may qualify for recertification by successfully completing any available certification option during the twelve month period preceding the expiration date of his or her certificate.

(e) *Recognition of other certificates.* The Administrator may issue a certificate to an individual possessing any other valid Federal, State or Tribal certificate without further demonstration of competency. The individual shall submit the EPA certification form and written evidence of valid certification to the appropriate EPA Regional Office. The Administrator may deny issuance of such certificate if the standards of competency for each category or subcategory identified in the other Federal, State or Tribal certificate are not sufficiently comparable to justify waiving further demonstration of competency. The Administrator may revoke, suspend, or modify such certificate if the Federal, State or Tribal certificate upon which it is based is revoked, suspended, or modified. Unless suspended or revoked, a certificate issued under this paragraph is valid for two years for commercial applicators and three years for private applicators, or until the expiration date of the original Federal, State or Tribal certificate, whichever occurs first.

(f) *Denial, suspension, modification or revocation of a certificate.* (1) The Administrator may suspend all or part of a certificate issued pursuant to this section, or, after opportunity for a hearing, may deny issuance of, or revoke or modify, a certificate issued pursuant to this section, if he or she finds that the applicant or certificate

holder has been convicted under section 14(b) of the amended FIFRA, has been subject to a final order imposing a civil penalty under section 14(a) of the amended FIFRA, or has committed any of the following acts:

(i) Used any registered pesticide in a manner inconsistent with its labeling;

(ii) Made available for use, or used, any registered pesticide classified for restricted use other than in accordance with section 3(d) of the amended FIFRA and any regulations promulgated thereunder;

(iii) Refused to keep and maintain any records required pursuant to this section;

(iv) Made false or fraudulent records, invoices or reports;

(v) Failed to comply with any limitations or restrictions on or in a duly issued certificate; or,

(vi) Violated any provision of the amended FIFRA and the regulations promulgated thereunder.

(2) If the Administrator decides to deny, revoke, or modify a certificate, he or she will:

(i) Notify the applicant or certificate holder of:

(A) The ground(s) upon which the denial, revocation or modification is based;

(B) The time period during which the denial, revocation or modification is effective, whether permanent or otherwise;

(C) The conditions, if any, under which the individual may become certified or recertified; and,

(D) Any additional conditions the Administrator may impose.

(ii) Provide the applicant or certificate holder an opportunity to request a hearing prior to final Agency action to deny, revoke or modify the certificate.

(3) If a hearing is requested by an applicant or certificate holder pursuant to paragraph (f)(2)(ii) of this section, the Administrator will:

(i) Notify the affected applicant or certificate holder of those assertions of law and fact upon which the action to deny, revoke or modify the certificate is based;

(ii) Provide the affected applicant or certificate holder an opportunity to offer written statements of facts, explanations, comments, and arguments relevant to the proposed action;

(iii) Provide the affected applicant or certificate holder such other procedural opportunities as the Administrator may deem appropriate to ensure a fair and impartial hearing; and

(iv) Appoint an attorney in the Agency as Presiding Officer to conduct the hearing. No person shall serve as Presiding Officer if he or she has had any prior connection with the specific case.

(4) The Presiding Officer appointed pursuant to paragraph (f)(3)(iv) of this section shall:

(i) Conduct a fair, orderly, and impartial hearing, without unnecessary delay;

(ii) Consider all relevant evidence, explanation, comment, and argument submitted pursuant to paragraphs (f)(3)(ii) and (iii) of this section; and,

(iii) Promptly notify the affected applicant or certificate holder of his or her decision and order. Such an order is a final Agency action subject to judicial review in accordance with Section 16 of the amended FIFRA.

(5) If the Administrator decides to suspend all or part of a certificate, he or she will:

(i) First determine that the public health, interest or welfare warrants immediate action to suspend the certificate;

(ii) Notify the certificate holder of the ground(s) upon which the suspension action is based;

(iii) Notify the certificate holder of the time period during which the suspension is effective; and,

(iv) Notify the certificate holder of his or her intent to revoke or modify the certificate, as appropriate, in accord with paragraph (f)(2) of this section. If such revocation or modification notice has not previously been issued, it will be issued at the same time the suspension notice is issued.

(6) In cases where the act constituting grounds for suspension, revocation, or modification of a certificate is neither willful nor contrary to the public interest, health, or safety, the affected certificate holder may have additional procedural rights under 5 U.S.C. 558(c).

(7) Any notice, decision, or order issued by the Administrator under

paragraph (f) of this section, and any documents filed by an applicant or certificate holder in a hearing under paragraph (f) of this section, shall be available to the public except as otherwise provided by section 10 of the amended FIFRA or by part 2 of this title. Any such hearing at which oral testimony is presented shall be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidentiality under section 10 of the amended FIFRA or under part 2 of this title.

(g) *Pesticide dealer reporting and recordkeeping requirements, availability of records, and failure to comply*—(1) *Reporting requirements.* Each person who is a restricted use pesticide retail dealer in a State or on an Indian Reservation where the Administrator conducts the applicator certification and training program shall:

(i) Report to the Environmental Protection Agency (EPA) the business name by which the restricted use pesticide retail dealer operates, and the name and business address of each of his dealerships. For dealers or dealerships in Nebraska this initial report must be submitted to EPA, Region VII, 324 E. 11th Street, Kansas City, MO 64106. For dealers or dealerships in Colorado this initial report must be submitted to EPA, Region VIII, 1860 Lincoln Street, Denver, Colorado 80295. This report shall be submitted to the appropriate EPA regional office no later than 60 days after the date the person first becomes a restricted use pesticide retail dealer, or within 60 days after the publication of the effective date of this final rule, whichever date is later.

(ii) Submit revisions to the initial report to the appropriate EPA regional office listed above reflecting any name changes, additions or deletions of dealerships. Revisions shall be submitted to EPA within 10 days of the occurrence of such change, addition or deletion.

(2) *Recordkeeping requirement.* Recordkeeping is required when making restricted use pesticides available to:

(i) *Certified applicators.* Each restricted use pesticide retail dealer shall maintain at each individual dealership records of each transaction where a restricted use pesticide is made available for use by that dealership to a certified applicator. Record of each such transaction shall be maintained for a period of 24 months after the date of the transaction, and shall include the following information:

(A) Name and address of the residence or principal place of business of each person to whom the pesticide was made available for use.

(B) The certification number on the document evidencing that person's certification, the State (or other governmental unit) that issued the doucment, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(C) The product name, EPA registration number, and the State special local need registration number, granted under section 24(c) of the FIFRA (if any) on the label of the pesticide.

(D) The quantity of the pesticide made available for use in the transaction.

(E) The date of the transaction.

(ii) *Uncertified persons.* No dealer or dealership may make a restricted use pesticide available to an uncertified person unless he can document that the restricted use pesticide will be used by a certified applicator, and he maintains the records required in this subsection. Each restricted use pesticide retail dealer shall maintain records at each individual dealership of each transaction where a restricted use pesticide was made available to an uncertified person for use by a certified applicator. Records of each such transaction shall be maintained for a period of 24 months after the date of the transaction, and shall include the following information:

(A) The name and address of the residence or principal place of business of the uncertified person to whom the restricted use pesticide is made available for use by a certified applicator.

(B) The name and address of the residence or principal place of business of the certified applicator who will use the restricted use pesticide.

(C) The certified applicator's certification number, the State (or other governmental unit) that issued his certification document, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(D) The product name, EPA registration number, and the State special local need registration number, granted under section 24(c) of the FIFRA (if any) on the label of the pesticide.

(E) The quantity of the pesticide made available for use in the transaction.

(F) The date of the transaction.

(G) At the time of each transaction, EPA recommends that the dealer obtain the information required in paragraph (g)(2)(ii) (A) through (C) of this section and assure himself that the restricted use pesticide is made available for use by a certified applicator by examining one of the following sets of documents:

(*1*) The original of the certified applicator's certification document, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(*2*) A photocopy or facsimile of the certified applicator's certification document, together with a statement signed by the certified applicator authorizing the uncertified person to purchase the restricted use pesticide on his behalf, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(*3*) A photocopy or facsimile of the certified applicator's certification document, together with a copy of a signed contract or agreement, between the uncertified person to whom the restricted use pesticide is being made available for use and the identified certified applicator, which provides for the use of the restricted use pesticide by the identified certified applicator, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(3) *Availability of required records.* Each pesticide dealer shall, upon request of any officer or employee of EPA duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and copy all records required to be maintained under this section.

(4) *Failure to comply.* Any person who fails to comply with the provisions of this rule may be subject to civil or criminal sanctions, under section 14 of the Act, or 18 U.S.C. 1001. Violations include failure to submit or falsification of any report required under this paragraph, failure to maintain or falsification of records as required under this section, and making available for use any pesticide classified for restricted use to a person who is not a certified commercial applicator other than in accordance with these regulations and section 3(d) of the amended FIFRA or rules promulgated thereunder.

[43 FR 24837, June 8, 1978, as amended at 48 FR 29855, June 29, 1983; 48 FR 53974, Nov. 29, 1983; 49 FR 17759, Apr. 25, 1984; 58 FR 34203, June 23, 1993]

PART 172—EXPERIMENTAL USE PERMITS

Subpart A—Federal Issuance of Experimental Use Permits

Sec.
172.1 Definitions.
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AUTHORITY: 7 U.S.C. 136c, 136w. Section 172.4 is also issued under 31 U.S.C. 9701.

SOURCE: 40 FR 18782, Apr. 30, 1975, unless otherwise noted.

Subpart A—Federal Issuance of Experimental Use Permits

§ 172.1 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

Act means the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

Applicant means any person who applies for an experimental use permit pursuant to section 5 of the Act.

Cooperator means any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.

Experimental animals means individual animals or groups of animals, regardless of species, intended for use and used solely for research purposes. The term does not include animals intended to be used for any food purposes

Participant means any person acting as a representative of the permittee and responsible for making available for use, or supervising the use or evaluation of, an experimental use pesticide to be applied at a specific application site.

Permittee means any applicant to whom an experimental use permit has been granted.

Value for pesticide purposes means that characteristic of a substance or mixture of substances which produces an efficacious action on a pest.

[73 FR 75599, Dec. 12, 2008]

§ 172.2 General.

(a) Pursuant to section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 983), and except as herein provided by § 172.3, any person wishing to accumulate information necessary to register under section 3 of the Act and the regulations thereunder (1) a pesticide not registered with this Agency or (2) a registered pesticide for a use not previously approved in the registration of the pesticide may apply to the Administrator at any time for an experimental use permit.

(b) Pesticides under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

§ 172.3 Scope of requirement.

(a) An experimental use permit (EUP) is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use. However, as described in paragraph (b) of this section, certain of such tests are presumed not to involve unreasonable adverse effects and, therefore, do not require an EUP.

(b) Except as provided in subpart C of this part or as specifically determined by the Environmental Protection Agency (EPA), it may be presumed that EUPs are not required when:

(1) The experimental use of the pesticide is limited to:

(i) Laboratory or greenhouse tests,

(ii) Limited replicated field trials as described in paragraph (c) of this section to confirm such tests, or

(iii) Other tests as described in paragraph (c) of this section whose purpose is only to assess the pesticide's potential efficacy, toxicity, or other properties.

(2) The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the pesticide's use.

(c) For purposes of paragraphs (b)(1)(ii) and (b)(1)(iii) of this section, the following types of experimental tests are presumed not to need an EUP:

(1) A small-scale test involving use of a particular pesticide that is conducted on a cumulative total of no more than 10 acres of land per pest, except that:

(i) When testing for more than one target pest occurs at the same time and in the same locality, the 10 acre limitation shall encompass all of the target pests.

(ii) Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of the tested pesticides) shall be destroyed or consumed only by experimental animals unless an appropriate tolerance or exemption from a tolerance has been established under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of the pesticide.

(2) A small-scale test involving the use of a particular pesticide that is conducted on a cumulative total of no more than 1 surface acre of water per pest, except that:

(i) When the testing for more than one target pest occurs at the same time and in the same locality, the 1 acre limitation shall encompass all of the target pests.

(ii) Waters which are involved in or affected by such tests are not used for irrigation purposes, drinking water supplies, or body contact recreational activities.

(iii) Testing shall not be conducted in any waters which contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed, unless an appropriate tolerance or exemption from a tolerance has been established under the FFDCA for residues of the pesticide.

(3) Animal treatment tests involving the use of a particular pesticide that are conducted only on experimental animals which will not be used for food or feed, unless an appropriate tolerance or an exemption from a tolerance has been established for animal products and byproducts under the FFDCA for residues of the pesticide.

(d) The examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section are not all-inclusive and do not preclude testing in larger areas or larger numbers of units if the intended use meets the criteria of paragraph (a) of this section. However, tests which do not come within the examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section, absent a specific determination by EPA to the contrary, require an EUP. Persons intending to conduct tests who are uncertain whether the testing may be conducted without a permit may submit a request for determination to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b). Such a request shall include the information listed in § 172.4(b)(1)(ii) and (b)(1)(iii) and in the case of an unregistered product, the information in § 172.4(b)(3)(i).

(e) Notwithstanding paragraphs (b) through (d) of this section, EPA may, on a case-by-case basis, require that certain testing of a particular pesticide or class of pesticides be carried out under an EUP, if it is determined that such EPA oversight is warranted. If EPA determines that an EUP is required, it will notify the developer of the pesticide of the need for an EUP and provide opportunity for comment or objections before imposing the requirement.

(f) No EUP is required for a substance or mixture of substances being put through tests for the sole purpose of gathering data required for approval of such substance or mixture under the FFDCA (21 U.S.C. 301 *et seq.*) as:

(1) A ''new drug'' (21 U.S.C. sec. 321(p) and sec. 355).

(2) A ''new animal drug'' (21 U.S.C. sec. 321(w) and sec. 360(b)), or

(3) An ''animal feed'' (21 U.S.C. sec. 321 (x)) containing a ''new animal drug'' (21 U.S.C. sec. 360(b)).

(g) Paragraph (f) of this section shall not apply when a purpose of such test is to accumulate information necessary to register a pesticide under section 3 of the Act.

[59 FR 45611, Sept. 1, 1994, as amended at 71 FR 35546, June 21, 2006; 73 FR 75599, Dec. 12, 2008]

§ 172.4 Applications.

(a) *Time for submission.* An application or request for amendment to an existing permit shall be submitted as far as possible in advance of the intended date of shipment or use to the Office of

Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(b) *Contents of applications*—(1) *General requirements.* (i) The name and address of the applicant;

(ii) The registration number of the product, if registered;

(iii) The purpose or objectives of the proposed testing; a description in detail of the proposed testing program including test parameters; a designation of the pest organism(s) involved; the amount of pesticide product proposed for use; the crops, fauna, flora, sites, modes, dosage rates, and situation of application on or in which the pesticide is to be used; the States in which the proposed program will be conducted; the number of acres, number of structural sites, or number of animals by State to be treated or included in the area of experimental use; the proposed dates or period(s) during which the testing program is to be conducted; and the manner in which supervision of the program will be accomplished;

(iv) The name, street address, telephone number, and qualifications of all participants in the program (whether or not in the employ of the applicant). A permit must be amended to add or change participants;

(v) The name and street address of all cooperators, if available at the time an application is submitted or as soon thereafter as available;

(vi) A description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine toxicity and effects in or on target organisms at the site of application; and to determine phytotoxicity and other forms of toxicity or effects on nontarget plants, animals, and insects at or near the site of application; and to determine adverse effects on the environment;

(vii) The proposed method of storage and disposition of any unused experimental use pesticide and its containers; and

(viii) Such other additional pertinent information as the Administrator may require.

(2) *Requirement for tolerance.* If the experimental use pesticide is to be used in such a manner that any residue can reasonably be expected to result in or on food or feed, the applicant must:

(i) Submit evidence that a tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug, and Cosmetic Act; or

(ii) Submit a petition proposing establishment of a tolerance or an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act; or

(iii) Certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment. The method of such destruction or disposition shall be provided in the application for the permit.

(3) *Additional requirements for unregistered pesticide products.* (i) A complete confidential statement of composition for the formulation to be tested giving the name and percentage by weight of each ingredient, active and inert;

(ii) Chemical and physical properties of each active ingredient of the formulation to be tested, including, but not limited to, the manufacturing or laboratory processes and analytical methods suitable for determining the active ingredients in the formulation;

(iii) Appropriate date, if available, on the rate of decline of residues on the treated crop or environmental site or other information for determination regarding entry of persons into treated areas; and

(iv) Results of toxicity tests and other data relevant to the product's potential for causing injury to the users or other persons who may be exposed, including any available epidemiological information as to man.

(c) *Fees.* The payment of fees for experimental use permits shall apply as specified in subpart U of part 152 of the chapter.

[40 FR 18782, Apr. 30, 1975, as amended at 53 FR 19115, May 26, 1988; 71 FR 35546, June 21, 2006; 73 FR 75599, Dec. 12, 2008]

§ 172.5 The permit.

(a) *Issuance.* The Experimental Use Permit shall be issued when the Administrator determines that the conditions of section 5 of the Act, and the regulations thereunder, have been met subject to such terms and conditions as the Administrator determines are warranted.

(b) *Duration.* Permits will be effective for a specified period of time, normally one year, depending upon the crop or site to be tested and the requirements of the testing program submitted. The applicant should propose a suitable duration of the permit commensurate with the program submitted. Permits and associated temporary tolerances may be renewed, extended, or amended upon request if circumstances warrant.

(c) *Limitations.* The quantity of a pesticide allowed by a permit may be less than requested if it is determined that the available information on efficacy, toxicity or other hazards, the need for data, or the adequacy of program supervision does not justify the quantity of the pesticide requested. Other limitations may also be placed in the permit if necessary for the protection of the public health and the environment.

(d) *Additions.* With respect to an experimental use pesticide containing any chemical or combination of chemicals not included in any previously registered pesticides, the Administrator may require that additional studies be conducted during the permit period to gather data to support the establishment of tolerances and/or registration. To the extent practicable, the applicant will be notified of any such requirements before or at the time an experimental use permit is issued.

(e) *Maintenance of records.* All producers of pesticides produced pursuant to an experimental use permit shall maintain records in accordance with part 169.

§ 172.6 Labeling.

(a) *Contents.* Except as provided by paragraph (b) of this section, all pesticides shipped or used under an experimental use permit shall be labeled with directions and conditions for use which shall include the following:

(1) The prominent statement, ''For Experimental Use Only'';

(2) The Experimental Use Permit number;

(3) The statement, ''Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program'';

(4) The name, brand, or trademark;

(5) The name and address of the permittee, producer, or registrant;

(6) The net contents;

(7) An ingredient statement;

(8) Warning or caution statements;

(9) Any appropriate limitations on entry of persons into treated areas;

(10) The establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and

(11) The directions for use, except that the Administrator may approve the use of the experimental program as labeling provided that such program is to be distributed with the product.

(b) *Supplemental labeling.* In the case of a registered pesticide, the Administrator may, at his discretion, permit a pesticide to be used under an experimental use permit with supplemental labeling as approved by him.

§ 172.7 Importation of technical material.

Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an Experimental Use Permit has been requested if the application for such permit states that such importation will occur.

§ 172.8 Program surveillance and reporting of data.

(a) The permittee shall supervise the test program and evaluate the results of testing at each site of application. It will further be the responsibility of the permittee to report immediately to the Administrator, or to any person designated by him, any adverse effects from use of, or exposure to, the pesticide.

(b) The permittee shall submit the following reports to the Registration Division during the experimental program.

(1) [Reserved]

(2) A final report shall be submitted within 180 days after the expiration of

the permit, unless a request for extension of time is approved, and shall include:

(i) All data gathered during the testing program; field notes need not be submitted but must be maintained and submitted upon request;

(ii) A description of the disposition of any pesticide containers and any unused pesticides including amounts disposed of and the method and site of disposition; and

(iii) The method of disposition of affected food and/or feed.

The data under paragraph (b)(2)(i) of this section above may be submitted as part of an application for registration submitted within 180 days after the expiration of the permit, provided that the final report shall include a statement that such application has been made, and the date of such application.

(c) In addition to the reporting requirements provided for elsewhere in this part, in the case of any meat-producing animals or birds that receive a direct treatment or application of any experimental use pesticide, the name and location of the packing plant where the animals will be processed shall be sent to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC 20250, at least 10 days before the animals are to be shipped for slaughter. This requirement may be waived, on request, by the USDA. These provisions do not exempt treated food-producing animals and their products from compliance with other applicable inspection requirements.

(d) Failure to submit required reports may constitute grounds for revocation of the permit.

(e) For the purpose of supervising the use of experimental use pesticides, the Agency may require the permittee or any participant to give reasonable advance notification of the intended dates, times, and sites on which such experimental use pesticide will be applied.

(f) The permittee or participants in the experimental use program will permit any authorized representative of the Agency, upon presentation of official identification, entry, at any reasonable time, to any premises involved in the testing program to inspect and to determine whether there has been compliance with the terms and conditions of the permit.

[40 FR 18782, Apr. 30, 1975, as amended at 60 FR 32097, June 19, 1995]

§ 172.9 Renewals.

Applications for renewal of experimental use permits and temporary tolerances, to provide for additional testing, shall be submitted prior to expiration of the permit. Requirements for renewals are the same as for applications under § 172.4, except that information previously submitted may be incorporated by reference.

§ 172.10 Refusals to issue and revocation.

(a) *Refusal.* At any time that the Administrator determines that an experimental use permit is not justified, or that the issuance of such a permit would cause unreasonable adverse effects on the environment, or that for any other reason provided for under the law a permit shall not be issued, he shall notify the applicant in writing.

(b) *Revocation.* The Administrator may revoke an experimental use permit if he finds that its terms or conditions are being violated or that its terms or conditions are inadequate to avoid unreasonable adverse effects on the environment, or if new evidence is obtained which demonstrates that the tolerance will be inadequate to protect the public health, or for failure to meet any other provision of this part 172. The Administrator will notify the permittee in writing of such revocation. The permittee shall notify all participants of such revocation as soon as possible after he receives notice of revocation. The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for the violations of the permit conditions or otherwise as authorized by law.

(c) *Hearing.* In the event that an applicant for an experimental use permit wishes to contest the refusal to issue an experimental use permit, or an experimental use permittee wishes to contest the revocation of any such permit, he shall, within twenty days after receipt of notice of such refusal or revocation, file with the Administrator a

written request for an opportunity to confer with the Administrator or his designee. Within twenty days after such conference, the applicant or permittee will be notified of the Administrator's final decision.

§ 172.11 Publication.

(a) *Notice of receipt of an experimental use permit application.* The Administrator shall publish notice in the FEDERAL REGISTER of receipt of an application for an experimental use permit upon finding that issuance of the experimental use permit may be of regional or national significance. This notice shall include:

(1) The active ingredients,
(2) Use pattern(s),
(3) Quantity of pesticide,
(4) Total acreage,
(5) Location of area of application,
(6) A statement soliciting comments from any interested persons regarding the application.

(b) *Public hearing.* The Administrator may hold a public hearing, and publish notice in the FEDERAL REGISTER of the date and location of the hearing, when he determines that there is sufficient interest in the application to warrant a hearing, based upon the comments received in response to the Notice of Receipt of an Application, or that a hearing would otherwise be in the public interest.

(c) *Issuance of experimental use permit.* The Administrator shall give prompt notice in the FEDERAL REGISTER of the issuance of an experimental use permit. The notice shall include:

(1) The active ingredients,
(2) Use pattern(s),
(3) Quantity of pesticide,
(4) Total acreage,
(5) Location of area of application,
(6) A statement indicating where the experimental use permit is available for public inspection.

Subpart B—State Issuance of Experimental Use Permits

SOURCE: 44 FR 41787, July 18, 1979, unless otherwise noted.

§ 172.20 Scope.

This subpart sets forth regulations governing State issuance of experimental use permits pursuant to section 5(f) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). It also sets forth regulations governing authorization by the Administrator of State experimental use permit programs.

§ 172.21 Definitions.

Terms used in this subpart shall have the meaning set forth in FIFRA and in § 172.1.

Designated State agency means the State agency designated by State law or other authority to be responsible for registering pesticides to meet special local needs.

Public or private agricultural research agency or educational institution means any organization engaged in research pertaining to the agricultural use of pesticides, or any educational institution engaged in pesticide research. Any research agency or educational institution whose principal function is to promote, or whose principal source of income is directly derived from, the sale or distribution of pesticides (or their active ingredients) does not come within the meaning of this term.

[73 FR 75599, Dec. 12, 2008]

§ 172.22 General.

(a) Experimental use permits are not required under this rule in those situations described in § 172.3 of subpart A pertaining to Federal experimental use permits.

(b) Subpart B is not applicable to experimental use permits issued by a State, as required by State law, to a permittee who already holds a valid Federal experimental use permit issued under subpart A for the same purpose, or who is not required to obtain a permit under this rule.

(c) Pesticide products used under experimental use permits may not be sold or distributed other than through participants, and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

(d) Establishments in which pesticide products under State experimental use permits are produced shall be registered as required by 40 CFR 167.2(a)

and producers of such products shall maintain books and records as required by 40 CFR 169.2.

(e) Pesticide products and their containers used under this rule must also be packaged, stored, transported, used, and disposed of in accordance with all applicable Federal laws and regulations, including the Resource Conservation and Recovery Act of 1976 as amended (Pub. L. 94–580; 90 Stat. 2795; 42 U.S.C. 6901 *et seq.*) (RCRA), and rules thereunder.

§ 172.23 State plans.

(a) *Submission.* (1) A State may, by submitting a State plan, request the Administrator to authorize the designated State agency to issue experimental use permits under section 5(f) of FIFRA.

(2) A State shall request authorization to issue experimental use permits by having the Governor or Chief Executive Officer or his designated agent submit a State plan in writing to the Administrator.

(b) *Contents.* A State plan shall include—

(1) A designation of the State agency responsible for the administration of the State experimental use permit program.

(2) An opinion of the State attorney general or the legal counsel of the designated State agency that the State has the requisite legal authorities as set forth in paragraph (c)(1)(i) of this section, accompanied by copies of the applicable State laws and regulations.

(3) A description of procedures that the designated State agency will follow:

(i) To review experimental use permit applications, to ensure that experimental use permits will be issued in accordance with the terms and conditions of the authorization, FIFRA, and this subpart; and

(ii) To supervise use pursuant to the permits, and to ensure that permits are used in accordance with their terms and conditions, FIFRA, and this subpart.

(c) *Criteria for EPA acceptance of State plan.* (1) The Administrator shall grant authorization to issue experimental use permits if the State plan establishes that the designated State agency—

(i) Has adequate legal authority under State law to implement the plan, including authority:

(A) To issue experimental use permits, subject to limitations necessary for the protection of public health and the environment;

(B) To supervise the use of a pesticide pursuant to an experimental use permit, as provided in § 172.25(c);

(C) To deny an experimental use permit if it determines that a permit is not justified, or that the issuance of the permit would cause unreasonable adverse effects on the environment;

(D) To amend or revoke an experimental use permit, if the designated State agency finds that:

(*1*) The terms and conditions of the permit are being violated, or are inadequate to avoid unreasonable adverse effects on the environment;

(*2*) Any required tolerance under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) has been revoked by EPA, or any exemption from the requirement for tolerance has been withdrawn by EPA; or

(*3*) A failure by the permittee or any cooperator to meet any other provision of FIFRA or this subpart has occurred;

(E) To enter, by consent or by warrant or by other legal means, in connection with an experimental use permit, a permittee's or cooperator's premises at reasonable times in order to sample or inspect any pesticides used or property treated, to inspect any equipment or records kept, or to observe any activities conducted, as necessary to enforce compliance with State law, the terms of the permit, and this subpart;

(F) To comply in all other respects with the requirements of this subpart, including labeling requirements; and

(ii) Utilizes procedures for the review of each permit which are adequate to ensure that the State program will be administered in accordance with the purposes of FIFRA and this subpart.

(2) After receiving a State plan, EPA shall publish a FEDERAL REGISTER notice announcing the fact and inviting interested parties to comment thereon.

(d) *Approval, rejection, and revocation.* (1) EPA shall approve or reject the

State plan within 90 days after receipt of all information necessary for final review of the plan, including copies of effective statutes and regulations which satisfy the requirements of this subpart.

(2) The Administrator may at any time revoke the authorization of a State to issue experimental use permits if he determines that the designated State agency has not complied with the requirements of this subpart or with the terms and conditions of such authorization. State experimental use permits issued prior to the revocation of authority shall remain valid until they expire or until three years from the date of revocation of the State's authority, whichever comes first, unless sooner revoked by EPA under § 172.26(c) of this subpart.

(3) Notices of approval, rejection, and revocation shall be published in the FEDERAL REGISTER, as well as the basis for such approval, rejection, or revocation.

(4) Prior to rejecting or revoking authorization, the Administrator shall notify the State in writing of his intention to take such action, along with the basis for such action, and shall afford the State the opportunity for a hearing, and time to take corrective action.

§ 172.24 State issuance of permits.

(a) *General.* Upon approval of a State plan by the Administrator under § 172.23, the designated State agency is authorized to issue, amend, renew, deny or revoke experimental use permits subject to the terms of the authorization and these regulations.

(b) *Authority.* A designated State agency may issue an experimental use permit—

(1) To any person for the purpose of gathering the data necessary to support the State registration of a pesticide to meet special local needs under section 24(c), FIFRA.

(2) To any agricultural research agency or educational institution conducting work within the State for the purpose of experimentation:

(i) Which is done within the State; and

(ii) Which is not directly intended to result in the registration of a specific pesticide product.

(3) For use of a restricted use pesticide only if the pesticide is to be used by, or under the direct supervision of, an applicator certified in accordance with section 11 of FIFRA.

(c) *Limitations.* (1) In the case of applicants who need to gather data required to register a pesticide product to meet a special local need under section 24(c) of FIFRA, a State may only issue experimental use permits for the types of pesticide products and uses which it has authority to register under section 24(c).

(2) A State may not issue an experimental use permit under § 172.24(b)(1) or § 172.24(b)(2) for any of the following:

(i) A product containing an active or inert ingredient not contained in any EPA-registered product;

(ii) A product containing an active or inert ingredient which is currently subject to an EPA cancellation or suspension of registration order, or which is currently subject to an EPA notice of intent to suspend or cancel registration because of human health, environmental or efficacy considerations; except that the State may issue a permit for such a product for a purpose or in a formulation—

(A) Which was not specifically considered in, or which is not subject to, such suspension or cancellation proceedings, after consultation with appropriate EPA officials; or

(B) Which was specifically considered during such proceedings but not suspended, cancelled, or subjected to a notice of intent to suspend or cancel;

(iii) A use of a product which has been the subject of a notice of denial of registration published in the FEDERAL REGISTER pursuant to section 3(c)(6) of FIFRA and part 154 of this chapter; or

(iv) A use of a product which may involve use in or on food or feed other than as authorized under § 172.24(d), *Requirement of tolerance.*

(3) A State may not issue an experimental use permit for use of a pesticide product in an area or in an amount in excess of that necessary to accomplish the purposes for which the permit was issued under paragraph (b) of this section.

(d) *Requirement of tolerance.* If the experimental use pesticide is to be used in or on food or feed, the applicant must—

(1) Submit evidence that:

(i) A tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug and Cosmetic Act; and

(ii) The proposed program would not reasonably be expected to result in residues of the pesticide in or on such food or feed in excess of that authorized under section 408 of the Federal Food, Drug and Cosmetic Act; and

(iii) All inert ingredients in the pesticide are exempted from the requirement of a tolerance under the appropriate section of 40 CFR part 180, subpart D; or

(2) Certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment. The method of destruction or disposal shall be described in the application for the permit.

[44 FR 41787, July 18, 1979, as amended at 50 FR 49020, Nov. 27, 1985; 73 FR 75599, Dec. 12, 2008]

§ 172.25 Administration of State programs.

(a) *General.* State experimental use permit programs shall be consistent with the Federal experimental use permit program, as set forth in subpart A of 40 CFR part 172.

(b) *Procedures leading to issuance.* An application for an experimental use permit shall be made in writing, and shall contain sufficient information, including a confidential statement of formula for any new product, to enable the State to determine whether use pursuant to the permit would be in accordance with the purposes of FIFRA and this subpart.

(c) *Labeling.* (1) New products shall bear labeling satisfying the requirements of § 172.6(a), except that the prominent statement ''For Distribution and Experimental Use Only Within (State)'' shall be used in place of ''For Experimental Use Only''. The designated State agency may approve, as directions for use on labeling, the experimental program, provided such program is to be distributed with the product.

(2) The designated State agency may permit an EPA or State registered pesticide to be used under an experimental use permit with supplemental labeling as approved by the State agency. In exercising this discretion, the designated State agency shall ensure that the supplemental labeling and the registered label together satisfy the requirements of § 172.6(a).

(d) *Duration.* State experimental use permits shall be issued for a specified period of time, not to exceed three years, depending upon the nature of the pest problem and the requirements of the testing program submitted. The designated State agency may renew, extend or amend the stated duration of a permit, if circumstances warrant.

(e) *Limitations.* The designated State agency shall impose such limitations in the permit as are necessary to protect health and the environment, including limitations on quantity, sites, area, disposal, and other aspects of pesticide use.

(f) *Program surveillance and reporting of data.* (1) The permittee shall supervise the test program and evaluate the results of testing at each site of application. The designated State agency shall require the permittee to report to it immediately any adverse effects resulting from use of, or exposure to, the pesticide.

(2) During the course of the program, the designated State agency shall require the permittee to submit such reports (both special and periodic) as are necessary to supervise effectively the progress of the program to prevent unreasonable adverse effects on man or the environment. The designated State agency shall also require the permittee to submit a final report at the conclusion of the program. Where applicable, such reports shall also be made available to the U.S. Department of Agriculture, Food Service and Quality Service (FSQS), as required by § 172.8(c).

(g) *Disposal.* All pesticides and pesticide containers, whether disposed of during the course of a State permit or

remaining at the termination of a permit, must either be:

(1) Disposed of in accordance with a disposal plan approved as part of the experimental program; or

(2) Returned to the permittee for storage or disposal in accordance with the requirements of RCRA and rules there under; or

(3) If the product is currently registered, used in accordance with the registered label.

[44 FR 41787, July 18, 1979, as amended at 60 FR 32097, June 19, 1995]

§ 172.26 EPA review of permits.

(a) *Notification of State action.* (1) Within 10 days after the issuance of an experimental use permit, the designated State agency shall notifiy EPA of the action by forwarding to the appropriate EPA Regional Office a copy of the permit, a description of the experimental program to be conducted under the terms of the permit, a copy of the approved labeling, and a copy of the confidential statement of formula for any new product.

(2) Within 10 days after amendment or revocation of an experimental use permit by a State, the designated State agency shall notify the appropriate EPA Regional Office in writing of the amendment or revocation. The notice shall include a brief explanation of the reason for the amendment or revocation. If amendments to permits include changes in the approved labeling, the designated State agency shall also forward a copy of the amended labeling.

(3) EPA shall give notice in the FEDERAL REGISTER of State issuance of experimental use permits.

(b) *Reports.* The designated State agency shall submit the following reports to EPA:

(1) An annual report covering the number of permits issued, the names and addresses of permittees, the names of the products covered by permits, and the State permit numbers issued;

(2) Reports, as requested by EPA, containing any information that EPA may determine necessary to ensure that a State has acted in compliance with provisions of FIFRA and this subpart; and

(3) Reports of any serious adverse effect(s), as soon thereafter as possible, from use of, or exposure to, a pesticide used pursuant to an experimental use permit.

(c) *Revocation by EPA.* (1) The Administrator may revoke an experimental use permit issued under this subpart if he finds:

(i) That its terms and conditions are being violated;

(ii) That its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment;

(iii) That new evidence demonstrates that any tolerance upon which the permit is based will be inadequate to protect the public health, or that any exemption from the requirement for a tolerance is no longer appropriate; or

(iv) That a failure by the permittee to meet any other provisions of FIFRA or this subpart has occurred.

(2) The Administrator shall, prior to revoking a State experimental use permit, consult with the State agency which issued the permit, except in cases where continued use of the pesticide under the permit would create an imminent hazard to man or the environment.

(3) The Administrator shall notify the designated State agency, in writing, of the revocation, and the State agency shall notify the permittee, also in writing, of the revocation.

(4) The permittee shall notify all participants of the revocation within 10 days after he receives notice of revocation.

(5) The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for violations of the permit conditions or other violations, as authorized by law.

(6) If a permittee wishes to contest the revocation of a State experimental use permit, he shall, within 30 days after receipt of notice of such revocation, file with the Administrator a written request for an opportunity to confer with the Administrator or his designee. The revocation of the permit shall remain effective pending the outcome of any conference requested under this paragraph.

(7) If a permittee requests a conference under paragraph (c)(6) of this section, the Administrator shall provide the permittee:

(i) With information as to the time, place and nature of the conference, and of the matters of fact and law asserted by the Agency as grounds for the revocation action;

(ii) An opportunity to offer a written statement of facts, explanations, and arguments relevant to the revocation action;

(iii) All other procedural opportunities to which the permittee may be entitled by law.

(8) The Administrator shall notify the affected permittee and State Agency, in writing, of his final decision on the revocation matter as expeditiously as possible and shall attempt to do so within 30 days after the conclusion of a conference conducted under paragraph (c)(7). The Administrator shall also provide the permittee and the State agency with a written statement of the reasons for his decision, which shall take into account the evidence presented pursuant to paragraph (c)(7)(ii) of this section.

(9) A decision to revoke a permit under paragraph (c)(8) of this section is a final Agency action subject to judicial review as provided by law.

[44 FR 41787, July 18, 1979, as amended at 73 FR 75599, Dec. 12, 2008]

Subpart C—Notification for Certain Genetically Modified Microbial Pesticides

SOURCE: 59 FR 45612, Sept. 1, 1994, unless otherwise noted.

§ 172.43 Definitions.

Terms used in this subpart shall, with the exception of those defined below, have the meaning set forth in the Act and in § 172.1.

Containment and inactivation controls means any combination of mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a facility.

Deliberately modified means the directed addition, rearrangement, or removal of nucleotide sequences to or from genetic material.

Introduction of genetic material means the movement of nucleotide sequences into a microorganism, regardless of the technique used.

Inversions of genetic material means the replacement of an internal section of a chromosome in the reverse orientation.

Microbial pesticide means a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaebacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

Microbial pesticides resulting from rearrangements means a microbial pesticide resulting from translocations or inversions of genetic material.

Microorganism means a bacterium, fungus, alga, virus, or protozoan.

Nonindigenous microbial pesticide means a microbial pesticide brought into one of the following geographic areas from outside that area:

(1) The continental United States, including Alaska, and the immediately adjoining countries (*i.e.*, Canada and Mexico).

(2) The Hawaiian Islands.

(3) The Caribbean Islands including Puerto Rico and the U.S. Virgin Islands.

Pesticidal property means a characteristic exhibited by a microorganism that contributes to the intentional use of the microorganism to prevent, destroy, repel, or mitigate a pest or to act as a plant regulator, defoliant, or desiccant.

Single genome means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under axenic culture conditions from that isolate.

Small-scale test means the experimental use of a microbial pesticide in a facility such as a laboratory or greenhouse, or use in limited replicated field trials or other tests as described in § 172.3(c).

Test or *testing* means any use of a microbial pesticide consistent with section 5 of the Act, including limited replicated field trials and associated activities.

Translocations of genetic material means a chromosomal configuration in which part of a chromosome becomes attached to a different chromosome, or inserts in a different location on the same chromosome.

[59 FR 45612, Sept. 1, 1994, as amended at 72 FR 61029, Oct. 26, 2007]

§ 172.45 Requirement for a notification.

(a) *Who must submit a Notification.* Notwithstanding § 172.3, any person who plans to conduct small-scale testing of a type of microbial pesticide identified in paragraph (c) of this section must submit a Notification to EPA and obtain prior approval for either of the following tests:

(1) Small-scale tests that involve an intentional environmental introduction of that microbial pesticide.

(2) Small-scale tests performed in a facility without adequate containment and inactivation controls as provided in paragraph (e) of this section.

(b) *Alternative to Notification.* In lieu of a Notification, any person required to submit a Notification under paragraph (a) of this section may submit an application for an experimental use permit (EUP) to EPA for approval.

(c) *Small-scale testing that requires a Notification.* As provided in paragraph (a) of this section, and notwithstanding any other approval by any governmental entity, EPA review and approval are required prior to the initiation of any small-scale test involving either of the following microbial pesticides:

(1) Microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.

(2) Nonindigenous microbial pesticides that have not been acted upon by the U.S. Department of Agriculture (*i.e.*, either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with the USDA).

(d) *Small-scale testing that does not require a Notification.* (1) Testing conducted with microbial pesticides identified in paragraph (c) of this section, but made exempt pursuant to § 172.52, does not require a Notification. The following microbial pesticides (or classes of pesticides) are exempt from the notification requirement in paragraph (a) of this section:

(i) Microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material that has been deliberately modified.

(ii) [Reserved]

(2) Testing conducted in a facility with adequate containment and inactivation controls, as provided in paragraph (e) of this section, does not require a Notification.

(e) *Selection and use of containment and inactivation controls.* (1) Selection and use of containment and inactivation controls for a particular microbial pesticide shall take into account the following:

(i) Factors relevant to the microbial pesticide's ability to survive in the environment.

(ii) Potential routes of release in air, solids, and liquids; in or on waste materials and equipment; in or on people (including maintenance and custodial personnel); and in or on other organisms such as insects and rodents.

(iii) Procedures for transfer of materials between facilities.

(iv) Plans for routine or emergency clean-up and test termination.

(2) For purposes of paragraph (e)(1) of this section, EPA will presume that compliance with the containment provisions of the National Institutes of Health (NIH) ''Guidelines for Research Involving Recombinant DNA Molecules'' (51 FR 16958, May 7, 1986) constitutes selection and use of adequate containment and inactivation controls.

(3) The selection of containment and inactivation controls shall be approved by an authorized official of the organization that is conducting the test prior to commencement of the test.

(4) Records shall be developed and maintained describing the selection

and use of the containment and inactivation controls, including contingency plans for emergency clean-up and test termination, that will be used during the test. These records shall be available for inspection at the test facility. In addition, these records shall be submitted to EPA at EPA's request and within the time frame specified in EPA's request.

(5) Subsequent to any EPA review of the containment/inactivation controls selected under paragraph (e)(1) of this section, changes to the controls necessary to prevent unreasonable adverse effects must be made upon EPA request. Failure to comply with EPA's request shall result in automatic revocation of the exemption from the requirement to submit a Notification.

§ 172.46 Submission of a notification.

(a) *When to submit a Notification.* A Notification shall be submitted for approval at least 90 days prior to the initiation of the proposed test.

(b) *Where to submit a notification.* A notification shall be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b), Attention: Biotechnology Notification Review.

(c) *How to format a Notification.* A Notification submitted under this section must comply with the following procedures, but is not required to comply with the format and other provisions governing submission of data in §§ 158.32 and 158.33 or 161.32 and 161.33 of this chapter. However, because data submitted with the Notification may subsequently be used to support other regulatory actions (e.g., used in EUP or registration applications), it is recommended that such data comply with EPA requirements in §§ 158.32 and 158.33 of this chapter.

(1) Each Notification must be accompanied by a transmittal document that clearly identifies the EPA action supported as a Biotechnology Notification Review.

(2) Five copies of each Notification must be submitted to EPA.

(3) Any claims of confidentiality for information submitted in the Notification must be made as described in paragraph (d) of this section.

(d) *How to make confidential business information (CBI) claims in a Notification.* Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as CBI, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a Notification (See part 2, subpart B of this chapter). To assert such a claim, the submitter must comply with the following procedures:

(1) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time will be considered a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of the Act, with no further notice to the submitter.

(2) Of the five copies of the Notification required by paragraph (c) of this section, four copies must be complete with the information that is claimed confidential clearly marked in the manner described in § 2.203(b) of this chapter. All information claimed as confidential must be deleted from the fifth copy, but it must be otherwise complete. The first page of the fifth copy must be marked ''Contains no information claimed as confidential.'' EPA may include the fifth copy in a public file without further notice. EPA will consider incomplete a Notification containing information claimed as CBI that is not submitted in accordance with this paragraph and will suspend the review period on the Notification until such procedures are followed.

(3) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter should refer to § 2.204(e)(4) of this chapter for points to address in the substantiation. If such comments are themselves claimed confidential and are marked confidential when submitted to EPA, they will be treated as such in accordance with § 2.205(c) of this chapter. EPA will consider incomplete all Notifications containing information

claimed as CBI that are not accompanied by substantiation, and will suspend the review period on such Notifications until the required substantiation is provided.

(4) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent and by means of the procedures set forth in section 10 of the Act, in this subpart, and in part 2 of this chapter.

[59 FR 45612, Sept. 1, 1994, as amended at 71 FR 35546, June 21, 2006; 72 FR 61029, Oct. 26, 2007; 73 FR 75600, Dec. 12, 2008]

§ 172.48 Data requirements for a notification.

This section identifies the data and information to be included in each Notification. When specific information is not submitted, an explanation of why it is not practical or necessary to provide the information is to be provided.

(a) The identity of the microorganism which constitutes the microbial pesticide including:

(1) Summary of data supporting the taxonomic designation and its interpretation.

(2) Means and limit of detection using sensitive and specific methods (e.g., note the use of any markers that are used to distinguish the introduced population from native microorganisms). Introduction into the microbial pesticide of a unique genetic marker is encouraged.

(b) Description of the natural habitat of the parental strain of the microbial pesticide including information on:

(1) Physical and chemical features important to growth and survival of the parental strain.

(2) Biological features of the parental strain that would have an impact on the microbial pesticide (e.g., presence of phages that infect the microorganism).

(3) Competitors.

(c) Information on the host range of the microbial pesticide, if any, with an assessment of infectivity and pathogenicity to nontarget organisms.

(d) Information on survival and the ability of the microbial pesticide to increase in numbers (biomass) in the environment (e.g., in the environment into which the microbial pesticide will be introduced, and in substantially different environments that may be in the immediate vicinity). These data may be derived from the scientific literature or from tests conducted in a laboratory or other containment facility.

(e) The identity of possible transmission vectors (e.g., insects).

(f) Data on relative environmental competitiveness compared to the parental strain of the microbial pesticide.

(g) Description of the methods used to genetically modify the microbial pesticide.

(h) The identity and location of the gene segments that have been rearranged or inserted/deleted (host source, nature, and, for example, base sequence data, or restriction enzyme map of the genes).

(i) Information on the control region of the genes, and a description of the new traits or characteristics that are expressed.

(j) Data on potential for genetic transfer and exchange with other organisms and on genetic stability of any inserted sequences in the microbial pesticide.

(k) A description of the proposed testing program including:

(1) The purpose or objectives of the proposed testing.

(2) Designation of the pest organisms involved (common and scientific names).

(3) The States in which the proposed program will be conducted.

(4) The exact location of the test sites (including proximity to residences and human activities, surface water, etc.).

(5) The crops, fauna, flora, geographical description of sites, modes, dosage rates, frequency, and situation of application on or in which the pesticide is to be used.

(6) The total amount of pesticide product proposed for use in the testing.

(7) The method of application.

(8) A comparison of the natural habitat of the microbial pesticide with the proposed test site.

(9) The number of acres, structural sites, or animals/plants by State, to be treated or included in the area of experimental use.

(10) Procedures to be used to protect the test area from intrusion by unauthorized individuals.

(11) The proposed dates or periods during which the testing program is to be conducted, and the manner in which supervision of the program will be accomplished.

(12) Description of procedures for monitoring the microbial pesticide within and adjacent to the test site during the test.

(13) The method of sanitation or disposal of plants, animals, soils, farm tools, machinery etc., that will be exposed to the microbial pesticide during or after the test.

(14) Means of evaluating potential adverse effects and methods of controlling the microbial pesticide if detected beyond the test area.

(l) A statement of composition for the formulation to be tested, giving:

(1) The name and percentage by weight (or other suitable units) of each ingredient, active and inert.

(2) Production methods.

(3) Extraneous microorganisms present as contaminants.

(4) Amount and potency of any toxin present.

(5) Where applicable, the number of viable microorganisms per unit weight or volume of the product or other appropriate system for designating the quantity of active ingredient.

(m) Any additional factual information regarding the potential for unreasonable adverse effects on the environment.

§ 172.50 Response to a notification.

(a) EPA will review and evaluate each Notification as expeditiously as possible and will make a determination no later than 90 days after receipt of the complete Notification; however, under no circumstances shall the proposed test proceed until the submitter has received notice from EPA of its approval of such test.

(b) For each Notification, EPA may make the following determinations:

(1) Require additional information from the submitter to assess the proposed test adequately.

(2) Approve the proposed test.

(3) Approve the proposed test provided that the submitter makes certain modifications to the test proposal.

(4) Require an EUP for the test.

(5) Disapprove the proposed test because of the potential for unreasonable adverse effects. Such disapproval by EPA shall be considered the equivalent of denial of an EUP and the remedies for such denial provided by § 172.10 are available to the submitter.

(c) If the proposed test is approved by EPA, then the submitter shall perform the test in the same manner described in the Notification, subject to any requirements imposed under paragraph (b)(3) of this section.

§ 172.52 Notification exemption process.

(a) *Initiation of the exemption process.* Pesticides may be added to the list of exemptions in § 172.45(d) by rule at EPA's initiative or in response to a petition submitted in accordance with paragraph (b) of this section.

(b) *Petitions for exemption from the requirement for a Notification*—(1) *Who may submit a petition.* Any person may submit a petition requesting an exemption from the notification requirements of this subpart for a specific microbial pesticide or class of microbial pesticides.

(2) *Where to submit a petition.* All petitions shall be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(3) *Content of petition.* Each petition shall contain the following:

(i) Name and address of petitioner and name, address, and telephone number of a person who may be contacted for further information.

(ii) Description of the exemption requested, including the specific microbial pesticide or class of microbial pesticides to be tested under the petition for exemption.

(iii) Basis for the petitioner's contention that the specific microbial pesticide or class of microbial pesticides meet the criteria of § 172.3 for small-scale tests of pesticides that do not require an EUP.

(iv) Discussion of the extent to which the microbial pesticide or class of microbial pesticides covered by the petition differ from microbial pesticides that are already registered or subject to an EUP under the Act.

(4) *Administrative action on a petition.* EPA will review and evaluate petitions as expeditiously as possible and may request further information from the petitioner to assess the proposed exemption adequately. No later than 180 days after the submission of a petition, or 90 days after the last submission of additional information by the petitioner, whichever is later, EPA will take one of the following actions with respect to the petition:

(i) Grant the petition and publish a notice of proposed rulemaking in the FEDERAL REGISTER for a 45–day comment period proposing the exemption requested by the petitioner.

(ii) Grant the petition and publish a notice of proposed rulemaking in the FEDERAL REGISTER for a 45–day comment period proposing an exemption under such terms and conditions as EPA deems appropriate.

(iii) Deny the petition and provide the petitioner with a written explanation of EPA's decision.

(5) *Confidential business information (CBI) claims.* To assert a claim of confidentiality, the petitioner must comply with the applicable procedures in § 172.46(d).

(6) *Supplements, amendments, and withdrawals.* The petitioner may supplement, amend, or withdraw his or her petition in writing without EPA approval at any time prior to the granting or denial of the petition under paragraph (b)(4) of this section. The withdrawal of a petition shall be without prejudice to the resubmission of the petition at a later date.

[59 FR 45612, Sept. 1, 1994, as amended at 71 FR 35546, June 21, 2006]

§ 172.57 Submission of information regarding potential unreasonable adverse effects.

Any person using a microbial pesticide in small-scale testing covered by this subpart who obtains information regarding potential unreasonable adverse effects on health or the environment must within 30 days of receipt of such information submit the information to EPA, unless the person has actual knowledge that EPA has been adequately informed of such information. The requirement to submit information applies both to those microbial pesticides subject to the notification requirements under § 172.45(c) and those that are exempt under § 172.45(d).

§ 172.59 Enforcement.

(a) *Imminent threat of substantial harm to health or the environment.* The use of a microbial pesticide in small-scale testing covered by this subpart (whether subject to the notification requirements of § 172.45(c) or exempt under § 172.45(d)) in a manner that creates an imminent threat of substantial harm to health or the environment is prohibited, and is considered a violation of section 12(a)(2)(S) of the Act.

(b) *EPA response to violations.* Under section 14 of the Act, EPA may seek civil or criminal penalties for violations of the Act. Failure to comply with the regulations in this part could result in civil or criminal penalties. Moreover, under sections 14 and 16(c) of the Act, EPA may at any time take appropriate action against violators to prevent or otherwise restrain use of a microbial pesticide in small-scale testing if it is determined that:

(1) Such use would create an imminent threat of substantial harm to health or the environment that is prohibited under paragraph (a) of this section; or

(2) The terms or conditions on which approval of the testing was granted under this subpart C are violated.

PART 173—PROCEDURES GOVERNING THE RESCISSION OF STATE PRIMARY ENFORCEMENT RESPONSIBILITY FOR PESTICIDE USE VIOLATIONS

Sec.

173.1 Applicability.
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173.4 Informal conference and settlement.
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173.9 Judicial review.

AUTHORITY: 7 U.S.C. 136w and 136w-2.

SOURCE: 46 FR 26059, May 11, 1981, unless otherwise noted.

§ 173.1 Applicability.

These procedures govern any proceeding to rescind a State's primary enforcement responsibility for pesticide use violations conducted under section 27(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. 136 *et seq.*

§ 173.2 Definitions.

For purposes of this part:

(a) *Administrator* means the Administrator of the United States Environmental Protection Agency or his delegate.

(b) *Notice of intent to rescind* means a notice to a State issued under § 173.3 which initiates a proceeding to rescind the State's primary enforcement responsibility for pesticide use violations.

(c) *State* means the agency or agencies primarily responsible for enforcing pesticide use laws or regulations within the State or jurisdiction undergoing rescission proceedings.

(d) *Party to the proceeding* shall mean the State or the Agency's Office of Enforcement.

(e) *Presiding Officer* means an attorney appointed by the Administrator to conduct the rescission proceeding. The Presiding Officer shall be an employee or representative of the Agency and shall not have had prior direct connection with the specific proceeding except in circumstances where subsequent hearings are in order.

§ 173.3 Initiation of rescission proceedings.

(a) Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out such responsibility, or cannot carry out such responsibility due to the lack of adequate legal authority, the Administrator shall notify the State in writing of his intent to rescind its primary enforcement responsibility, in whole or in part, by serving upon the State a notice of intent to rescind.

(b) The notice of intent to rescind shall:

(1) Specify those aspects of the State's pesticide use enforcement program determined to be inadequate;

(2) Specify the facts which underlie the findings contained in the rescission notice;

(3) Have attached thereto copies of any relevant documents discoverable under the Federal Rules of Civil Procedure and the Freedom of Information Act which contain data relied upon by the Administrator in making his decision to issue the notice;

(4) Have attached thereto a copy of this part; and

(5) Be sent to the State by certified mail, return receipt requested.

(c) The State may respond in writing to the findings specified in the notice of intent to rescind.

§ 173.4 Informal conference and settlement.

(a) After receipt of a notice of intent to rescind, the State may request that an informal conference be held between appropriate State and EPA officials to discuss the findings made in the notice of intent to rescind. The informal conference shall then be held in the State. If the Administrator finds, on the basis of information submitted by the State at the conference, that the deficiencies specified in the notice did not exist or were corrected by the State, the Administrator shall issue an order withdrawing the notice of intent to rescind and terminating the rescission proceeding.

(b) At any time after receipt of a notice of intent to rescind and before the issuance of a final order, the State and EPA may resolve the issues raised in the notice by agreement. Any settlement agreement shall be in writing and signed by the parties and shall:

(1) Detail the deficiencies found in the State program;

(2) Specify the steps the State has taken or will take to remedy the deficiencies; and

(3) Set forth a precise schedule for each remedial action yet to be initiated.

(c) If a written agreement is signed by the parties, the Administrator shall issue an order withdrawing the notice of intent to rescind and terminating the rescission proceeding. If the State

does not comply with the terms of the settlement agreement, the Administrator may reissue the notice of intent to rescind.

§ 173.5 Request for hearing.

A State may request a hearing before a Presiding Officer not later than sixty (60) days after receipt of a notice of intent to rescind.

§ 173.6 Publication of the notice; scheduling the hearing.

(a) If the Administrator has not issued an order terminating the rescission proceeding within sixty (60) days after service of the notice of intent to rescind upon the State, the Administrator shall publish the notice of intent to rescind in the FEDERAL REGISTER. The Administrator may modify the original notice of intent to rescind before its publication by deleting those deficiencies listed in the original notice which have been corrected or which were shown not to have existed. The public may submit comments upon the matters specified in the published notice of intent to rescind within the time specified therein.

(b) Concurrently with the publication of the notice of intent to rescind, the Administrator shall schedule a hearing in the State if one has been requested by the State. The date, time, and location of the hearing shall be published in the FEDERAL REGISTER along with the notice of intent to rescind.

(c) If a hearing is requested and the Administrator has not issued an order terminating the rescission proceeding, the Administrator shall provide for a hearing as scheduled. Representatives of the State, EPA, and the public may present evidence at the hearing. The Administrator shall appoint a Presiding Officer who shall preside over the hearing and make a recommended decision regarding the adequacy of the State's pesticide use enforcement program. The Administrator, after consultation with the State, may prescribe additional procedures governing the conduct of the hearing.

(d) If a termination order is issued or the hearing is rescheduled after the notice of intent to rescind is published in the FEDERAL REGISTER, such order or notice rescheduling the hearing shall also be published in the FEDERAL REGISTER.

§ 173.7 Hearing and recommended decision.

(a) The Presiding Officer shall:

(1) Conduct a fair and impartial hearing, without unnecessary delay;

(2) Ensure that the facts are fully elicited; and

(3) Consider all evidence, comment, and argument which is submitted by persons who will be affected by the outcome of the proceeding and which is not irrelevant, immaterial, unduly repetitious, or otherwise unreliable or of little probative value. The Presiding Officer may require any prospective witness to make available, in advance of the hearing, a brief summary of his or her testimony.

(b) If, following the close of the hearing, the Presiding Officer finds that the State has corrected, or has agreed in writing to correct, the deficiencies specified in the notice of intent to rescind or has shown that such deficiencies do not exist, the Presiding Officer shall issue a decision recommending that the notice of intent to rescind be withdrawn and that the rescission proceeding be terminated.

(c) If, following the close of the hearing, the Presiding Officer finds that the State has not corrected the deficiencies in its program, the Presiding Officer shall issue a decision recommending that the State's primary enforcement responsibility for pesticide use violations be rescinded in whole or in part.

(d) The recommended decision of the Presiding Officer shall become final Agency action forty-five (45) days after its service upon the parties and without further proceedings unless (1) an appeal to the Administrator is taken from it by a party to the proceeding, or (2) the Administrator elects, sua sponte, to review the recommended decision.

§ 173.8 Final order.

(a) If the State does not request a hearing within the sixty-day time period and the Administrator has not issued an order withdrawing the notice of intent to rescind, the Administrator shall issue a final order as soon as

practicable after the time for public comment on the notice of intent to rescind has elapsed. The final order shall either withdraw the notice of intent to rescind and terminate the proceeding or rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(b) If a hearing has been held and the Presiding Officer has made a recommended decision, then either the Office of Enforcement or the State may appeal the recommended decision to the Administrator or the Administrator may elect to review the recommended decision on his own initiative.

(c) After an appeal or sua sponte review the Administrator shall issue a final order terminating the rescission proceeding or rescinding, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(d) In no event may the Administrator issue his final decision sooner than ninety (90) days after service of the notice of intent to rescind on a State.

(e) Any final order, or a recommended decision which becomes a final order under § 173.7(c), shall be published in the FEDERAL REGISTER.

§ 173.9 Judicial review.

The State may appeal an order rescinding, in whole or in part, its primary enforcement responsibility for pesticide use violations to the appropriate federal court pursuant to section 16 of FIFRA.

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

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174.505 Bacillus thuringiensis modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.
174.506 Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.
174.507 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.
174.508 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.
174.509 Bacillus thuringiensis Cry3A protein; exemption from the requirement of a tolerance.
174.510 Bacillus thuringiensis Cry1Ac protein in all plants; exemption from the requirement of a tolerance.
174.511 Bacillus thuringiensis Cry1Ab protein in all plants; exemption from the requirement of a tolerance.

174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.
174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.
174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus; exemption from the requirement for a tolerance.
174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.
174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.
174.517 Bacillus thuringiensis Cry9C protein in corn; exemption from the requirement of a tolerance.
174.518 Bacillus thuringiensis Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.
174.519 Bacillus thuringiensis Cry2Ab2 protein in corn and cotton; exemption from the requirement of a tolerance.
174.520 Bacillus thuringiensis Cry1F protein in corn; exemption from the requirement of a tolerance.
174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.
174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.
174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.
174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.
174.525 E. coli B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.
174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.
174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.
174.529 Bacillus thuringiensis modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 in cotton; exemption from the requirement of a tolerance.
174.530 Bacillus thuringiensis Cry2Ae protein in cotton; temporary exemption from the requirement of a tolerance.

Subpart X—List of Approved Inert Ingredients

174.700 Scope and purpose.
174.705 Inert ingredients from sexually compatible plant.

Subparts Y–Z [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

SOURCE: 66 FR 37814, July 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 174.1 Scope and purpose.

The characteristics of plant-incorporated protectants such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment distinguish them from traditional chemical pesticides. Therefore, plant-incorporated protectants are subject to some different regulatory requirements and procedures than traditional chemical pesticides. This part sets forth regulatory requirements, criteria, and procedures applicable to plant-incorporated protectants under FIFRA and FFDCA. When applied to plant-incorporated protectants, the definitions and regulations in this part supersede the regulations found in parts 150 through 180 of this chapter to the extent that the regulations conflict. Unless otherwise superseded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.

§ 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following terms have the meaning set forth in this section.

Active ingredient means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance.

Administrator means the Administrator of the United States Environmental Protection Agency or his/her delegate.

Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant

resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

Cell fusion means the fusion *in vitro* of two or more cells or protoplasts.

Conventional breeding of plants means the creation of progeny through either: The union of gametes, *i.e.*, syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

EPA means the United States Environmental Protection Agency.

Exudate means a substance gradually discharged or secreted across intact cellular membranes or cell walls and present in the intercellular spaces or on the exterior surfaces of the plant.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*).

Food includes articles used for food or drink by humans or other animals.

Food plant means a plant which either in part or *in toto*, is used as food.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance; and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

Genome means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

In a living plant means inside the living plant, on the surface of the living plant, or as an exudate from the living plant.

Inert ingredient, means any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Nucleic acids means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil; polymers of the deoxyribose-5′-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3′-5′ phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5′-monophosphates of uracil, cytosine, guanine, and adenine linked by successive 3′-5′ phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.

Pesticidal substance, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose, during any part of a plant's life cyle (e.g., in the embryo, seed, seedling, mature plant).

Plant, for plant-incorporated protectants, means an organism classified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. This includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Produce thereof, when used with respect to plants containing plant- incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains, and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not ''produce thereof'' when the residues are not intended to serve a pesticidal purpose in the produce.

Recipient plant means the living plant in which the plant-incorporated protectant is intended to be produced and used.

Recombinant DNA means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

Sexually compatible, when referring to plants, means a viable zygote is formed only through the union of two gametes through conventional breeding.

Source means the donor of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance.

Vegetative reproduction means either:

(1) In seed plants, reproduction by apomixis, or

(2) In other plants, reproduction by fragmentation, or division of the somatic body.

Wide crosses means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

§ 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, the submitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in §2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.

Subpart B—Exemptions

§ 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of

FIFRA, other than the requirements of § 174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of the sections in §§ 174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in a crop used as food, the residues of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) as codified at §§ 174.507 through 174.508, or no tolerance would otherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at § 174.705. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

[66 FR 37814, July 19, 2001, as amended at 72 FR 20434, Apr. 25, 2007]

§ 174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

§ 174.71 Submission of information regarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under supart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans or other nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where the incident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[66 FR 37814, July 19, 2001, as amended at 71 FR 35546, June 21, 2006]

Subparts E–F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I [Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L–T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V [Reserved]

Subpart W—Tolerances and Tolerance Exemptions

§ 174.500 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerance for residues of plant-incorporated protectants in or on food commodities.

[72 FR 20434, Apr. 25, 2007]

§ 174.501 Bacillus thuringiensis Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa proteins in or on corn or cotton are exempt from the requirement of a tolerance when used as plant–incorporated protectants in or on the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[73 FR 45624, Aug. 6, 2008]

§ 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.

(a) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of corn; corn, field, flour; corn, field, forage; corn, field, grain; corn, field, grits; corn, field, meal; corn, field, refined oil; corn, field, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husk removed; corn, sweet, stover; corn, pop, grain and corn, pop, stover are exempt from the requirement of a tolerance when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed corn commodities.

(b) A time-limited exemption from the requirement of a tolerance is established for residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of cotton; cotton, forage; cotton, gin byproducts; cotton, hay; cotton, hulls; cotton, meal; cotton, refined oil; and cotton, undelinted seed when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed cotton commodities. The exemption from the requirement of a tolerance expires and is revoked on November 22, 2010.

[74 FR 23639, May 20, 2009]

§ 174.504 Bacillus thuringiensis Cry1F protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in food and feed commodities of cotton.

[72 FR 20434, Apr. 25, 2007]

§ 174.505 Bacillus thuringiensis modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]

§ 174.506 Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins in corn are exempted from the requirement of a tolerance when used as plant-incorporated protectants in the food and

feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]

§ 174.507 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.

Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

[66 FR 37830, July 19, 2001. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.508 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37854, July 19, 2001. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.509 Bacillus thuringiensis Cry3A protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3A protein are exempted from the requirement of a tolerance when used as a plant-incorporated protectant in potatoes.

[72 FR 20435, Apr. 25, 2007]

§ 174.510 Bacillus thuringiensis Cry1Ac protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ac protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.511 Bacillus thuringiensis Cry1Ab protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ab protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.

Residues of Coat Protein of Potato Virus Y are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant-incorporated protectant Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus; exemption from the requirement for a tolerance.

Residues of Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Papaya Ringspot Virus are exempt from the requirement of a tolerance when used as

a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Cucumber Mosaic Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.517 Bacillus thuringiensis Cry9C protein in corn; exemption from the requirement of a tolerance.

The plant-incorporated protectant *Bacillus thuringiensis* Cry9C protein in corn is exempted from the requirement of a tolerance for residues, only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

[72 FR 20435, Apr. 25, 2007]

§ 174.518 Bacillus thuringiensis Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3Bb1 protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20435, Apr. 25, 2007]

§ 174.519 Bacillus thuringiensis Cry2Ab2 protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ab2 protein in or on corn or cotton are exempt from the requirement of a tolerance when used as a plant–incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts.

[73 FR 37850, July 2, 2008]

§ 174.520 Bacillus thuringiensis Cry1F protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20435, Apr. 25, 2007]

§ 174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.

Residues of the neomycin phosphotransferase II (NPTII) enzyme are exempted from the requirement of a tolerance in all food commodities when used as a plant-incorporated protectant inert ingredient.

[72 FR 20435, Apr. 25, 2007]

§ 174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.

Residues of the Phosphinothricin Acetyltransferase (PAT) enzyme are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.

Residues of the CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase enzyme in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.

Residues of the Glyphosate Oxidoreductase GOX or GOXv247 enzyme in all plants are exempt from the requirement of a tolerance when used

as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.525 E. coli B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.

Residues of *E. coli* B-D-glucuronidase enzyme are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.

Residues of the Hygromycin B phosphotransferase (APH4) enzyme in all plants are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in cotton.

[72 FR 20435, Apr. 25, 2007]

§ 174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.

Residues of the phosphomannose isomerase (PMI) enzyme in plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.529 Bacillus thuringiensis modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[73 FR 40764, July 16, 2008]

§ 174.530 Bacillus thuringiensis Cry2Ae protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ae protein in or on the food commodities of cotton, cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts are exempt temporarily from the requirement of a tolerance when *Bacillus thuringiensis* Cry2Ae protein in cotton plants is used as a Plant-Incorporated Protectant in accordance with the terms of Experimental Use Permit 264–EUP–143. This temporary exemption from the requirement of a tolerance will expire on December 31, 2012.

[73 FR 52594, Sept. 10, 2008]

Subpart X—List of Approved Inert Ingredients

§ 174.700 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA and FFDCA section 408 requirements and may be used in a plant-incorporated protectant listed in subpart B of this part.

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

§ 174.705 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:

(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

Subparts Y–Z [Reserved]

PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

Sec.
176.1 Scope and applicability.
176.3 Definitions.
176.5 Establishment of a time-limited tolerance or exemption.
176.7 Information needed to establish a tolerance.
176.9 Publication of a tolerance.
176.11 Duration of a tolerance.
176.13 Modification of a time-limited tolerance.
176.15 Effect of a tolerance.

AUTHORITY: 21 U.S.C. 346a and 371.

SOURCE: 65 FR 64131, Oct. 25, 2000, unless otherwise noted.

§ 176.1 Scope and applicability.

This part describes the procedures and criteria under which EPA will establish time-limited tolerances and exemptions from the requirement of a tolerance for pesticide chemical residues associated with use of pesticides under emergency or crisis exemptions under FIFRA section 18. This part applies only to tolerances issued on the initiative of EPA as the result of the issuance of an emergency exemption or the declaration of a crisis exemption. This part does not cover time-limited tolerances in any other circumstances.

§ 176.3 Definitions.

The terms have the same meaning as in the Federal Insecticide, Fungicide, and Rodenticide Act section 2, and in the Federal Food, Drug, and Cosmetic Act section 201 and § 166.3 of this chapter. In addition, the following terms are defined for the purposes of this part.

Agency means the U.S. Environmental Protection Agency.

Applicant means any entity authorized under section 18 of FIFRA to request an emergency exemption that requests such an exemption under § 166.20 of this chapter, or issues a crisis exemption under § 166.40 of this chapter.

Crisis exemption means an exemption authorized under FIFRA section 18, in accordance with §§ 166.40 through 166.53 of this chapter.

Emergency exemption means a specific, quarantine, or public health exemption authorized under FIFRA section 18 and the regulations at §§ 166.20 through 166.35 of this chapter.

EPA means the U.S. Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C 136 *et seq.*).

Tolerance means the maximum amount of a pesticide chemical residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.

Tolerance exemption means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C 346a(c), that no tolerance is needed for a given pesticide chemical residue in or on a particular food commodity. For purposes of this part, the term ''tolerance'' shall include an exemption from the requirement of a tolerance.

§ 176.5 Establishment of a time-limited tolerance or exemption.

EPA will establish a time-limited tolerance for pesticide chemical residues in or on raw or processed food or feed resulting from the use of a pesticide chemical, if EPA authorizes an emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant acting under authority of FIFRA section 18 either has requested an emergency exemption, has stated its intention to issue a crisis exemption, or has issued a crisis exemption for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

§ 176.7 Information needed to establish a tolerance.

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into

account the limited duration and emergency nature of a section 18 application, and based on the available data the Agency cannot conclude that there is a reasonable certainty that no harm will result from the use proposed by the applicant or granted pursuant to a crisis exemption, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

§ 176.9 Publication of a tolerance.

(a) If EPA issues an emergency exemption or crisis exemption under FIFRA section 18, and EPA concludes that the tolerance for residues resulting from use of the pesticide under the exemption will be safe, then EPA will establish the tolerance by publishing an amendment to 40 CFR part 180 in the FEDERAL REGISTER.

(b) A tolerance under this part may be established without prior publication of a proposed tolerance or comment period.

§ 176.11 Duration of a tolerance.

(a) Tolerances issued under this part will become effective upon publication in the FEDERAL REGISTER, unless otherwise specified by the Administrator.

(b) Unless extended, tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the final rule published in FEDERAL REGISTER.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

§ 176.13 Modification of a time-limited tolerance.

If additional emergency or crisis exemptions are authorized that would extend use beyond the date originally authorized, or if EPA determines that the duration of a time-limited tolerance is insufficient to allow treated commodities to clear the channels of trade, EPA may modify the time-limited tolerance by publication of a final rule in the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

Subpart A—General Provisions

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178.20 Right to submit objections and requests for a hearing.
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178.30 Response by Administrator to objections and to requests for hearing.
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Subpart C [Reserved]

Subpart D—Judicial Review

178.65 Judicial review.
178.70 Administrative record.

AUTHORITY: 21 U.S.C. 346a, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 178.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart B—Procedures for Filing Objections and Requests for Hearing

§ 178.20 Right to submit objections and requests for a hearing.

(a) On or before the 60th day after the date of publication in the FEDERAL REGISTER of an order under part 180 of this chapter establishing, modifying, or revoking a regulation, or denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an evidentiary hearing on such objection in accordance with § 178.27

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 178.25 Form and manner of submission of objections.

(a) To be considered by the Administrator, an objection must:

(1) Be in writing.

(2) Specify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought.

(3) Be signed by the objector.

(4) State the objector's name and mailing address.

(5) Be accompanied by the fee prescribed by § 180.33(i) of this chapter, if the objection is to an order or regulation issued under part 180 of this chapter.

(6) Be submitted to the hearing clerk.

(7) Be received by the Hearing Clerk not later than the close of business of the 60th day following the date of the publication in the FEDERAL REGISTER of the order to which the objection is taken (or, if such 60th day is a Saturday, Sunday, or Federal holiday, not later than the close of business of the next government business day after such 60th day).

(b) Submissions to the hearing clerk shall be made as follows:

(1) Mailed submissions should be addressed to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(2) For hand/courier delivery the Office of the Hearing Clerk is located at Suite 350, 1099 14th St., NW., Washington, DC 20005.

[55 FR 50291, Dec. 5, 1990, as amended at 69 FR 39864, July 1, 2004; 70 FR 33359, June 8, 2005; 71 FR 35546, June 21, 2006]

§ 178.27 Form and manner of submission of request for evidentiary hearing.

To be considered by the Administrator, a request for an evidentiary hearing must meet the criteria in § 178.32, and must:

(a) Be submitted as a part of, and specifically request an evidentiary hearing on an objection that complies with the requirements of § 178.25.

(b) Include a statement of the factual issue(s) on which a hearing is requested and the requestor's contentions on each such issue.

(c) Include a copy of any report, article, survey, or other written document (or the pertinent pages thereof) upon which the objector relies to justify an

evidentiary hearing, unless the document is an EPA document that is routinely available to any member of the public.

(d) Include a summary of any evidence not described in paragraph (a)(3) of this section upon which the objector relies to justify an evidentiary hearing.

(e) Include a discussion of the relationship between the factual issues and the relief requested by the objection.

§ 178.30 Response by Administrator to objections and to requests for hearing.

The Administrator will respond to objections, and to requests for a hearing on such objections, as set forth in this section.

(a) *Denial of objections that are improperly submitted or that seek an unavailable form of relief.* The Administrator will by order issued under § 178.37 deny each objection and each request for a hearing that is included with such an objection, if:

(1) The objection is found not to conform to § 178.25.

(2) The action requested by the objection is inconsistent with any provision of FFDCA.

(3) The action requested by the objection is inconsistent with any generic, e.g., non-chemical specific, interpretation of a provision of FFDCA in any regulation in this chapter (the proper procedure in such a case is for the person to petition for an amendment of the regulation involved).

(b) *Denial of improperly submitted requests for hearing.* The Administrator will then determine whether any objection that has not been denied under paragraph (a) of this section was accompanied by a request for an evidentiary hearing that conforms to § 178.27. The Administrator will deny under § 178.37 each request that does not conform to § 178.27.

(c) *Grouping of certain related objections.* If the Administrator then finds (1) That two or more undenied objections are substantially similar, or are related in such a way that any judicial review of the Administrator's action on those objections should occur at the same time, and (2) that one or more of those objections was accompanied by an undenied request for an evidentiary hearing on that objection, the Administrator will treat those objections as a group and will rule on them only after ruling under § 178.32 on the associated request for hearing.

(d) *Rulings on objections for which a request for hearing has been granted.* If the Administrator rules under § 178.32 that an evidentiary hearing should be held on an objection, the Administrator will resolve the issues raised by any other objection grouped with it under paragraph (c) of this section in conjunction with the evidentiary hearing upon which the hearing request was granted, unless the Administrator for good cause determines otherwise.

(e) *Rulings on objections for which no request for hearing was received, or for which each request for hearing was denied.* Except as provided in paragraphs (c) and (d) of this section, if no hearing was requested on an objection, or if each such request that was made is denied under the criteria of paragraphs (a) or (b) of this section or § 178.32(b), the Administrator will rule on the objection under § 178.37.

§ 178.32 Rulings on requests for hearing.

(a) In the case of each request for an evidentiary hearing that was not denied under § 178.30(a) or (b), the Administrator will determine whether such a hearing on one or more of the objections is justified, and will publish in the FEDERAL REGISTER the determination in an order issued under § 178.37 or a Notice of Hearing issued under § 179.20 of this chapter. If some requests for a hearing are denied and others pertaining to the same order or regulation are granted, the denial order and the hearing notice may be combined into a single document and shall be issued at the same time unless the Administrator for good cause determines otherwise.

(b) A request for an evidentiary hearing will be granted if the Administrator determines that the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by

the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(c) Where appropriate, the Administrator will make rulings on any issues raised by an objection which are necessary for resolution prior to determining whether a request for an evidentiary hearing should be granted.

§ 178.35 Modification or revocation of regulation or prior order.

(a) If the Administrator determines upon review of an objection or request for hearing that the regulation or prior order in question should be modified or revoked, the Administrator will publish an order setting forth any revision to the regulation or prior order that the Administrator has found to be warranted.

(b) The Administrator will provide an opportunity for objections and requests for hearing on such order to the extent required by law. Such objections to the modification or revocation of the regulation, and requests for a hearing on such objections, may be submitted under §§ 178.20 through 178.27.

(c) Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in accordance with this part.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 178.37 Order responding to objections on which a hearing was not requested or was denied.

(a) The Administrator will publish in the FEDERAL REGISTER an order under FFDCA section 408(g)(2)(B) or section 408(g)(2)(C) setting forth the Administrator's determination on each denial of a request for a hearing, and on each objection submitted under § 178.20 on which:

(1) A hearing was not requested.

(2) A hearing was requested, but denied.

(b) Each order published under paragraph (a) of this section must state the reasons for the Administrator's determination. If the order denies a request for a hearing on the objection, the order also must state the reason for that denial (e.g., why the request for a hearing did not conform to § 178.27, or why the request was denied under § 178.32).

(c) Each order published under paragraph (a) of this section must state its effective date.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

Subpart C [Reserved]

Subpart D—Judicial Review

§ 178.65 Judicial review.

An order issued under § 178.37 is final agency action reviewable in the courts as provided by FFDCA section 408(h), as of the date of publication of the order in the FEDERAL REGISTER. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

[70 FR 33359, June 8, 2005]

§ 178.70 Administrative record.

(a) For purposes of judicial review, the record of an administrative proceeding that culminates in an order under § 178.37 consists of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under §180.7(g) of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(3) Any order issued under §180.29(f) of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(4) Any comments submitted by members of the public in response to the Notice of Filing or Notice of Proposed Rulemaking, any data or information submitted as part of the comments, the Administrator's response to comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(5) All other documents or information submitted to the docket for the rulemaking in question.

(6) The order issued under §178.37.

(b) The record will be closed as of the date of the Administrator's decision unless another date for closing of the record is specified in the order issued under §178.37.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

PART 179—FORMAL EVIDENTIARY PUBLIC HEARING

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AUTHORITY: 21 U.S.C. 346a, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50293, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§179.3 Definitions.

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator has delegated the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of OPPTS to whom the Assistant Administrator has delegated the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136–136y.

Judicial Officer means a person who has been designated by the Administrator under § 179.117 to serve as a judicial officer.

Office of the Administrator means the Agency's Administrator and Deputy Administrator and their immediate staff, including the judicial officer.

OPPTS means the Agency's Office of Prevention, Pesticides and Toxic Substances.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

§ 179.5 Other authority.

Questions regarding procedural matters arising under this part or part 178 of this chapter that are not addressed by this part or part 178 of this chapter shall be resolved by the Administrator or presiding officer, as appropriate.

Subpart B—Initiation of Hearing

§ 179.20 Notice of hearing.

(a) If the Administrator determines under § 178.32 of this chapter that a hearing is justified on any issue, the Administrator will file with the hearing clerk and publish in the FEDERAL REGISTER a Notice of Hearing. The Notice of Hearing will set forth:

(1) The docket number for the hearing.

(2) Each order, regulation, or petition denial that is the subject of the hearing, and a statement specifying any part of any such regulation or order that has been stayed in the Administrator's discretion.

(3) The identity of each person whose request for a hearing has been granted, and of any other person whose petition under § 180.7 of this chapter occasioned the order that the hearing concerns.

(4) A statement of the issues of fact on which a hearing has been found to be justified.

(5) A statement of the objections whose resolution depends on the resolution of those issues of fact.

(6) A statement that the presiding officer will be designated by the Chief Administrative Law Judge.

(7) The time within which notices of participation should be filed under § 179.42.

(8) The date, time, and place of the preliminary conference, or a statement that the date, time, and place will be announced in a later notice, and the place of the hearing.

(9) The time within which parties must submit written information and views under § 179.83.

(10) Designations with respect to separation of functions published under § 179.24(b)(2).

(b) The statement of the issues of fact on which a hearing has been justified determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A party may obtain interlocutory review by the Administrator of a decision by the presiding officer to revise the issues to include an issue on which the Administrator has not granted a request for a hearing or to eliminate an issue on which a request for a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the Notice of Hearing.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 179.24 Ex parte discussions; separation of functions.

(a) Any person may meet or correspond with any officer or employee of the Agency concerning a matter under parts 178 or 180 of this chapter prior to publication of a Notice of Hearing under § 179.20.

(b) Upon publication of a Notice of Hearing, the following separation of function rules apply:

(1) OPPTS, as a party to the hearing, is responsible for presentation of its position at the hearing and in any pleading or oral argument before the Administrator. The Pesticides and

Toxic Substances Division of the Office of General Counsel shall advise and represent OPPTS with respect to the hearing and in any pleading or oral argument before the Administrator. An employee or other representatives of OPPTS may not participate in or advise the Administrator or any of his representatives on any decision under this part, other than as witness or counsel in public proceedings, except as provided by paragraph (b)(2) of this section. There is to be no other communication between representatives of OPPTS and the presiding officer or any representative of the Office of the Administrator concerning the merits of the hearing until after issuance of the decision of the Administrator.

(2) The Administrator may designate persons who otherwise would be regarded as representatives of OPPTS, to serve as representatives of the Office of the Administrator on matters pertaining to the hearing, and may also designate persons who otherwise would be regarded as representatives of the Office of the Administrator to serve as representatives of OPPTS. Such designations will be included in the Notice of Hearing published under § 179.20.

(3) The Office of the Administrator is responsible for the final decision of the matter, with the advice and participation of anyone in the Agency other than representatives of OPPTS.

(c) Between the date of publication of the Notice of Hearing and the date of the Administrator's final decision on the matter, communication concerning the matter involved in the hearing will be restricted as follows:

(1) No person outside the Agency may have an ex parte communication with the presiding officer or any representative of the Office of the Administrator concerning the merits of the hearing. Neither the presiding officer nor any representative of the Office of the Administrator may have any ex parte communication with a person outside the Agency concerning the merits of the hearing.

(2) A written communication contrary to this section must be immediately served on all other participants and filed with the hearing clerk by the presiding officer at the hearing, or by the Administrator, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other parties and filed with the hearing clerk. A person, including a representative of a party in the hearing, who is involved in an oral communication contrary to this section, must, to the extent necessary to determine the substance of the communication, be made available for cross-examination during the hearing with respect to the substance of that communication. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted.

(d) The prohibitions specified in paragraph (c) of this section also apply to a person who, in advance of the publication of a Notice of Hearing, knows that the notice has been signed. The prohibitions become applicable to such a person as of the time the knowledge is acquired.

(e) The making of a communication contrary to this section may, consistent with the interests of justice and the policies underlying the FFDCA, result in a decision adverse to the person knowingly making or causing the making of the communication.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992; 70 FR 33359, June 8, 2005]

Subpart C—Participation and Appearance; Conduct

§ 179.42 Notice of participation.

(a) OPPTS shall be a party to a hearing under this part. Any other person may participate as a party in such a hearing to the extent specified by this section.

(b) A person desiring to participate in a hearing must file with the hearing clerk within 30 days after publication of the Notice of Hearing under § 179.20, a Notice of Participation in the following form:

NOTICE OF PARTICIPATION

Docket No. _____

Under 40 CFR part 179, please enter the participation of: _____

(Name) _____

(Street address) _____

(City and State) _____
(Telephone number) _____
Service on the above will be accepted by: _____
(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____
Signed: _____
Date: _____

(c) An amendment to a Notice of Participation must be filed with the hearing clerk and served on all parties.

(d) No person may participate in a hearing who has not filed a written Notice of Participation or whose participation has been stricken under paragraph (f) of this section.

(e) The presiding officer may permit the late filing of a Notice of Participation upon a showing of good cause. Arrangements and agreements previously made in the proceeding shall apply to any party admitted late.

(f) The presiding officer may strike the participation of a person for failure to comply with any requirement of this subpart. Any person whose participation is striken may obtain interlocutory review thereof by the Administrator.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

§ 179.45 Appearance.

(a) A party to a hearing may appear in person or by counsel or other representative in the hearing.

(b) The presiding officer may strike a person's right to appear in the hearing for violation of the rules of conduct in § 179.50.

§ 179.50 Conduct at oral hearings or conferences.

The parties and their representatives must conduct themselves with dignity and observe the same standards of practice and ethics that would be required of parties in a judicial proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing constitute grounds for immediate exclusion from the proceeding by the presiding officer.

Subpart D—Presiding Officer

§ 179.60 Designation and qualifications of presiding officer.

The presiding officer in a hearing will be an administrative law judge qualified under 5 U.S.C. 3105 and designated by the Agency's chief administrative law judge.

§ 179.70 Authority of presiding officer.

The presiding officer shall conduct the hearing in a fair and impartial manner subject to the precepts of the Administrative Procedure Act. The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to:

(a) Specify and change the date, time, and place for conferences, and issue and modify a schedule for the hearing.

(b) Establish an orderly manner for developing evidentiary facts at preliminary conferences under § 179.87, for making rulings on oral testimony and cross-examination under § 179.93, and for making other similar evidentiary rulings in accord with these regulations.

(c) Prepare statements of the areas of factual disagreement among the participants.

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing.

(e) Administer oaths and affirmations.

(f) Control the course of the hearing and the conduct of the participants.

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions.

(h) Rule on, admit, exclude, or limit evidence.

(i) Set the time for filing pleadings.

(j) Rule on motions and other procedural matters.

(k) Rule on motions for summary decision under § 179.90.

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex.

(m) Strike the participation of any person under § 179.42(f), or exclude any person from the hearing under § 179.50,

or take other reasonable disciplinary action.

(n) Take any other action for the fair, expeditious, and orderly conduct of the hearing that is not in conflict with law or these rules.

§ 179.75 Disqualification of deciding officials.

(a) A deciding official in a hearing under this part (including, e.g., the Administrator, judicial officer, or presiding officer) shall not decide any matter in connection with which he or she has a financial interest in any of the parties, or a relationship that would make it otherwise inappropriate for him or her to act.

(b) A party may request that a deciding official disqualify himself/herself and withdraw from the proceeding. The party may obtain interlocutory review by the Administrator of a denial of such a request made to any deciding official other than the Administrator.

(c) A deciding official who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 179.78 Unavailability of presiding officer.

If the presiding officer is unable to act for any reason, his or her powers with respect to the hearing will be assigned by the Chief Administrative Law Judge to another presiding officer. The substitution will not affect the hearing, *i.e.*, the testimony of the witnesses will not be taken anew except as the new presiding officer may order upon the request of a party where the credibility of a witness is of particular importance.

Subpart E—Hearing Procedures

§ 179.80 Filing and service.

(a) All documents required or authorized to be filed by a party to a hearing under this part regarding any matter to be decided by the presiding officer, the judicial officer, or the Administrator shall be filed in triplicate with the hearing clerk, in the manner specified by § 178.25(b) of this chapter. Each filing shall prominently note the docket number. To determine compliance with deadlines in a hearing, a document is considered filed on the date it is actually received by the hearing clerk. When this part allows a response by a party to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) Each notice, order, decision, or other document issued under this part by the presiding officer, the judicial officer, or the Administrator shall be filed with the hearing clerk. The hearing clerk shall immediately serve all parties with a copy of such order, decision, or other document.

(c) At the same time that a party files any document with the hearing clerk, the party shall serve a copy thereof on each other party, unless the presiding officer specifies otherwise. Each filing shall be accompanied by a certificate of service, or a statement that service is not required. Service on a party is accomplished by mailing a submission to the address shown in the Notice of Participation or by personal delivery.

(d) The presiding officer may grant an extension of time for the filing of any pleading, document, or motion (1) Upon timely motion by a party, for good cause shown, and after consideration of prejudice to other parties, or (2) upon the presiding officer's own motion.

(e) A motion by a party for an extension may only be made after serving a copy of the motion on all other parties, unless the movant can show good cause why doing so is impracticable. The motion shall be filed in advance of the date on which the pleading, document, or motion is due to be filed, unless the failure of the party to make a timely motion for an extension was the result of excusable neglect.

§ 179.81 Availability of documents.

(a) All orders, decisions, pleadings, transcripts, exhibits, and other docket entries shall become part of the official docket and shall be retained by the hearing clerk. Except as otherwise provided by paragraph (b) of this section or part 2 of this chapter, all documents that are a part of the official docket shall be made available to the public

for reasonable inspection during Agency business hours. Copies of such documents may be obtained by members of the public as provided in part 2 of this chapter.

(b) Whenever any information or data are required to be produced or examined in a hearing and any party makes a business confidentiality claim regarding such information under part 2 of this chapter, the availability of such information to the other parties or to the public shall be determined by EPA in accordance with part 2 of this chapter, including specifically the procedures and principles set forth in §2.30l(g)(3) and (g)(4) of this chapter. The presiding officer shall make the determinations with respect to the matters referred to in §2.301(g)(3) and (g)(4) to the extent provided, and shall take such steps as are necessary for the protection of information entitled to confidential treatment or otherwise exempt from public disclosure, including issuance of protective orders to parties or taking testimony in a closed hearing.

§ 179.83 Disclosure of data and information.

(a) Within 60 days of the publication of the Notice of Hearing under §179.20, or, if no party will be prejudiced, within another period set by the presiding officer, the Assistant Administrator shall file with the hearing clerk, in accordance with §179.80, the following documents numbered and organized in the manner prescribed by the presiding officer:

(1) The portions of the administrative record of the proceeding developed under part 178 of this chapter, and under part 180 of this chapter, that are relevant to the issues in the hearing.

(2) All documents in the files of OPPTS containing factual information or expert opinion, whether favorable or unfavorable to the position of OPPTS, which relate to the issues involved in the hearing. For purposes of this paragraph, ''files'' means the principal files in OPPTS in which documents relating to each of the issues in the hearing are ordinarily kept. Documents that are internal memoranda reflecting the deliberative process, or are attorney work product, or were prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information upon which OPPTS plans to rely upon in the hearing.

(4) A narrative position statement on the factual issues in the Notice of Hearing and the nature of the supporting evidence that OPPTS intends to introduce.

(5) A signed statement that, to the best knowledge and belief of the Assistant Administrator, the submission complies with this section.

(b) Within 70 days of the publication of the Notice of Hearing or, if no party will be prejudiced, within another period of time set by the presiding officer, each party other than OPPTS shall submit to the hearing clerk in accordance with §179.80 the following documents, numbered and organized in the manner prescribed by the presiding officer:

(1) Any objections that the administrative record filed under paragraph (a)(l) of this section is incomplete.

(2) All documents (other than those filed under paragraph (a) of this section) in the party's files containing factual information or expert opinion, whether favorable or unfavorable to the party's position, that relates to the issues involved in the hearing. For purposes of this paragraph, ''files'' means the party's principal files in which documents relating to each of the issues in the hearing are ordinarily kept. Documents that are attorney work product, or were prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information the party plans to rely upon in the hearing.

(4) A narrative position statement on the factual issues in the Notice of Hearing and the nature of the supporting evidence the party intends to introduce.

(5) A signed statement that, to the best knowledge and belief of the party, the submission complies with this section.

(c) Submissions required by paragraphs (a) and (b) of this section may

be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known by or available to the party when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

(d) If a party fails to comply substantially and in good faith with this section, the presiding officer may infer that such failure was for the purpose of withholding information that is unfavorable to the party's position, and may make such further adverse inferences and findings with respect to such failure as are warranted.

(e) Parties may reference each other's submissions. To reduce duplicative submissions, parties are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992; 70 FR 33359, June 8, 2005]

§ 179.85 Purpose of preliminary conference.

The presiding officer will conduct one or more preliminary conferences for the following purposes:

(a) To determine the areas of factual disagreement to be considered at the hearing.

(b) To establish any necessary procedural rules to control the course of the hearing and the schedule for the hearing.

(c) To group parties with substantially similar interests, for purposes of presenting evidence, making objections, cross-examination, and presenting oral argument.

(d) To obtain stipulations and admissions of facts.

(e) To take other action that may expedite the hearing.

§ 179.86 Time and place of preliminary conference.

A preliminary conference will commence at the date, time, and place announced in the Notice of Hearing, or as otherwise specified by the Administrator or presiding officer in a subsequent notice. The preliminary conference may not commence until after expiration of the time for filing notices of participation under § 179.42. The presiding officer may specify that two or more such conferences shall be held.

§ 179.87 Procedures for preliminary conference.

Parties in a hearing must appear at the preliminary conference(s) prepared to present a position on the matters specified in § 179.85. A preliminary conference may be held by telephone, or other electronic means, if appropriate.

(a) To expedite the hearing, parties are encouraged to prepare in advance for the conference. Parties should cooperate with each other and should request information and begin preparation of testimony at the earliest possible time. Failure of a party to appear at the preliminary conference or to raise matters that could reasonably be anticipated and resolved at that time will not delay the progress of the hearing, and constitutes a waiver of the rights of the party regarding such matters as objections to the agreements reached, actions taken, or rulings issued. Such failure to appear may also be grounds for striking the party's participation under § 179.42(f).

(b) Each party shall bring to the preliminary conference the following specific information, which will be filed with the hearing clerk under § 179.80:

(1) Any additional information to supplement the submission which may have been filed under § 179.83, and/or which may be filed if approved under § 179.83(c).

(2) A list setting forth each person who has been identified as a witness whose oral or written testimony will be offered by the party at the hearing, with a full curriculum vitae for each and a summary of the expected testimony (including a list of the principal exhibits on which the witness will rely) or a statement as to when such a summary will be furnished. A party may

amend its witness and document list to add, delete, or substitute witnesses or documents.

(c) The presiding officer may hold preliminary conferences off the record in an effort to reach agreement on disputed factual or procedural questions.

(d) The presiding officer shall issue and file under § 179.80 a written order reciting the actions taken at each preliminary conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 179.89 Motions.

A motion, unless made in the course of a preliminary conference or a transcribed oral hearing before the presiding officer, must be filed in the manner prescribed by § 179.80 and include a draft order. A response may be filed within 10 days of service of a motion. The moving party has no right to reply, except as permitted by the presiding officer. The presiding officer shall rule upon the motion.

§ 179.90 Summary decisions.

(a) After the hearing commences, a party may file a written motion, with or without supporting affidavits or brief, for a summary decision on any issue in the hearing. Any other party may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause shown, serve opposing affidavits or brief or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs if not submitted by the parties.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine disagreement as to any material fact bearing on the issue and that a party is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a party opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must demonstrate specifically that there is a genuine issue of material fact for the hearing.

(d) Should it appear from the affidavits of a party opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If a summary decision is not rendered upon all issues or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A party may obtain interlocutory review by the Administrator of a summary decision of the presiding officer.

§ 179.91 Burden of going forward; burden of persuasion.

(a) The party whose request for an evidentiary hearing was granted has the burden of going forward in the hearing with evidence as to the issues relevant to that request for a hearing.

(b) The party or parties who contend that a regulation satisfies the criteria of section 408 of the FFDCA has the burden of persuasion in the hearing on that issue, whether the proceeding concerns the establishment, modification, or revocation of a tolerance or exemption from the requirement for a tolerance.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 179.93 Testimony.

(a) The presiding officer will conduct such proceedings as are necessary for the taking of oral direct testimony and for the conduct of oral examination of witnesses by the parties. The presiding officer shall limit oral examination to prevent irrelevant, immaterial or unduly repetitious examination.

(b) Direct testimony shall be submitted in writing, except that the presiding officer may order direct testimony to be presented orally in those unusual cases where the memory or demeanor of the witness is of importance. Written direct testimony shall be in the form of a verified statement of fact or opinion prepared by the witness, in narrative form or in question-and-answer form. Written direct testimony may incorporate exhibits. Such a verified statement or exhibit may not be admitted into evidence sooner than 14 days (or such other reasonable period as the presiding officer may order) after the witness has delivered to the presiding officer and each party a copy of the statement or exhibit. The admissibility of the evidence contained in such a statement is subject to the same rules as if such testimony had been given orally.

(c) Oral cross-examination of witnesses will be permitted. Each exhibit that a party intends to rely upon in cross-examining a witness shall be furnished to the other parties not later than 3 days (or such other reasonable period as the presiding officer may order) before such exhibit is used in the cross-examination.

(d) Witnesses shall give testimony under oath or affirmation.

§ 179.94 Transcripts.

(a) The hearing clerk shall make arrangements to have all oral testimony stenographically reported or recorded and transcribed, with evidence that is admitted in the form of written testimony or exhibits attached or incorporated as appropriate.

(b) Unless the presiding officer orders otherwise, parties shall have 15 days from the date that the transcript of particular oral testimony first becomes available to propose corrections in the transcript of that testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

(c) As soon as practicable after the taking of the last evidence, the presiding officer shall certify:

(1) That the original transcript is a true transcript of the oral testimony offered or received at the hearing, except in such particulars as the presiding officer specifies.

(2) That the written testimony and exhibits accompanying the transcript are all the written testimony and exhibits introduced at the hearing, with such exceptions as the presiding officer specifies.

(3) The transcript with attached or incorporated material, as so certified by the presiding officer, shall be submitted to and filed by the hearing clerk under § 179.80.

(d) Copies of the transcript shall be available to the public in accordance with § 179.81; parties may make special arrangements through the hearing clerk to obtain copies on an ongoing, expedited basis.

§ 179.95 Admission or exclusion of evidence; objections; offers of proof.

(a) Written material identified as direct testimony or as an evidentiary exhibit and offered by a party in a hearing, and oral testimony, whether on direct or on cross-examination, is admissible as evidence unless the presiding officer excludes it (on objection of a party or on the presiding officer's own initiative) because it is irrelevant, immaterial, or unduly repetitive, or because its exclusion is necessary to enforce a specific requirement of this part relating to the admissibility of evidence.

(b) If a party objects to the admission or rejection of any evidence or to the limitation of the scope of any examination or cross-examination, the party shall state briefly the grounds for such objection. The transcript shall include any argument or debate thereon, unless the presiding officer, with the consent of all the parties, orders that such argument not be transcribed. The ruling and the reasons given therefor by the presiding officer on any objection shall be a part of the transcript. An automatic exception to that ruling will follow.

(c) Whenever evidence is deemed inadmissible, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof for excluded oral testimony shall consist of a brief statement describing the nature of the

evidence excluded. If the evidence consists of a document or exhibit, it shall be inserted in the record in total. If the Administrator in reviewing the record under § 179.112 decides that the presiding officer's ruling in excluding the evidence was erroneous and prejudicial, the hearing may be reopened to permit the taking of such evidence, or, where appropriate, the Administrator may evaluate the evidence and proceed to a final decision.

(d) Official notice may be taken of Agency proceedings, any matter that might be judicially noticed by the courts of the United States, or any other fact within the knowledge and experience of the Agency as an expert agency. Any party shall be given adequate opportunity to show that such facts are erroneously noticed by presenting evidence to the contrary.

§ 179.97 Conferences during hearing.

The presiding officer may schedule and hold conferences as needed to monitor the progress of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, or other matters concerning the development of the evidence.

§ 179.98 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

Subpart F—Decisions and Appeals

§ 179.101 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 179.20(b), 179.42(f), 179.75(b), and 179.90(f), rulings of the presiding officer may not be appealed to the Administrator before the Administrator's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Administrator if the presiding officer certifies on the record or by document submitted under § 179.80 that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any party or substantial harm to the public interest. When an order or ruling is not certified by the presiding officer, it shall be reviewed by the Administrator only upon appeal from the initial decision except when the Administrator determines upon the request of a party and in exceptional circumstances, that delaying review would be deleterious to vital public or private interests. Except in extraordinary circumstances, proceedings will not be stayed pending an interlocutory appeal. Where a stay is granted, a stay of more than 30 days must be approved by the Administrator.

(c) Ordinarily, the interlocutory appeal will be decided on the basis of the submission made to the presiding officer, but the Administrator may allow further briefs and oral arguments. Any oral argument will be transcribed and the transcript will be prepared and certified in the same manner as provided in § 179.94.

§ 179.105 Initial decision.

(a) After the filing of briefs and any oral argument, the presiding officer shall prepare and file an initial decision on the issues of fact in the hearing and the objections relating to those issues.

(b) The initial decision must be based on a fair evaluation of the entire record, and must contain:

(1)(i) A conclusion that no change is warranted in the order or regulation to which objection was taken; or

(ii) A conclusion that changes in the order or regulation are warranted, the language of the order or regulation as changed, and an effective date for the order or regulation as changed.

(2) Findings of fact supported by reliable, probative and substantial evidence that has been found admissible by the presiding officer, and adequate citations to the record supporting those findings.

(3) Conclusions on legal and policy issues, if such conclusions are necessary to resolve the objections.

(4) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any party.

(c) Except as otherwise provided by order of the Administrator filed in accordance with § 179.80, after the initial decision is filed, the presiding officer has no further jurisdiction over the matter and any motions or requests filed with the hearing clerk will be decided by the Administrator.

(d) The initial decision becomes the final decision of the Administrator by operation of law unless a party files exceptions with the hearing clerk under § 179.107 or the Administrator files a notice of review under § 179.110.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33360, June 8, 2005]

§ 179.107 Appeal from or review of initial decision.

(a) A party may appeal an initial decision to the Administrator by filing exceptions with the hearing clerk, and serving them on the other parties, within the period specified in the initial decision. The period may not exceed 30 days, unless extended by the Administrator under paragraph (d) of this section.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law or policy in the initial decision and, if errors in the findings of fact are alleged, must provide supporting citations to evidence of record. Oral argument before the Administrator may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within the timeperiod specified in the initial decision. The timeperiod may not exceed 30 days after the end of the period (including any extensions) for filing exceptions, unless extended by the Administrator under paragraph (d) of this section.

(d) The Administrator may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) If the Administrator decides to hear oral argument, the parties will be informed of the date, time, and place; the amount of time allotted to each party, and the issues to be addressed.

§ 179.110 Determination by Administrator to review initial decision.

Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Administrator may file with the hearing clerk, and serve on the parties, a notice of the Administrator's determination to review the initial decision. The Administrator may invite the parties to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

§ 179.112 Decision by Administrator on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Administrator shall have the same powers as did the presiding officer in making the initial decision. On the Administrator's own initiative or on motion, the Administrator may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal to, or on review by the Administrator is the same as the scope of the issues before the presiding officer, unless the Administrator specifies otherwise.

(c) After the filing of briefs and any oral argument, the Administrator will issue a final decision on the issues of fact in the hearing and the objections related to those issues. A final decision must contain the elements required for an initial decision by § 179.105(b).

(d) The Administrator may adopt the initial decision as the final decision.

(e) The Administrator's decision, or a summary of the decision and a notice of its availability, will be published in the FEDERAL REGISTER.

§ 179.115 Motion to reconsider a final order.

A party may file a motion requesting the Administrator to reconsider a final decision under this part. Any such motion must be filed within 10 days after service of the final decision, and must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such a motion shall not stay the effective date of the final decision unless specifically so ordered by the Administrator.

§ 179.117 Designation and powers of judicial officer.

(a) One or more judicial officers may be designated by the Administrator. A judicial officer shall be an attorney who is a permanent or temporary employee of the Agency or of another Federal agency. A judicial officer may perform other duties. A judicial officer who performs any duty under this part may not be employed by OPPTS, by the Pesticides and Toxic Substances Division of the Office of General Counsel, or by any other person who is a representative of OPPTS in the hearing. A person may not be designated as a judicial officer in a hearing if he or she performed any prosecutorial or investigative functions in connection with that hearing or any other factually related hearing.

(b) The Administrator may delegate to the judicial officer all or part of the Administrator's authority to act in a given proceeding under this part. Such a delegation does not prevent the judicial officer from referring any motion or case to the Administrator when appropriate.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart G—Judicial Review

§ 179.125 Judicial review.

(a) The Administrator's final decision is final agency action reviewable in the courts as provided by FFDCA section 408(h), as of the date of publication of the order in the FEDERAL REGISTER. The failure of a person to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

(b) The record for judicial review of a final decision under this part consists of the record described in § 179.130.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33360, June 8, 2005]

§ 179.130 Administrative record.

(a) For purposes of judicial review, the record of a hearing that culminates in a final decision of the Administrator under § 179.105(d) or § 179.112(c) ruling on an objection shall consist of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under § 180.7(g) of this chapter to which the objection related, and:

(i) The regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(3) Any order issued under § 180.29(f) of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(4) The comments submitted by members of the public in response to the Notice of Filing or Notice of Proposed Rulemaking, and the information submitted as part of the comments, the Administrator's response to comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(5) All other documents or information submitted to the docket for the rulemaking in question under parts 177 or part 180 of this chapter.

(6) The Notice of Hearing published under § 179.20.

(7) All notices of participation filed under § 179.42.

(8) Any FEDERAL REGISTER notice issued under this part that pertains to the proceeding.

(9) All submissions filed under § 179.80.

(10) Any document of which official notice was taken under § 179.95.

(b) The record of the administrative proceeding is closed:

(1) With respect to the taking of evidence, when specified by the presiding officer.

(2) With respect to pleadings, at the time specified in § 179.98(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence

at any time before the filing of the initial decision.

[55 FR 50293, Dec. 5, 1990, as amended at 70 FR 33360, June 8, 2005]

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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180.3 Tolerances for related pesticide chemicals.
180.4 Exceptions.
180.5 Zero tolerances.
180.6 Pesticide tolerances regarding milk, eggs, meat, and/or poultry; statement of policy.

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180.9 Substantive amendments to petitions.
180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.
180.30 Judicial review.
180.31 Temporary tolerances.
180.32 Procedure for modifying and revoking tolerances or exemptions from tolerances.
180.33 Fees.
180.34 Tests on the amount of residue remaining.
180.35 Tests for potentiation.
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180.103 Captan; tolerances for residues.
180.106 Diuron; tolerances for residues.
180.108 Acephate; tolerances for residues.
180.110 Maneb; tolerances for residues.
180.111 Malathion; tolerances for residues.
180.114 Ferbam; tolerances for residues.
180.116 Ziram; tolerances for residues.
180.117 S-Ethyl dipropylthiocarbamate; tolerances for residues.
180.121 Methyl parathion; tolerances for residues.
180.122 Parathion; tolerances for residues.
180.123 Inorganic bromide residues resulting from fumigation with methyl bromide; tolerances for residues.
180.123a Inorganic bromide residues in peanut hay and peanut hulls; statement of policy.
180.127 Piperonyl butoxide; tolerances for residues.
180.128 Pyrethrins; tolerances for residues.
180.129 o-Phenylphenol and its sodium salt; tolerances for residues.
180.130 Hydrogen Cyanide; tolerances for residues.
180.132 Thiram; tolerances for residues.
180.133 Lindane; tolerances for residues.
180.136 Basic copper carbonate; tolerance for residues.
180.142 2,4-D; tolerances for residues.
180.144 Cyhexatin; tolerances for residues.
180.145 Fluorine compounds; tolerances for residues.
180.149 Mineral oil; tolerances for residues.
180.151 Ethylene oxide; tolerances for residues.
180.153 Diazinon; tolerances for residues.
180.154 *O,O*-Dimethyl *S*-[(4-oxo-1,2,3-benzotriazin-3(4*H*)-yl)methyl]phosphorodithioate; tolerances for residues.
180.155 1-Naphthaleneacetic acid; tolerances for residues.
180.157 Methyl 3-[(dimethoxyphosphinyl) oxy]butenoate, alpha and beta isomers; tolerances for residues.
180.163 1,1-Bis(4-chlorophenyl)-2,2,2-trichloroethanol; tolerances for residues.
180.169 Carbaryl; tolerances for residues.
180.172 Dodine; tolerances for residues.
180.173 Ethion; tolerances for residues.
180.175 Maleic hydrazide; tolerances for residues.
180.176 Mancozeb; tolerances for residues.
180.178 Ethoxyquin; tolerances for residues.
180.180 Orthoarsenic acid; tolerance for residues.
180.181 Chlorpropham; tolerances for residues.
180.182 Endosulfan; tolerances for residues.
180.183 *O,O*-Diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate; tolerances for residues.
180.184 Linuron; tolerances for residues.
180.185 DCPA; tolerances for residues.
180.189 Coumaphos; tolerances for residues.
180.190 Diphenylamine; tolerances for residues.
180.191 Folpet; tolerances for residues.
180.198 Trichlorfon; tolerances for residues.
180.200 Dicloran; tolerances for residues.
180.202 *p*-Chlorophenoxyacetic acid; tolerances for residues.
180.204 Dimethoate; tolerances for residues.
180.205 Paraquat; tolerances for residues.
180.206 Phorate; tolerances for residues.
180.207 Trifluralin; tolerances for residues.
180.208 Benfluralin; tolerances for residues.
180.209 Terbacil; tolerances for residues.
180.210 Bromacil; tolerances for residues.
180.211 Propachlor; tolerances for residues.

180.212 *S*-Ethyl cyclohexylethylthiocarbamate; tolerances for residues.
180.213 Simazine; tolerances for residues.
180.214 Fenthion; tolerances for residues.
180.215 Naled; tolerances for residues.
180.217 Ammoniates for [ethylenebis-(dithiocarbamato)] zinc and ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides; tolerances for residues.
180.220 Atrazine; tolerances for residues.
180.221 *O*-Ethyl *S*-phenyl ethylphosphonodithioate; tolerances for residues.
180.222 Prometryn; tolerances for residues.
180.225 Phosphine; tolerances for residues.
180.226 Diquat; tolerances for residues.
180.227 Dicamba; tolerances for residues.
180.228 *S*-Ethyl hexahydro-1*H*-azepine-1-carbothioate; tolerances for residues.
180.229 Fluometuron; tolerances for residues.
180.231 Dichlobenil; tolerances for residues.
180.232 Butylate; tolerances for residues.
180.235 Dichlorvos; tolerances for residues.
180.236 Triphenyltin hydroxide; tolerances for residues.
180.239 Phosphamidon; tolerances for residues.
180.241 Bensulide; tolerances for residues.
180.242 Thiabendazole; tolerances for residues.
180.243 Propazine; tolerances for residues.
180.245 Streptomycin; tolerances for residues.
180.249 Alachlor; tolerances for residues.
180.252 Tetrachlorvinphos; tolerances for residues.
180.253 Methomyl; tolerances for residues.
180.254 Carbofuran; tolerances for residues.
180.257 Chloroneb; tolerances for residues.
180.258 Ametryn; tolerances for residues.
180.259 Propargite; tolerances for residues.
180.261 *N*-(Mercaptomethyl) phthalimide *S*-(*O*,*O*-dimethyl phosphorodithioate) and its oxygen analog; tolerances for residues.
180.262 Ethoprop; tolerances for residues.
180.263 Phosalone; tolerances for residues.
180.269 Aldicarb; tolerances for residues.
180.272 Tribuphos; tolerances for residues.
180.274 Propanil; tolerances for residues.
180.275 Chlorothalonil; tolerances for residues.
180.276 Formetanate hydrochloride; tolerances for residues.
180.278 Phenmedipham; tolerances for residues.
180.284 Zinc phosphide; tolerances for residues.
180.287 Amitraz; tolerances for residues.
180.288 2-(Thiocyanomethylthio) benzothiazole; tolerances for residues.
180.289 Methanearsonic acid; tolerances for residues.
180.291 Pentachloronitrobenzene; tolerance for residues.
180.292 Picloram; tolerances for residues.
180.293 Endothall; tolerances for residues.
180.294 Benomyl; tolerances for residues.
180.296 Dimethyl phosphate of 3-hydroxy-*N*-methyl-*cis*-crotonamide; tolerances for residues.
180.297 *N*-1-Naphthyl phthalamic acid; tolerances for residues.
180.298 Methidathion; tolerances for residues.
180.299 Dicrotophos; tolerances for residues.
180.300 Ethephon; tolerances for residues.
180.301 Carboxin; tolerances for residues.
180.303 Oxamyl; tolerances for residues.
180.304 Oryzalin; tolerances for residues.
180.309 α-Naphthaleneacetamide; tolerances for residues.
180.311 Cacodylic acid; tolerances for residues.
180.312 4-Aminopyridine; tolerances for residues.
180.314 Triallate; tolerances for residues.
180.315 Methamidophos; tolerances for residues.
180.316 Pyrazon; tolerances for residues.
180.317 Propyzamide; tolerances for residues.
180.318 4-(2-Methyl-4-chlorophenoxy) butyric acid; tolerance for residues.
180.319 Interim tolerances.
180.324 Bromoxynil; tolerances for residues.
180.325 2-(m-Chlorophenoxy) propionic acid; tolerances for residues.
180.328 Napropamide; tolerances for residues.
180.330 S-(2-(Ethylsulfinyl)ethyl) O,O-dimethyl phosphorothioate; tolerances for residues.
180.331 4-(2,4-Dichlorophenoxy) butyric acid; tolerances for residues.
180.332 Metribuzin; tolerances for residues.
180.337 Oxytetracycline; tolerance for residues.
180.339 MCPA; tolerances for residues.
180.341 2,4-Dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate; tolerances for residues.
180.342 Chlorpyrifos; tolerances for residues.
180.345 Ethofumesate; tolerances for residues.
180.349 Fenamiphos; tolerances for residues.
180.350 Nitrapyrin; tolerances for residues.
180.352 Terbufos; tolerances for residues.
180.353 Desmedipham; tolerances for residues.
180.355 Bentazon; tolerances for residues.
180.356 Norflurazon; tolerances for residues.
180.360 Asulam; tolerance for residues.
180.361 Pendimethalin; tolerances for residues.
180.362 Hexakis (2-methyl-2-phenylpropyl)distannoxane; tolerances for residues.
180.364 Glyphosate; tolerances for residues.
180.367 *n*-Octyl bicycloheptenedicarboximide; tolerances for residues.
180.368 Metolachlor; tolerances for residues.
180.369 Difenzoquat; tolerances for residues.

180.370 5-Ethoxy-3-(trichloromethyl)-1, 2, 4-thiadiazole; tolerances for residues.
180.371 Thiophanate-methyl; tolerances for residues.
180.372 2,6-Dimethyl-4-tridecylmorpholine; tolerances for residues.
180.373 [Reserved]
180.377 Diflubenzuron; tolerances for residues.
180.378 Permethrin; tolerances for residues.
180.379 Cyano(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl) benzeneacetate; tolerances for residues.
180.380 Vinclozolin; tolerances for residues.
180.381 Oxyfluorfen; tolerances for residues.
180.383 Sodium salt of acifluorfen; tolerances for residues.
180.384 Mepiquat (N,N-dimethylpiperidinium); tolerances for residues.
180.385 Diclofop-methyl; tolerances for residues.
180.388–180.389 [Reserved]
180.390 Tebuthiuron; tolerances for residues.
180.395 Hydramethylnon; tolerances for residues.
180.396 Hexazinone; tolerances for residues.
180.399 Iprodione; tolerances for residues.
180.401 Thiobencarb; tolerances for residues.
180.403 Thidiazuron; tolerances for residues.
180.404 Profenofos; tolerances for residues.
180.405 Chlorsulfuron; tolerances for residues.
180.406 Dimethipin; tolerances for residues.
180.407 Thiodicarb; tolerances for residues.
180.408 Metalaxyl; tolerances for residues.
180.409 Pirimiphos-methyl; tolerances for residues.
180.410 Triadimefon; tolerances for residues.
180.411 Fluazifop-P-butyl; tolerances for residues.
180.412 Sethoxydim; tolerances for residues.
180.413 Imazalil; tolerances for residues.
180.414 Cyromazine; tolerances for residues.
180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.
180.416 Ethalfluralin; tolerances for residues.
180.417 Triclopyr; tolerances for residues.
180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.
180.419 Chlorpyrifos-methyl; tolerances for residues.
180.420 Fluridone; tolerances for residues.
180.421 Fenarimol; tolerances for residues.
180.422 Tralomethrin; tolerances for residues.
180.425 Clomazone; tolerances for residues.
180.426 2-[4,5-Dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-3-quinoline carboxylic acid; tolerance for residues.
180.427 Tau-Fluvalinate; tolerances for residues.
180.428 Metsulfuron methyl; tolerances for residues.
180.429 Chlorimuron ethyl; tolerances for residues.
180.430 Fenoxaprop-ethyl; tolerances for residues.
180.431 Clopyralid; tolerances for residues.
180.432 Lactofen; tolerances for residues.
180.433 Fomesafen; tolerances for residues.
180.434 Propiconazole; tolerances for residues.
180.435 Deltamethrin; tolerances for residues.
180.436 Cyfluthrin and the isomer beta-cyfluthrin; tolerances for residues.
180.437 Methyl 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*p*-toluate and methyl 6-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*m*-toluate; tolerances for residues.
180.438 Lambda-cyhalothrin and an isomer gamma-cyhalothrin; tolerances for residues.
180.439 Thifensulfuron methyl; tolerances for residues.
180.440 Tefluthrin; tolerances for residues.
180.441 Quizalofop ethyl; tolerances for residues.
180.442 Bifenthrin; tolerances for residues.
180.443 Myclobutanil; tolerances for residues.
180.444 Sulfur dioxide; tolerances for residues.
180.445 Bensulfuron methyl; tolerances for residues.
180.446 Clofentezine; tolerances for residues.
180.447 Imazethapyr; tolerances for residues.
180.448 Hexythiazox; tolerance for residues.
180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.
180.450 Beta-(4-Chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol; tolerances for residues.
180.451 Tribenuron methyl; tolerances for residues.
180.452 Primisulfuron-methyl; tolerances for residues.
180.454 Nicosulfuron, [3-pyridinecarboxamide, 2-((((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl))-N,N-dimethyl]; tolerances for residues.
180.455 Procymidone; tolerances for residues.
180.456 Oxadixyl; tolerances for residues.
180.457 *Beta*-([1,1′-biphenyl]-4-yloxy)-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol; tolerances for residues.
180.458 Clethodim; tolerances for residues.
180.459 Triasulfuron; tolerances for residues.
180.460 Benoxacor; tolerances for residues.
180.461 Cadusafos; tolerances for residues.
180.462 Pyridate; tolerances for residues.
180.463 Quinclorac; tolerances for residues.
180.464 Dimethenamid; tolerances for residues.
180.465 4-(Dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane.
180.466 Fenpropathrin; tolerances for residues.
180.467 Carbon disulfide; tolerances for residues.

180.468 Flumetsulam; tolerances for residues.
180.469 Dichlormid; tolerances for residues.
180.470 Acetochlor; tolerances for residues.
180.471 Furilazole; tolerances for residues.
180.472 Imidacloprid; tolerances for residues.
180.473 Glufosinate ammonium; tolerances for residues.
180.474 Tebuconazole; tolerances for residues.
180.475 Difenoconazole; tolerances for residues.
180.476 Triflumizole; tolerances for residues.
180.477 Flumiclorac pentyl; tolerances for residues.
180.478 Rimsulfuron; tolerances for residues.
180.479 Halosulfuron-methyl; tolerances for residues.
180.480 Fenbuconazole; tolerances for residues.
180.481 Prosulfuron; tolerances for residues.
180.482 Tebufenozide; tolerances for residues.
180.483 *O*-[2-(1,1-Dimethylethyl)-5-pyrimidinyl] *O*-ethyl-*O*-(1-methylethyl) phosphorothioate; tolerances for residues.
180.484 Flutolanil (*N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide); tolerances for residues.
180.485 Cyproconazole; tolerances for residues.
180.486 Phosphorothioic acid, *0,0*-diethyl *0*-(1,2,2,2-tetrachloroethyl) ester; tolerances for residues.
180.487 Pyrithiobac sodium; tolerances for residues.
180.490 Imazapic-ammonium; tolerances for residues.
180.491 Propylene oxide; tolerances for residues.
180.492 Triflusulfuron methyl; tolerances for residues
180.493 Dimethomorph; tolerances for residues.
180.494 Pyridaben; tolerance for residues.
180.495 Spinosad; tolerances for residues.
180.496 Thiazopyr; tolerances for residues.
180.497 Clofencet; tolerances for residues.
180.498 Sulfentrazone; tolerances for residues.
180.499 Propamocarb hydrochloride, tolerances for residues.
180.500 Imazapyr; tolerances for residues.
180.501 Hydroprene; tolerances for residues.
180.502 Aminoethoxyvinylglycine hydrochloride (aviglycine HCl); tolerances for residues.
180.503 Cymoxanil, tolerance for residues.
180.504 [Reserved]
180.505 Emamectin; tolerances for residues.
180.506 Cyclanilide; tolerances for residues.
180.507 Azoxystrobin; tolerances for residues.
180.509 Mefenpyr-diethyl; tolerance for residues.
180.510 Pyriproxyfen; tolerances for residues.
180.511 Buprofezin; tolerances for residues.
180.512 [Reserved]
180.513 Chlorfenapyr; tolerances for residues.
180.514 Cloransulam-methyl; tolerances for residues.
180.515 Carfentrazone-ethyl; tolerances for residues.
180.516 Fludioxonil; tolerances for residues.
180.517 Fipronil; tolerances for residues.
180.518 Pyrimethanil; tolerances for residues.
180.519 Bromide ion and residual bromine; tolerances for residues.
180.521 Fumigants for grain-mill machinery; tolerances for residues.
180.522 Fumigants for processed grains used in production of fermented malt beverage; tolerances for residues.
180.523 Metaldehyde; tolerances for residues.
180.525 Resmethrin; tolerances for residues.
180.526 Synthetic isoparaffinic petroleum hydrocarbons; tolerances for residues.
180.527 Flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-N-methylethyl benzenamine tolerances for residues.
180.530 2,2-Dimethyl-1,3-benzodioxol-4-ol methylcarbamate; tolerances for residues.
180.532 Cyprodinil; tolerances for residues.
180.533 Esfenvalerate; tolerances for residues.
180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.
180.536 Triazamate; tolerances for residues.
180.537 Isoxaflutole; tolerances for residues.
180.538 Copper; tolerances for residues.
180.539 d-Limonene; tolerances for residues.
180.540 Fenitrothion; tolerances for residues.
180.541 Propetamphos; tolerances for residues.
180.543 Diclosulam; tolerances for residues.
180.544 Methoxyfenozide; tolerances for residues.
180.545 Prallethrin (*RS*)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1*RS*)-*cis*, *trans*-chrysanthemate; tolerances for residues.
180.546 Mefenoxam; tolerances for residues.
180.547 Prohexadione calcium; tolerances for residues.
180.548 Tralkoxydim; tolerances for residues.
180.549 Diflufenzopyr; tolerances for residues.
180.550 Arsanilic acid [(4-aminophenyl) arsonic acid]; tolerances for residues.

180.551 Fluthiacet-methyl; tolerances for residues.
180.552 Sulfosulfuron; tolerances for residues.
180.553 Fenhexamid; tolerances for residues.
180.554 Kresoxim-methyl; tolerances for residues.
180.555 Trifloxystrobin; tolerances for residues.
180.556 Pymetrozine; tolerances for residues.
180.557 Tetraconazole; tolerances for residues.
180.558 *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride; tolerances for residues.
180.559 Clodinafop-propargyl; tolerances for residues.
180.560 Cloquintocet-mexyl; tolerances for residues.
180.561 Acibenzolar-*S*-methyl; tolerances for residues.
180.562 Flucarbazone-sodium; tolerances for residues.
180.563 Ethametsulfuron-methyl; tolerances for residues.
180.564 Indoxacarb; tolerances for residues.
180.565 Thiamethoxam; tolerances for residues.
180.566 Fenpyroximate; tolerances for residues.
180.567 Zoxamide; tolerances for residues.
180.568 Flumioxazin; tolerances for residues.
180.569 Forchlorfenuron; tolerances for residues.
180.570 Isoxadifen-ethyl; tolerances for residues.
180.571 Mesotrione; tolerances for residues.
180.572 Bifenazate; tolerance for residues.
180.573 Tepraloxydim; tolerances for residues.
180.574 Fluazinam; tolerances for residues.
180.575 Sulfuryl fluoride; tolerances for residues.
180.576 Cyhalofop-butyl; tolerances for residues.
180.577 Bispyribac-sodium; tolerances for residues.
180.578 Acetamiprid; tolerances for residues.
180.579 Fenamidone; tolerances for residues.
180.580 Iodosulfuron-Methyl-Sodium; tolerances for residues.
180.581 Iprovalicarb; tolerances for residues.
180.582 Pyraclostrobin; tolerances for residues.
180.583 Triticonazole; tolerances for residues.
180.584 Tolylfluanid; tolerances for residues.
180.585 Pyraflufen-ethyl; tolerances for residues.
180.586 Clothianidin; tolerances for residues.
180.587 Famoxadone; tolerance for residues.
180.588 Quinoxyfen; tolerances for residues.
180.589 Boscalid; tolerances for residues.
180.590 2, 6-Diisopropylnaphthalene (2, 6-DIPN); tolerances for residues.
180.591 Trifloxysulfuron; tolerances for residues.
180.592 Butafenacil; tolerances for residues.
180.593 Etoxazole; tolerances for residues.
180.594 Thiacloprid; tolerances for residues.
180.595 Flufenpyr-ethyl; tolerances for residues.
180.596 Fosthiazate; tolerances for residues.
180.597 Mesosulfuron-methyl; tolerances for residues.
180.598 Novaluron; tolerances for residues.
180.599 Acequinocyl; tolerances for residues.
180.600 Propoxycarbazone; tolerances for residues
180.601 Cyazofamid; tolerances for residues.
180.602 Spiroxamine; tolerances for residues.
180.603 Dinotefuran; tolerances for residues.
180.604 Mepanipyrim; tolerances for residues.
180.605 Penoxsulam; tolerances for residues.
180.607 Spiromesifen; tolerances for residues.
180.608 Spirodiclofen; tolerances for residues.
180.609 Fluoxastrobin; tolerances for residues.
180.610 Aminopyralid; tolerances for residues.
180.611 Pinoxaden; tolerances for residues.
180.612 Topramezone; tolerances for residues.
180.613 Flonicamid; tolerances for residues.
180.614 Kasugamycin; tolerances for residues.
180.615 Amicarbazone; tolerances for residues.
180.616 Fenpropimorph; tolerances for residues.
180.617 Metconazole; tolerances for residues.
180.618 Benthiavalicarb-isopropyl; tolerance for residues.
180.619 Epoxiconazole; tolerances for residues.
180.620 Etofenprox; tolerances for residues.
180.621 Dithianon; tolerances for residues.
180.622 Ethaboxam; tolerances for residues.
180.623 Flufenoxuron; tolerances for residues.
180.624 Metrafenone; tolerances for residues.
180.625 Orthosulfamuron; tolerances for residues.
180.626 Prothioconazole; tolerances for residues.
180.627 Fluopicolide; tolerances for residues.
180.628 Chlorantraniliprole; tolerances for residues.
180.629 Flutriafol; tolerance for residues.
180.630 Flusilazole; tolerances for residues.
180.631 Pyrasulfotole; tolerances for residues.
180.632 Fenazaquin; import tolerances for residues.
180.633 Florasulam; tolerances for residues.
180.634 Tembotrione; tolerances for residues.
180.635 Spinetoram; tolerances for residues.

180.636 1,3-dichloropropene; tolerances for residues.
180.637 Mandipropamid; tolerances for residues.
180.638 Pyroxsulam; tolerances for residues.
180.639 Flubendiamide; tolerances for residues.
180.640 Pyridalyl; tolerances for residues.
180.641 Spirotetramat; tolerances for residues.
180.642 Gentamicin; tolerances for residues.
180.643 Uniconazole; tolerances for residues.
180.644 Cyprosulfamide; tolerances for residues.
180.645 Thiencarbazone-methyl; tolerances for residues.
180.646 Ipconazole; tolerances for residues.

Subpart D—Exemptions From Tolerances

180.900 Exemptions from the requirement of a tolerance.
180.905 Pesticide chemicals; exemptions from the requirement of a tolerance.
180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.
180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.
180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.
180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).
180.950 Tolerance exemptions for minimal risk active and inert ingredients.
180.960 Polymers; exemptions from the requirement of a tolerance.
180.1011 Viable spores of the microorganism *Bacillus thuringiensis* Berliner; exemption from the requirement of a tolerance.
180.1016 Ethylene; exemption from the requirement of a tolerance.
180.1017 Diatomaceous earth; exemption from the requirement of a tolerance.
180.1019 Sulfuric acid; exemption from the requirement of a tolerance.
180.1020 Sodium chlorate; exemption from the requirement of a tolerance.
180.1021 Copper; exemption from the requirement of a tolerance.
180.1022 Iodine-detergent complex; exemption from the requirement of a tolerance.
180.1023 Propanoic acid; exemptions from the requirement of a tolerance.
180.1025 Xylene; exemption from the requirement of a tolerance.
180.1027 Nuclear polyhedrosis virus of Heliothis zea; exemption from the requirement of a tolerance.
180.1033 Methoprene; exemption from the requirement of a tolerance.
180.1035 Pine oil; exemption from the requirement of a tolerance.
180.1037 Polybutenes; exemption from the requirement of a tolerance.
180.1040 Ethylene glycol; exemption from the requirement of a tolerance.
180.1041 Nosema locustae; exemption from the requirement of a tolerance.
180.1043 Gossyplure; exemption from the requirement of a tolerance.
180.1049 Carbon dioxide; exemption from the requirement of a tolerance.
180.1050 Nitrogen; exemption from the requirements of a tolerance.
180.1052 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine; exemption from the requirement of a tolerance.
180.1054 Calcium hypochlorite; exemptions from the requirement of a tolerance.
180.1056 Boiled linseed oil; exemption from requirement of tolerance.
180.1057 Phytophthora palmivora; exemption from requirement of tolerance.
180.1058 Sodium diacetate; exemption from the requirement of a tolerance.
180.1064 Tomato pinworm insect pheromone; exemption from the requirement of a tolerance.
180.1065 2-Amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one; exemption from the requirement of a tolerance.
180.1067 Methyl eugenol and malathion combination; exemption from the requirement of a tolerance.
180.1068 C_{12}-C_{18} fatty acid potassium salts; exemption from the requirement of a tolerance.
180.1069 (*Z*)-11-Hexadecenal; exemption from the requirement of a tolerance.
180.1070 Sodium chlorite; exemption from the requirement of a tolerance.
180.1071 Peanuts, Tree Nuts, Milk, Soybeans, Eggs, Fish, Crustacea, and Wheat; exemption from the requirement of a tolerance.
180.1072 Poly-*D*-glucosamine (chitosan); exemption from the requirement of a tolerance.
180.1073 Isomate-M; exemption from the requirement of a tolerance.
180.1074 F.D.&C. Blue No. 1; exemption from the requirement of a tolerance.
180.1075 *Colletotrichum gloeosporioides* f. sp. *aeschynomene;* exemption from the requirement of a tolerance.
180.1076 Viable spores of the microorganism *Bacillus popilliae;* exemption from the requirement of a tolerance.
180.1080 Plant volatiles and pheromone; exemptions from the requirement of a tolerance.
180.1083 Dimethyl sulfoxide; exemption from the requirement of a tolerance.
180.1084 Monocarbamide dihydrogen sulfate; exemption from the requirement of a tolerance.
180.1086 3,7,11-Trimethyl-1,6,10-dodecatriene-1-ol and 3,7,11-trimethyl-2,6,10-

dodecatriene-3-ol; exemption from the requirement of a tolerance.
180.1087 Sesame stalks; exemption from the requirement of a tolerance.
180.1089 Poly-*N*-acetyl-*D*-glucosamine; exemption from the requirement of a tolerance.
180.1090 Lactic acid; exemption from the requirement of a tolerance.
180.1091 Aluminum isopropoxide and aluminum secondary butoxide; exemption from the requirement of a tolerance.
180.1092 Menthol; exemption from the requirement of a tolerance.
180.1095 Chlorine gas; exemptions from the requirement of a tolerance.
180.1097 GBM-ROPE; exemption from the requirement of a tolerance.
180.1098 Gibberellins [Gibberellic Acids (GA3 and GA4 + GA7), and Sodium or Potassium Gibberellate]; exemption from the requirement of a tolerance.
180.1100 *Gliocladium virens* isolate GL-21; exemption from the requirement of a tolerance.
180.1101 Parasitic (parasitoid) and predatory insects; exemption from the requirement of a tolerance.
180.1102 *Trichoderma harzianum* KRL-AG2 (ATCC #20847) strain T–22; exemption from requirement of a tolerance.
180.1103 Isomate-C; exemption from the requirement of a tolerance.
180.1107 Delta endotoxin of *Bacillus thuringiensis* variety *kurstaki* encapsulated into killed *Pseudomonas fluorescens;* exemption from the requirement of a tolerance.
180.1108 Delta endotoxin of *Bacillus thuringiensis* variety *San Diego* encapsulated into killed *Pseudomonas fluorescens;* exemption from the requirement of a tolerance.
180.1110 3-Carbamyl-2,4,5-trichlorobenzoic acid; exemption from the requirement of a tolerance.
180.1111 Bacillus subtilis GB03; exemption from the requirement of a tolerance.
180.1113 Lagenidium giganteum; exemption from the requirement of a tolerance.
180.1114 *Pseudomonas fluorescens* A506, *Pseudomonas fluorescens* 1629RS, and *Pseudomonas syringae* 742RS; exemptions from the requirement of a tolerance.
180.1118 *Spodoptera exigua* nuclear polyhedrosis virus; exemption from the requirement of a tolerance.
180.1119 Azadirachtin; exemption from the requirement of a tolerance.
180.1120 *Streptomyces* sp. strain K61; exemption from the requirement of a tolerance.
180.1121 Boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate; exemptions from the requirement of a tolerance.
180.1122 Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.
180.1124 Arthropod pheromones; exemption from the requirement of a tolerance.
180.1126 Codlure, (E,E)-8,10-Dodecadien-1-ol; exemption from the requirement of a tolerance.
180.1127 Biochemical pesticide plant floral volatile attractant compounds: cinnamaldehyde, cinnamyl alcohol, 4-methoxy cinnamaldehyde, 3-phenyl propanol, 4-methoxy phenethyl alcohol, indole, and 1,2,4-trimethoxybenzene; exemptions from the requirement of a tolerance.
180.1128 *Bacillus subtilis* MBI 600; exemption from the requirement of a tolerance.
180.1130 *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.
180.1131 *Ampelomyces quisqualis* isolate M10; exemption from the requirement of a tolerance.
180.1135 *Pasteuria penetrans;* exemption from the requirement of a tolerance.
180.1139 Sodium 5-nitroguaiacolate; exemption from the requirement of a tolerance.
180.1140 Sodium *o*-nitrophenolate; exemption from the requirement of a tolerance.
180.1141 Sodium *p*-nitrophenolate; exemption from the requirement of a tolerance.
180.1142 1,4-Dimethylnaphthalene; exemption from the requirement of a tolerance.
180.1143 Methyl anthranilate; exemption from the requirement of a tolerance.
180.1144 *Candida oleophila* isolate I-182; exemption from the requirement of a tolerance.
180.1145 *Pseudomonas syringae;* exemption from the requirement of a tolerance.
180.1146 *Beauveria bassiana* Strain GHA; exemption from the requirement of a tolerance.
180.1148 Occlusion Bodies of the Granulosis Virus of *Cydia pomenella;* tolerance exemption.
180.1149 Inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera;* exemption from the requirement of a tolerance.
180.1150 6-Benzyladenine; exemption from the requirement of a tolerance.
180.1153 Lepidopteran pheromones; exemption from the requirement of a tolerance.
180.1154 CryIA(c) and CryIC derived delta-endotoxins of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens,* and the expression plasmid and cloning vector genetic constructs.
180.1156 Cinnamaldehyde; exemption from the requirement of a tolerance.
180.1157 Cytokinins; exemption from the requirement of a tolerance.
180.1158 Auxins; exemption from the requirement of a tolerance.

180.1159 Pelargonic acid; exemption from the requirement of tolerances.
180.1160 Jojoba oil; exemption from the requirement of a tolerance.
180.1161 Clarified hydrophobic extract of neem oil; exemption from the requirement of a tolerance.
180.1162 Acrylate polymers and copolymers; exemption from the requirement of a tolerance.
180.1163 Killed *Myrothecium verrucaria;* exemption from the requirement of a tolerance.
180.1165 Capsaicin; exemption from the requirement of a tolerance.
180.1167 Allyl isothiocyanate as a component of food grade oil of mustard; exemption from the requirement of a tolerance.
180.1176 Sodium bicarbonate; exemption from the requirement of a tolerance.
180.1177 Potassium bicarbonate; exemption from the requirement of a tolerance.
180.1178 Formic acid; exemption from the requirement of a tolerance.
180.1179 Plant extract derived from *Opuntia lindheimeri, Quercus falcata, Rhus aromatica,* and *Rhizophoria mangle;* exemption from the requirement of a tolerance.
180.1180 Kaolin; exemption from the requirement of a tolerance.
180.1181 *Bacillus cereus* strain BPO1; exemption from the requirement of a tolerance.
180.1187 L-glutamic acid; exemption from the requirement of a tolerance.
180.1188 Gamma aminobutyric acid; exemption from the requirement of a tolerance.
180.1189 Methyl salicylate; exemption from the requirement of a tolerance.
180.1191 Ferric phosphate; exemption from the requirement of a tolerance.
180.1193 Potassium dihydrogen phosphate; exemption from the requirement of a tolerance.
180.1195 Titanium dioxide; exemption from the requirement of a tolerance.
180.1196 Peroxyacetic acid; exemption from the requirement of a tolerance.
180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.
180.1198 *Gliocladium catenulatum* strain J1446; exemption from the requirement of a tolerance.
180.1199 Lysophosphatidylethanolamine (LPE); exemption from the requirement of a tolerance.
180.1200 *Pseudomonas fluorescens* strain PRA–25; temporary exemption from the requirement of a tolerance.
180.1201 *Trichoderma harzianum* strain T-39; exemption from the requirement of a tolerance.
180.1202 *Bacillus sphaericus;* exemption from the requirement of a tolerance.
180.1204 Harpin protein; exemption from the requirement of a tolerance.
180.1205 *Beauveria bassiana* ATCC #74040; exemption from the requirements of a tolerance.
180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.
180.1207 N-acyl sarcosines and sodium N-acyl sarcosinates; exemption from the requirement of a tolerance.
180.1209 *Bacillus subtilis* strain QST 713; exemption from the requirement of a tolerance.
180.1210 Phosphorous acid; exemption from the requirement of a tolerance.
180.1212 *Pseudomonas chlororaphis* Strain 63–28; exemption from the requirement of a tolerance.
180.1213 *Coniothyrium minitans* strain CON/M/91–08; exemption from the requirement of a tolerance.
180.1218 Indian Meal Moth Granulosis Virus; exemption from the requirement of a tolerance.
180.1219 Foramsulfuron; exemption from the requirement of a tolerance.
180.1220 1-Methylcyclopropene; exemption from the requirement of a tolerance.
180.1221 *Pseudozyma flocculosa* strain PF-A22 UL; exemption from the requirement of a tolerance.
180.1222 Sucrose octanoate esters; exemption from the requirement of a tolerance.
180.1223 Imazamox; exemption from the requirement of a tolerance.
180.1224 *Bacillus pumilus* GB34; exemption from the requirement of a tolerance.
180.1225 Decanoic acid; exemption from the requirement of a tolerance.
180.1226 *Bacillus pumilus* strain QST2808; temporary exemption from the requirement of a tolerance.
180.1228 Diallyl sulfides; exemption from the requirement of a tolerance.
180.1230 Ferrous sulfate; exemption from the requirement of a tolerance.
180.1231 Lime; exemption from the requirement of a tolerance.
180.1232 Lime-sulfur; exemption from the requirement of a tolerance.
180.1233 Potassium sorbate; exemption from the requirement of a tolerance.
180.1234 Sodium carbonate; exemption from the requirement of a tolerance.
180.1235 Sodium hypochlorite; exemption from the requirement of a tolerance.
180.1236 Sulfur; exemption from the requirement of a tolerance.
180.1237 Sodium metasilicate; exemption from the requirement of a tolerance.
180.1240 Thymol; exemption from the requirement of a tolerance.
180.1241 Eucalyptus oil; exemption from the requirement of a tolerance.
180.1243 *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24; exemption from the requirement of a tolerance.
180.1244 Ammonium bicarbonate; exemption from the requirement of a tolerance.

180.1245 Rhamnolipid biosurfactant; exemption from the requirement of a tolerance.
180.1246 Yeast Extract Hydrolysate from *Saccharomyces cerevisiae:* exemption from the requirement of a tolerance.
180.1248 Exemption of citronellol from the requirement of a tolerance.
180.1250 C8, C10, and C12 fatty acid monoesters of glycerol and propylene glycol; exemption from the requirement of a tolerance.
180.1251 Geraniol; exemption from the requirement of a tolerance.
180.1253 *Streptomyces lydicus* WYEC 108; exemption from the requirement of a tolerance.
180.1254 Aspergillus flavus NRRL 21882 on peanut; exemption from requirement of a tolerance.
180.1255 *Bacillus pumilus* strain QST 2808; exemption from the requirement of a tolerance.
180.1256 *Alternaria destruens* strain 059; exemption from the requirement of a tolerance.
180.1257 *Paecilomyces lilacinus* strain 251; exemption from the requirement of a tolerance.
180.1258 Acetic acid; exemption from the requirement of a tolerance.
180.1259 *Reynoutria sachalinensis* extract; exemption from the requirement of a tolerance.
180.1260 *Muscodor albus* QST 20799 and the volatiles produced on rehydration; exemption from the requirement of a tolerance.
180.1261 *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific Bacteriophages.
180.1262 Sorbitol octanoate; exemption from the requirement of a tolerance.
180.1263 Tetrahydrofurfuryl alcohol; exemption from the requirement of a tolerance.
180.1267 Pantoea agglomerans strain C9–1; exemption from the requirement of a tolerance.
180.1268 Potassium silicate; exemption from the requirement of a tolerance.
180.1269 Bacillus mycoides Isolate J: exemption from the requirement of a tolerance.
180.1270 Isophorone; exemption from the requirement of a tolerance.
180.1271 Eucalyptus oil; exemption from the requirement of a tolerance.
180.1272 Pantoea agglomerans strain E325; exemption from the requirement of a tolerance.
180.1273 Beauveria bassiana HF23; exemption from the requirement of a tolerance.
180.1274 Tris (2-ethylhexyl) phosphate; exemption from the requirement of a tolerance.
180.1275 Pythium; exception from the requirement of a tolerance.
180.1276 Tobacco mild green mosaic tobamovirus (TMGMV); temporary exemption from the requirement of a tolerance.
180.1277 Dibasic esters; exemption from the requirement of a tolerance.
180.1278 Quillaja saponaria extract (saponins); exemption from the requirement of a tolerance.
180.1279 Zucchini yellow mosaic virus—weak strain; exemption from the requirement of a tolerance.
180.1280 Poly(hexamethylenebiguanide) hydrochloride (PHMB); exemption from the requirement of a tolerance.
180.1281 S-Abscisic Acid; exemption from the requirement of a tolerance.
180.1282 Bacillus firmus I-1582; exemption from the requirement of a tolerance.
180.1283 (Z)-7,8-epoxy-2-methyloctadecane (Disparlure); exemption from the requirement of a tolerance.
180.1284 Ammonium salts of higher fatty acids (C_8–C_{18} saturated; C_8–C_{12} unsaturated); exemption from the requirement of a tolerance.
180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.
180.1287 Extract of Chenopodium ambrosioides near ambrosioides; exemption from the requirement of a tolerance.
180.1288 Tristyrylphenol ethoxylates; exemption from the requirement of a tolerance.
180.1289 *Candida oleophila* Strain O; exemption from the requirement of a tolerance.

Subpart E—Pesticide Chemicals Not Requiring a Tolerance or an Exemption from a Tolerance

180.2000 Scope.
180.2003 Definitions.
180.2010 Threshold of regulation determinations.
180.2020 Non-food determinations.

AUTHORITY: 21 U.S.C. 321(q), 346a and 371.

SOURCE: 36 FR 22540, Nov. 25, 1971, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 180 appear at 62 FR 66023, Dec. 17, 1997.

GLOSSARY

NOTE: The items in this glossary were compiled as an aid to the users of the Code of Federal Regulations. Inclusion or exclusion from this glossary has no legal significance.

APPLI = APPLICATION
C-I MET = CHOLINESTERASE-INHIBITING METABOLITES
CARB = CARBAMATES
EPWRR = EDIBLE PORTION WITH RIND REMOVED
EXC = EXCEPT
I (IN PPM COLUMN) = INTERIM TOLERANCE
INC = INCLUDING

K=CWHR = KERNEL PLUS COB WITH HUSK REMOVED
MBYP = MEAT BYPRODUCTS
MIN = MINIMUM
N (IN PPM COLUMN) = NEGLIGIBLE RESIDUES
NMT = NOT MORE THAN
NON-PER BAG/PKGD RAC = NON-PERISHABLE PACKAGED OR BAGGED RAW AGRICULTURAL COMMODITY
PPM = PART(S) PER MILLION
POST-H = POSTHARVEST APPLICATION
PRE-H = PREHARVEST APPLICATION
PRE-S = PRESLAUGHTER APPLICATION
PRODS = PRODUCTS rollert
T (IN PPM COLUMN) = TEMPORARY TOLERANCE

[41 FR 4537, Jan. 30, 1976]

Subpart A—Definitions and Interpretative Regulations

§ 180.1 Definitions and interpretations.

(a) *Administrator,* without qualification, means the Administrator of the Environmental Protection Agency.

(b) *Agency,* without qualification, means the Environmental Protection Agency.

(c) *FFDCA* means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

(d) Raw agricultural commodities include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce. It does not include foods that have been processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.

(e) Where a raw agricultural commodity bearing a pesticide chemical residue that has been exempted from the requirement of a tolerance, or which is within a tolerance permitted under FFDCA section 408, is used in preparing a processed food, the processed food will not be considered unsafe within the meaning of FFDCA sections 402 and 408(a), despite the lack of a tolerance or exemption for the pesticide chemical residue in the processed food, if:

(1) The pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section;

(2) The pesticide chemical residue has been removed to the extent possible in good manufacturing practice; and

(3) The concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue on the raw agricultural commodity.

(f) For the purpose of computing fees as required by § 180.33, each group of related crops listed in § 180.34(e) and each crop group or subgroup listed in § 180.41 is counted as a single raw agricultural commodity in a petition or request for tolerances or exemption from the requirement of a tolerance.

(g) Tolerances and exemptions established for pesticide chemicals in or on the general category of raw agricultural commodities listed in column A apply to the corresponding specific raw agricultural commodities listed in column B. However, a tolerance or exemption for a specific commodity in column B does not apply to the general category in column A.

A	B
Alfalfa	*Medicago sativa L. Subsp. sativa*, (alfalfa, lucerne); *Onobrychis viciifolia Scop.* (sainfoin, holy clover, esparcet); and *Lotus corniculatus L.* (trefoil); and varieties and/or hybrids of these.
Banana	Banana, plantain.
Bean	*Cicer arietinum* (chickpea, garbanzo bean); *Lupinus* spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine). *Phaseolus* spp. (including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, and waxbean; *Vicia faba* (broad bean, fava bean); *Vigna* spp. (including asparagus bean, blackeyed pea and cowpea).
Bean, dry	All beans above in dry form only.

A	B
Bean, succulent	All beans above in succulent form only.
Blackberry	*Rubus eubatus* (including bingleberry, black satin berry, boysenberry Cherokee blackberry, Chesterberry, Cheyenne blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, Himalayaberry, hullberry, Lavacaberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, nectarberry, olallieberry, Oregon evergreen berry, phenomenalberry, rangerberry, ravenberry, rossberry, Shawnee blackberry, and varieties and/or hybrids of these).
Broccoli	Broccoli, chinese broccoli (gia lon, white flowering broccoli).
Cabbage	Cabbage, Chinese cabbage (tight-heading varieties only).
Caneberry	*Rubus* spp. (including blackberry); *Rubus caesius* (youngberry); *Rubus loganbaccus* (loganberry); *Rubus idaeus* (red and black raspberry); cultivars, varieties, and/or hybrids of these.
Celery	Celery, Florence fennel (sweet anise, sweet fennel, finochio) (fresh leaves and stalks only).
Cherry	Cherry, sweet, and cherry, tart.
Endive	Endive, escarole.
Fruit, citrus	Grapefruit, lemon, lime, orange, tangelo, tangerine, citrus citron, kumquat, and hybrids of these.
Garlic	Garlic, great headed; garlic, and serpent garlic.
Lettuce	Lettuce, head; and lettuce, leaf
Lettuce, head	Lettuce, head; crisphead varieties only
Lettuce, leaf	Lettuce, leaf; cos (romaine), butterhead varieties
Marjoram	*Origanum* spp. (includes sweet or annual marjoram, wild marjoram or oregano, and pot marjoram).
Melon	Muskmelon, including hybrids and/or varieties of *Cucumis melo* (including true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon); and watermelon, including hybrids and/or varieties of (*Citrullus* spp.).
Muskmelon	*Cucumis melo* (includes true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon, and other varieties and/or hybrids of these.)
Onion	Bulb onion; green onion; and garlic.
Onion, bulb	Bulb onion; garlic; great headed garlic; serpent garlic; Chinese onion; pearl onion; potato onion; and shallot, bulb.
Onion, green	Green onion; lady's leek; leek; wild leek; Beltsville bunching onion; fresh onion; tree onion, tops; Welsh onion; and shallot, fresh leaves.
Peach	Peach, nectarine
Pea	*Cajanus cajan* (includes pigeon pea); *Cicer* spp. (includes chickpea and garbanzo bean); *Lens culinaris* (lentil); *Pisum* spp. (includes dwarf pea, garden pea, green pea, English pea, field pea, and edible pod pea). [Note: A variety of pesticide tolerances have been previously established for pea and/or bean. Chickpea/garbanzo bean is now classified in both the bean and the pea categories. For garbanzo bean/chickpea only, the highest established pea or bean tolerance will apply to pesticide residues found in this commodity.]
Pea, dry	All peas in dry form only.

A	B
Pea, succulent	All peas in succulent form only.
Pepper	All varieties of pepper including pimento and bell, hot, and sweet pepper.
Radish, oriental, roots	*Raphanus sativus* var. *longipinnatus* (roots and tops), including Chinese or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these.
Radish, oriental, tops)	*Raphanus sativus* var. *longipinnatus* (roots and tops), including Chinese or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these.
Rapeseed	*Brassica napus*, *B. campestris*, and *Crambe abyssinica* (oilseed-producing varieties only which include canola and crambe.)
Raspberry	*Rubus* spp. (including bababerry; black raspberry; blackcap; caneberry; framboise; frambueso; himbeere; keriberry; mayberry; red raspberry; thimbleberry; tulameen; yellow raspberry; and cultivars, varieties, and/or hybrids of these).
Sorghum, grain, grain	*Sorghum* spp. [sorghum, grain, sudangrass (seed crop), and hybrids of these grown for its seed].
Sorghum, forage, stover	*Sorghum* spp. [sorghum, forage; sorghum, stover; sudangrass, and hybrids of these grown for forage and/or stover.
Squash	Pumpkin, summer squash, and winter squash.
Sugar apple	*Annona squamosa L.* (sugar apple, sweetsop, anon), and its hybrid *A. squamosa L. x A. cherimoya M.* (atemoya). Also *A. reticulata L.* (true custard apple).
Squash, summer	Fruits of the gourd (*Cucurbitaceae*) family that are consumed when immature, 100% of the fruit is edible either cooked or raw, once picked it cannot be stored, has a soft rind which is easily penetrated, and if seeds were harvested they would not germinate; e.g., *Cucurbita pepo* (*i.e.*, crookneck squash, straightneck squash, scallop squash, and vegetable marrow); *Lagenaria* spp. (*i.e.*, spaghetti squash, hyotan, cucuzza); *Luffa* spp. (*i.e.*, hechima, Chinese okra); *Momordica* spp. (*i.e.*, bitter melon, balsam pear, balsam apple, Chinese cucumber); *Sechium edule* (chayote); and other cultivars and/or hybrids of these.
Sweet potato	Sweet potato, yam.
Tangerine	Tangerine (mandarin or mandarin orange); tangelo, tangor, and other hybrids of tangerine with other citrus.
Tomato	Tomato, tomatillo.
Turnip tops or turnip greens	Broccoli raab (raab, raab salad), hanover salad, turnip tops (turnip greens).
Wheat	Wheat, triticale.

(h) Unless otherwise specified, tolerances and exemptions established under the regulations in this part apply to residues from only preharvest application of the chemical.

(i) Unless otherwise specified in this paragraph or in tolerance regulations prescribed in this part for specific pesticide chemicals, the raw agricultural commodity or processed food to be examined for pesticide residues, shall consist of the whole raw agricultural commodity or processed food.

(1) The raw agricultural commodity bananas, when examined for pesticide residues, shall not include any crown tissue or stalk.

(2) Shell shall be removed and discarded from nuts before examination for pesticide residues.

(3) Caps (hulls) shall be removed and discarded from strawberries before examination for pesticide residues.

(4) Stems shall be removed and discarded from melons before examination for pesticide residues.

(5) Roots, stems, and outer sheaths (or husks) shall be removed and discarded from garlic bulbs and dry bulb onions, and only the garlic cloves and onion bulbs shall be examined for pesticide residues.

(6) Where a tolerance is established on a root vegetable including tops and/or with tops, and the tops and the roots are marketed together, they shall be analyzed separately and neither the pesticide residue on the roots nor the pesticide residue on the tops shall exceed the tolerance level, except that in the case of carrots, parsnips, and rutabagas, the tops shall be removed and discarded before analyzing roots for pesticide residues.

(7) The crowns (leaves at the top of the fruit) shall be removed and discarded from pineapples before examination for pesticide residues.

(8) The term *lima beans* means the beans and the pod.

(9) The term *peanuts* means the peanut meat after removal of the hulls.

(10) For processed foods consisting primarily of one ingredient and sold in a form requiring further preparation prior to consumption (e.g., fruit juice concentrates, dehydrated vegetables, and powdered potatoes), the processed food to be examined for residues shall be the whole processed commodity after compensating for or reconstituting to the commodity's normal moisture content, unless a tolerance for the concentrated or dehydrated food form is included in this part. If there exists a tolerance for a specific pesticide on the processed food in its concentrated or dehydrated food form, for the purpose of determining whether the food is in compliance with that tolerance, the processed food to be examined for residues shall be the whole processed commodity on an ''as is'' basis.

(j) The term *pesticide chemical* shall have the meaning specified in FFDCA section 201(q)(1), as amended, except as provided in § 180.4.

(k) The term *negligible residue* means any amount of a pesticide chemical remaining in or on a raw agricultural commodity or group of raw agricultural commodities that would result in a daily intake regarded as toxicologically insignificant on the basis of scientific judgment of adequate safety data. Ordinarily this will add to the diet an amount which will be less than 1/2,000th of the amount that has been demonstrated to have no effect from feeding studies on the most sensitive animal species tested. Such toxicity studies shall usually include at least 90-day feeding studies in two species of mammals.

(l) The term *nonperishable raw agricultural commodity* means any raw agricultural commodity not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are cocoa beans, coffee beans, field-dried beans, field-dried peas, grains, and nuts. Not included are eggs, milk, meat, poultry, fresh fruits, and vegetables such as onions, parsnips, potatoes, and carrots.

(m) The term *tolerance with regional registration* means any tolerance which is established for pesticide residues resulting from the use of the pesticide pursuant to a regional registration. Such a tolerance is supported by residue data from specific growing regions for a raw agricultural commodity. Individual tolerances with regional registration are designated in separate subsections in 40 CFR 180.101 through 180.999, as appropriate. Additional residue data which are representative of the proposed use area are required to expand the geographical area of usage of a pesticide on a raw agricultural commodity having an established ''tolerance with regional registration.'' Persons seeking geographically broader registration of a crop having a ''tolerance with regional registration'' should contact the appropriate EPA product manager concerning additional residue data required to expand the use area.

(n) The term *pesticide chemical residue* shall have the meaning specified in FFDCA section 201(q)(2), as amended, except as provided in § 180.4.

(o) The term *food commodity* means:

(1) Any raw agricultural commodity (food or feed) as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (FFDCA); and

(2) Any processed food or feed as defined in section 201(gg) of the FFDCA.

[36 FR 22540, Nov. 25, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.3 Tolerances for related pesticide chemicals.

(a) Pesticide chemicals that cause related pharmacological effects will be regarded, in the absence of evidence to the contrary, as having an additive deleterious action. (For example, many pesticide chemicals within each of the following groups have related pharmacological effects: Chlorinated organic pesticides, arsenic-containing chemicals, metallic dithiocarbamates, cholinesterase-inhibiting pesticides.)

(b) Tolerances established for such related pesticide chemicals may limit the amount of a common component (such as As_2O_3) that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present, or may limit the total amount of related pesticide chemicals (such as chlorinated organic pesticides) that may be present.

(c)(1) Where tolerances for inorganic bromide in or on the same raw agricultural commodity are set in two or more sections in this part (example: §§ 180.123 and 180.199), the overall quantity of inorganic bromide to be tolerated from use of the same pesticide in different modes of application or from two or more pesticide chemicals for which tolerances are established is the highest of the separate applicable tolerances. For example, where the bromide tolerance on asparagus from methyl bromide commodity fumigation is 100 parts per million (40 CFR 180.123) and on asparagus from methyl bromide soil treatment is 300 parts per million (40 CFR 180.199), the overall inorganic bromide tolerance for asparagus grown on methyl bromide-treated soil and also fumigated with methyl bromide after harvest is 300 parts per million.

(2) Where tolerances are established in terms of inorganic bromide residues only from use of organic bromide fumigants on raw agricutural commodities, such tolerances are sufficient to protect the public health, and no additional concurrent tolerances for the organic pesticide chemicals from such use are necessary. This conclusion is based on evidence of the dissipation of the organic pesticide or its conversion to inorganic bromide residues in the food when ready to eat.

(d)(1) Where tolerances are established for both calcium cyanide and hydrogen cyanide on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as hydrogen cyanide.

(2) Where tolerances are established for residues of both *O,O*-diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate and demeton (a mixture of *O,O*-diethyl *O*-(and *S*-) [2-(ethylthio)ethyl] phosphorothioates) on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as demeton.

(3) Where tolerances are established for both terpene polychlorinates (chlorinated mixture of camphene, pinene, and related terpenes, containing 65–66 percent chlorine) and toxaphene (chlorinated camphene containing 67–69 percent chlorine) on the same raw agricultural commodities, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as a chlorinated terpene of molecular weight 396.6 containing 67 percent chlorine.

(4) Where a tolerance is established for more than one pesticide containing arsenic found in, or on a raw agricultural commodity, the total amount of such pesticide shall not exceed the highest established tolerance calculated as As_2O_3.

(5) Where tolerances are established for more than one member of the class of dithiocarbamates listed in paragraph (e)(3) of this section on the same raw agricultural commodity, the total residue of such pesticides shall not exceed that permitted by the highest tolerance established for any one member of the class, calculated as zinc ethylenebisdithiocarbamate.

(6) Where tolerances are established for residues of both *S,S,S*-tributyl phosphorotrithioate and tributyl phosphorotrithioite in or on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the higher of the two tolerances, calculated as *S,S,S*-tributyl phosphorotrithioate.

(7) Where tolerances are established for residues of α-naphthaleneacetamide and/or α-naphthaleneacetic acid in or on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the higher of the two tolerances, calculated as α-naphthaleneacetic acid.

(8) Where tolerances are established for residues of *O,S*-dimethyl phosphoramidothioate, resulting from the use of acephate (*O,S*-dimethyl acetylphos-phoramidothioate) and/or *O,S*-dimethylphosphoramidothioate on the same agricultural commodity, the total amount of *O,S*-dimethyl-phosphoramidothioate shall not yield more residue than that permitted by the higher of the two tolerances.

(9) Where a tolerance is established for more than one pesticide having the metabolites 1-(3,4-dichlorophenyl)-3-methylurea (DCPMU) and 3,4-dichlorophenylurea (DCPU) found in or on a raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for a pesticide having these metabolites.

(10) Where a tolerance is established for more than one pesticide having as metabolites compounds containing the benzimidazole moiety found in or on a raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for a pesticide having these metabolites.

(11) Where a tolerance is established for triclopyr, chloropyrifos, and chlorpyrifos-methyl having the common metabolite 3,5,6-trichloro-2-pyridinol on the same raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for any of the pesticides having the metabolites.

(12) Where tolerances are established for more than one pesticide having the metabolite 3,5,6-trichloro-2-pyridinol found in or on the raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for a pesticide having this metabolite.

(13) Where tolerances are established for residues of methomyl, resulting from the use of thiodicarb and/or methomyl on the same raw agricultural commodity, the total amount of methomyl shall not yield more residue than that permitted by the higher of the two tolerances.

(e) Except as noted in paragraphs (e)(1) and (2) of this section, where residues from two or more chemicals in the same class are present in or on a raw agricultural commodity the tolerance for the total of such residues shall be the same as that for the chemical having the lowest numerical tolerance in this class, unless a higher tolerance level is specifically provided for the combined residues by a regulation in this part.

(1) Where residues from two or more chemicals in the same class are present in or on a raw agricultural commodity and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(i) Determine the quantity of each residue present.

(ii) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(iii) Add the percentages so obtained for all residues present.

(iv) The sum of the percentages shall not exceed 100 percent.

(2) Where residues from two or more chemicals in the same class are present in or on a raw agricultural commodity and there are available methods that permit quantitative determinations of one or more, but not all, of the residues, the amounts of such residues as may be determinable shall be deducted from the total amount of residues present and the remainder shall have the same tolerance as that for the chemical having the lowest numerical

tolerance in that class. The quantity of combined residues that are within the tolerance may be determined as follows:

(i) Determine the quantity of each determinable residue present.

(ii) Deduct the amounts of such residues from the total amount of residues present and consider the remainder to have the same tolerance as that for the chemical having the lowest numerical tolerance in that class.

(iii) Divide the quantity of each determinable residue by the tolerance that would apply if it occurred alone and the quantity of the remaining residue by the tolerance for the chemical having the lowest numerical tolerance in that class and multiply by 100 to determine the percentage of the permitted amount of residue present.

(iv) Add the percentages so obtained for all residues present.

(v) The sum of the percentages shall not exceed 100 percent.

(3) The following pesticides are members of the class of dithiocarbamates:

A mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides.
2-Chloroallyl diethyldithiocarbamate.
Coordination product of zinc ion and maneb containing 20 percent manganese, 2.5 percent zinc, and 77.5 percent ethylenebisdithiocarbamate.
Ferbam.
Maneb.
Manganous dimethyldithiocarbamate.
Sodium dimethyldithiocarbamate.
Thiram.
Zineb.
Ziram.

(4) The following are members of the class of chlorinated organic pesticides:

Aldrin.
BHC (benzene hexachloride).
1,1-Bis(*p*-chlorophenyl)-2,2,2-trichloroethanol.
Chlorbenside (*p*-chlorobenzyl *p*-chlorophenyl sulfide).
Chlordane.
Chlorobenzilate (ethyl 4,4′-dichlorobenzilate).
p-Chlorophenoxyacetic acid.
p-Chlorophenyl-2,4,5-trichlorophenyl sulfide.
2,4-D (2,4-dichlorophenoxyacetic acid).
DDD (TDE).
DDT.
1,1-Dichloro-2,2-bis(*p*-ethylphenyl) ethane.
2,6-Dichloro-4-nitroaniline.
2,4-Dichlorophenyl *p*-nitrophenyl ether.
Dieldrin.
Dodecachlorooctahydro-1,3,4-metheno-2*H*-cyclobuta[*cd*]pentalene.
Endosulfan (6,7,8,9,10,10-hexachloro-1,5,5a, 6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide).
Endosulfan sulfate (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide).
Heptachlor (1,4,5,6,7,8,8-heptachlor-3a,4,7, 7a-tetrahydro-4,7-methanoindene).
Heptachlor epoxide (1,4,5,6,7,8,8-heptachloro-2,3-epoxy-2,3,3a,4,7,7a-hexahydro-4,7-methanoindene).
Hexachlorophene (2,2′-methylenebis(3,4,6-trichlorophenol) and its monosodium salt.
Isopropyl 4,4′-dichlorobenzilate.
Lindane.
Methoxychlor.
Ovex (*p*-chlorophenyl *p*-chlorobenzenesulfonate).
Sesone (sodium 2,4-dichlorophenoxyethyl sulfate, SES).
Sodium 2,4-dichlorophenoxyacetate.
Sodium trichloroacetate.
Sulphenone (*p*-chlorophenyl phenyl sulfone).
Terpene polychlorinates (chlorinated mixture of camphene, pinene, and related terpenes 65-66 percent chlorine).
2,3,5,6-Tetrachloronitrobenzene.
Tetradifon (2,4,5,4′-tetrachlorodiphenyl sulfone).
Toxaphene (chlorinated camphene).
Trichlorobenzoic acid.
Trichlorobenzyl chloride.

(5) The following are members of the class of cholinesterase-inhibiting pesticides:

Acephate (*O,S*-dimethyl acetylphosphoramidothioate) and its cholinesterase-inhibiting metabolite *O,S*-dimethyl phosphoramidothioate.
Aldicarb (2-methyl-2-(methylthio) propionaldehyde *O*-(methylcarbamoyl)oxime) and its chlorinesterase-inhibiting metabolites 2-methyl-2-(methylsulfinyl)propionaldehyde *O*-(methycarbamoyl) oxime and 2-methyl-2-(methylsulfonyl)propionaldehyde *O*-(methylcarbamoyl)oxime.
4-*tert*-Butyl-2-chlorophenyl methyl methyl phosphoramidate.
S-[(*tert*-Butylthio)methyl] *O,O*-diethyl phosphorodithioate and its cholinesterase-inhibiting metabolites.
Carbaryl (1-naphthyl *N*-methylcarbamate).
Carbofuran (2,3,-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate).
Carbofuran metabolite (2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benofuranyl *N*-methylcarbamate).
Carbophenothion (*S*-[(*p*-chlorophenyl) thiolmethyl] *O,O*-diethyl

phosphorodithioate) and its cholinesterase-inhibiting metabolites.
Chlorpyrifos (*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate).
Chlorpyrifos-methyl (*O,O*-dimethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate.
2-Chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate.
2-Chloro-1-(2,4-dichlorophenyl) vinyl diethyl phosphate.
Coumaphos (*O,O*-diethyl *O*-3-chloro-4-methyl-2-oxo-2*H*-1-benzopyran-7-yl phosran-7-yl phosphate).
Coumaphos oxygen analog (*O,O*-diethyl *O*-3-chloro-4-methyl-2-oxo-2*H*-1-benzopyphorothioate).
Dialifor (*S*-(2-chloro-1-phthalimidoethyl) *O,O*-diethyl phosphorodithioate).
Dialifor oxygen analog (*S*-(2-chloro-1-phthalimidoethyl) *O,O*-diethyl phosphorothioate).
Demeton (a mixture of *O,O*-diethyl *O*-(and *S*) [2-ethylthio)ethyl] phosphorothioates).
Ethiolate (*S*-ethyl diethylthiocarbamate).
2,2-Dichlorovinyl dimethyl phosphate.
O,O-Diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate and its cholinesterase-inhibiting metabolites.
O,O-Diethyl *O*-(2-diethylamino-6-methyl-4-pyrimidinyl) phosphorothioate and its oxygen analog diethyl 2-diethylamino-6-methyl-4-pyrimidinyl phosphate.
O,O-Diethyl *O*-(2-isoprophyl-4-methyl-6-pyrimidinyl) phosphorothioate.
O,O-Diethyl *O*-[*p*-(methylsulfinyl)phenyl] phosphorothioate and its cholinesterase-inhibiting metabolites.
Diethyl 2-pyrazinyl phosphate.
O,O-Diethyl *O*-2-pyrazinyl phosphorothioate.
S-(*O,O*-Diisopropyl phosphorodithioate) of *N*-(2-mercaptoethyl) benzenesulfonamide
S-(*O,O*-Diisopropyl phosphorodithioate) of *N*-(2-mercaptoethyl) benzenesulfonamide
2-(Dimethylamino)-5.6-dimethyl-4-pyrimidinyl dimethylcarbamate and its metabolites 5,6-dimethyl-2-(formylmethylamino)-4-pyrimidinyl dimethylcarbamate and 5,6-dimethyl-2-(methylamino)-4-pyrimidinyl dimethylcarbamate (both calculated as parent).
Dimethoate (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate).
Dimethoate oxygen analog (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate).
O,O-Dimethyl *O*-*p*-(dimethylsulfamoyl) phenyl phosphate.
O,O-Dimethyl *O*-*p*-(dimethylsulfamoyl) phenyl phosphorothioate.
3,5-Dimethyl-4-(methylthio) phenyl methylcarbamate.
O,O-Dimethyl *S*-[4-oxo-1,2,3-benzotriazin-3-(4*H*)-ylmethyl] phosphorodithioate.
Dimethyl phosphate of 3-hydroxy-*N,N*-dimethyl-*cis*-crotonamide.
Dimethyl phosphate of 3-hydroxy-*N*-methyl-*cis*-crotonamide.
Dimethyl phosphate of α-methylbenzyl 3-hydroxy-*cis*-crotonate.
O,O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.
O,O-Dimethyl phosphorodithioate, *S*-ester with 4-(mercaptomethyl)-2-methozy-Δ2-1,3,4-thiadiazolin-5-one.
Dioxathion (2,3-*p*-dioxanedithiol *S,S*-bis (*O,O*-diethylphosphorodithioate)) containing approximately 70 percent *cis* and *trans* isomers and approximately 30 percent related compounds.
EPN.
Ethephon ((2- - chloroethyl) phosphonic acid).
Ethion.
Ethion oxygen analog (*S*-[[(diethoxyphosphinothioyl)thio] methyl] *O,O*-diethyl phosphorothioate).
O- Ethyl *O*-[4-(methylthio) phenyl] *S*-propyl phosphorodithioate and its cholinesterase-inhibiting metabolites.
O-Ethyl *S,S*-dipropylphosphorodithioate.
Ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl) phosphoramidate and its cholinesterase-inhibiting metabolites.
O-Ethyl *S*-phenyl ethylphosphonodithioate.
O-Ethyl *S*-phenyl ethylphosphonothiolate.
m-(1-Ethylpropyl)phenyl methylcarbamate.
S-[2-Ethylsulfinyl)ethyl] *O,O*-dimethyl phosphorothioate and its cholinesterase-inhibiting metabolites, (primarily *S*-[2-(ethyl-sulfonyl)ethyl] *O,O*-dimethyl phosphorothioate).
Fenthion (*O,O*-dimethyl *O*-[3-methyl-4-(methylthio)phenyl]phosphorothioate and its cholinesterase-inhibiting metabolites.
Malathion.
N-(Mercaptomethyl)phthalimide *S*-(*O,O*-dimethyl phosphorodithioate).
N-(Mercaptomethyl)phthalimide *S*-(*O,O*-dimethyl phosphorothioate).
Methomyl (*S*-methyl *N*-[(methylcarbamoyl)oxy]thioacetimidate).
1-Methoxycarbonyl-1-propen-2-yl dimethyl phosphate and its beta isomer.
m-(1-Methylbutyl)phenyl methylcarbamate.
Methyl parathion.
Naled (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate).
Oxamyl (methyl N′,N′-dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamimidate)
Parathion.
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-diethylcarbamoyl-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 phosphorotritlioite.
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 on GPO Access.

§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]

§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.

(4) Data showing the recommended amount, frequency, method, and time of application of the pesticide chemical.

(5) Full reports of tests and investigations made with respect to the

safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations.

(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.

(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 with an earlier application, the present petition may incorporate it by reference to the earlier one.

(d) Except as noted in paragraph (e) of this section, a petition shall not be accepted for filing if any of the data prescribed by FFDCA 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. The Administrator shall make the full text of the summary referenced in paragraph (b)(1) of this section available to the public in the public docket at *http://www.regulations.gov* no later than publication in the FEDERAL REGISTER of the notice of the petition filing.

(e) The Administrator shall notify the petitioner within 15 days after its receipt of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If petitioner desires, the petitioner may supplement a deficient petition after notification as to deficiencies. 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.

(f) A notice of the filing of a petition for a pesticide chemical residue tolerance that the Administrator determines has met the requirements of paragraph (b) of this section shall be published in the FEDERAL REGISTER by the Administrator within 30 days after such determination. The notice shall state the name of the pesticide chemical residue and the commodities for which a tolerance is sought and announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall explicitly reference the specific docket identification number in the public docket at *http://*

www.regulations.gov where the full text of the summary required in paragraph (b) of this section is located, and refer interested parties to this document for further information on the petition. 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]

§ 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 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 shall accompany the resubmission of the petition.

[70 FR 33361, June 8, 2005]

§ 180.9 Substantive amendments to petitions.

After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date.

[70 FR 33361, June 8, 2005]

§ 180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.

(a) Upon the Administrator's own initiative, the Administrator may propose, under FFDCA section 408(e), 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.

(b) The Administrator shall provide a period of not less than 60 days for persons to comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(c) 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.

(d) 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.

[70 FR 33361, June 8, 2005]

§ 180.30 Judicial review.

(a) Under FFDCA section 408(h), judicial review is available in the United

States Courts of Appeal as to the following actions:

(1) Regulations establishing general procedures and requirements under FFDCA section 408(e)(1)(C).

(2) Orders issued under FFDCA section 408(f)(1)(C) requiring the submission of data.

(3) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to establishment, modification, or revocation of a tolerance or exemption under FFDCA section 408(d)(4), or any regulation that is the subject of such an order. The underlying action here is Agency disposition of a petition seeking the establishment, modification, or revocation of a tolerance or exemption.

(4) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the denial of a petition under FFDCA section 408(d)(4).

(5) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the establishment, modification, suspension, or revocation of a tolerance or exemption under FFDCA section 408(e)(1)(A) or (e)(1)(B). The underlying action here is the establishment, modification, suspension, or revocation of a tolerance or exemption upon the initiative of EPA including EPA actions pursuant to FFDCA sections 408(b)(2)(B)(v), 408(b)(2)(E)(ii), 408(d)(4)(C)(ii), 408(l)(4), and 408(q)(1).

(6) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the revocation or modification of a tolerance or exemption under FFDCA section 408(f)(2) for noncompliance with requirements for the submission of data.

(7) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to rules issued under FFDCA sections 408(n)(3) and 408(d) or (e) regarding determinations pertaining to State authority to establish regulatory limits on pesticide chemical residues.

(8) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to orders issued under FFDCA section 408(n)(5)(C) authorizing States to establish regulatory limits not identical to certain tolerances or exemptions.

(b) Any issue as to which review is or was obtainable under paragraph (a) of this section shall not be the subject of judicial review under any other provision of law. In part, this means that, for the Agency actions subject to the objection procedure in FFDCA section 408(g)(2), judicial review is not available unless an adversely affected party exhausts these objection procedures, and any petition procedures preliminary thereto.

[70 FR 33362, June 8, 2005]

§ 180.31 Temporary tolerances.

(a) A temporary tolerance (or exemption from a tolerance) established under the authority of FFDCA section 408(r) shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of FFDCA section 408(a)(1) or (a)(2) and for the purposes of § 180.30.

(b) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained or is seeking an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by such data as are available on subjects outlined in § 180.7(b) and an advance deposit to cover fees as provided in § 180.33.

(c) To obtain a temporary tolerance, a requestor must comply with the petition procedures specified in FFDCA section 408(d) and § 180.7 except as provided in this section.

(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 if the Administrator concludes that the safety standard in FFDCA section 408(b)(2) or (c), as applicable, is met. Subject to the requirements of FFDCA section 408(e), 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 does not meet the safety standard in FFDCA section 408(b)(2) or (c), as applicable.

(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 permit for which the temporary tolerance is established will keep records of production, distribution, and performance for a period of 2 years and, on request, at any reasonable time, make these records available to any authorized officer or employee of the Environmental Protection Agency.

[70 FR 33362, June 8, 2005]

§ 180.32 Procedure for modifying and revoking tolerances or exemptions from tolerances.

(a) The Administrator on his/her own initiative may propose the issuance of a regulation modifying or revoking a tolerance for a pesticide chemical residue on raw agricultural commodities or processed foods or modifying or revoking an exemption from tolerance for such residue.

(b) Any person may file with the Administrator a petition proposing the issuance of a regulation modifying or revoking a tolerance or exemption from a tolerance for a pesticide chemical residue. The petition shall furnish reasonable grounds for the action sought. Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such tolerance or exemption from tolerance and an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its modification or revocation. Evidence that a person has registered or has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act will be regarded as evidence that the person has a substantial interest in a tolerance or exemption from the requirement of a tolerance for a pesticide chemical that consists in whole or in part of the pesticide. New data should be furnished in the form specified in § 180.7(b) for submitting petitions, as applicable.

(c) The procedures for completing action on an Administrator initiated proposal or a petition shall be those specified in §§ 180.29 and 180.7, as applicable.

[70 FR 33362, June 8, 2005]

§ 180.33 Fees.

(a) Each petition for the establishment of a new tolerance or a tolerance higher than already established, shall be accompanied by a fee of $80,950, plus $2,025 for each raw agricultural commodity more than nine on which the establishment of a tolerance is requested, except as provided in paragraphs (b), (d), and (h) of this section.

(b) Each petition for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the same pesticide chemical, or for the establishment of a tolerance on additional raw agricultural commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a fee of $18,500 plus $1,225 for each raw agricultural commodity on which a tolerance is requested.

(c) Each petition for an exemption from the requirement of a tolerance or repeal of an exemption shall be accompanied by a fee of $14,925.

(d) Each petition or request for a temporary tolerance or a temporary exemption from the requirement of a tolerance shall be accompanied by a fee of $32,325 except as provided in paragraph (e) of this section. A petition or

request to renew or extend such temporary tolerance or temporary exemption shall be accompanied by a fee of $4,600.

(e) A petition or request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level or a higher numerical level shall be accompanied by a fee of $16,075, plus $1,225 for each raw agricultural commodity on which the temporary tolerance is sought.

(f) Each petition for revocation of a tolerance shall be accompanied by a fee of $10,125. Such fee is not required when, in connection with the change sought under this paragraph, a petition is filed for the establishment of new tolerances to take the place of those sought to be revoked and a fee is paid as required by paragraph (a) of this section.

(g) If a petition or a request is not accepted for processing because it is technically incomplete, the fee, less $2,025 for handling and initial review, shall be returned. If a petition is withdrawn by the petitioner after initial processing, but before significant Agency scientific review has begun, the fee, less $2,025 for handling and initial review, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were being submitted for the first time.

(h) Each petition for a crop group tolerance, regardless of the number of raw agricultural commodities involved, shall be accompanied by a fee equal to the fee required by the analogous category for a single tolerance that is not a crop group tolerance, *i.e.*, paragraphs (a) through (f) of this section, without a charge for each commodity where that would otherwise apply.

(i) Objections under section 408(d)(5) of the Act shall be accompanied by a filing fee of $4,050.

(j) The person who files a petition for judicial review of an order under section 408(h) of the Act shall pay the costs of preparing the record on which the order is based unless the person has no financial interest in the petition for judicial review.

(k) No fee under this section will be imposed on the Interregional Research Project Number 4 (IR-4 Program).

(l) The Administrator may waive or refund part or all of any fee imposed by this section if the Administrator determines in his or her sole discretion that such a waiver or refund will promote the public interest or that payment of the fee would work an unreasonable hardship on the person on whom the fee is imposed. A request for waiver or refund of a fee shall be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b). A fee of $2,025 shall accompany every request for a waiver or refund, as specified in paragraph (m) of this section, except that the fee under this paragraph shall not be imposed on any person who has no financial interest in any action requested by such person under paragraphs (a) through (j) of this section. The fee for requesting a waiver or refund shall be refunded if the request is granted.

(m) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All deposits and fees shall be forwarded to the Environmental Protection Agency, Headquarters Accounting Operations Branch, Office of Pesticide Programs (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. The payments should be specifically labeled ''Tolerance Petition Fees'' and should be accompanied only by a copy of the letter or petition requesting the tolerance. The actual letter or petition, along with supporting data, shall be forwarded within 30 days of payment to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b). A petition will not be accepted for processing until the required fees have been submitted. A petition for which a waiver of fees has been requested will not be accepted for processing until the fee has been waived or, if the waiver has been denied, the proper fee is submitted after notice of denial. A request for waiver or refund will not be accepted after scientific review has begun on a petition.

(n) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale. In addition, processing costs and fees will periodically be reviewed and changes will be made to the schedule as necessary. When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the FEDERAL REGISTER as a final rule to become effective 30 days or more after publication, as specified in the rule. When changes are made based on periodic reviews, the changes will be subject to public comment.

(o) No fee required by this section shall be levied during the period beginning on October 1, 2003, and ending September 30, 2008.

[68 FR 24371, May 7, 2003, as amended at 69 FR 12544, Mar. 17, 2004; 70 FR 33363, June 8, 2005; 71 FR 35547, June 21, 2006]

§ 180.34 Tests on the amount of residue remaining.

(a) Data in a petition on the amount of residue remaining in or on a raw agricultural commodity should establish the residue that may remain when the pesticide chemical is applied according to directions registered under the Federal Insecticide, Fungicide, and Rodenticide Act, or according to directions contained in an application for registration. These data should establish the residues that may remain under conditions most likely to result in high residues on the commodity.

(b) The petition should establish the reliability of the residue data reported in it. Sufficient information should be submitted about the analytical method to permit competent analysts to apply it successfully.

(c) If the pesticide chemical is absorbed into a living plant or animal when applied (is systemic), residue data may be needed on each plant or animal on which a tolerance or exemption is requested.

(d) If the pesticide chemical is not absorbed into the living plant or animal when applied (is not systemic), it may be possible to make a reliable estimate of the residues to be expected on each commodity in a group of related commodities on the basis of less data than would be required for each commodity in the group, considered separately.

(e) Each of the following groups of crops lists raw agricultural commodities that are considered to be related for the purpose of paragraph (d) of this section. Commodities not listed in this paragraph are not considered to be related for the purpose of paragraph (d) of this section.

(1) Apples, crabapples, pears, quinces.

(2) Avocados, papayas.

(3) Blackberries, boysenberries, dewberries, loganberries, raspberries.

(4) Blueberries, currants, gooseberries, huckleberries.

(5) Cherries, plums, prunes.

(6) Oranges, citrus citron, grapefruit, kumquats, lemons, limes, tangelos, tangerines.

(7) Mangoes, persimmons.

(8) Peaches, apricots, nectarines.

(9) Beans, peas, soybeans (each in dry form).

(10) Beans, peas, soybeans (each in succulent form).

(11) Broccoli, brussels sprouts, cauliflower, kohlrabi.

(12) Cantaloups, honeydew melons, muskmelons, pumpkins, watermelons, winter squash.

(13) Carrots, garden beets, sugar beets, horseradish, parsnips, radishes, rutabagas, salsify roots, turnips.

(14) Celery, fennel.

(15) Cucumbers, summer squash.

(16) Lettuce, endive (escarole), Chinese cabbage, salsify tops.

(17) Onions, garlic, leeks, shallots (green, or in dry bulb form).

(18) Potatoes, Jerusalem-artichokes, sweetpotatoes, yams.

(19) Spinach, beet tops, collards, dandelion, kale, mustard greens, parsley, Swiss chard, turnip tops, watercress.

(20) Tomatoes, eggplants, peppers, pimentos.

(21) Pecans, almonds, brazil nuts, bush nuts, butternuts, chestnuts, filberts, hazelnuts, hickory nuts, walnuts.

(22) Field corn, popcorn, sweet corn (each in grain form).

(23) Milo, sorghum (each in grain form).

(24) Wheat, barley, oats, rice, rye (each in grain form).

(25) Alfalfa, Bermuda grass, bluegrass, brome grass, clovers, cowpea

hay, fescue, lespedeza, lupines, orchard grass, peanut hay, peavine hay, rye grass, soybean hay, sudan grass, timothy, and vetch.

(26) Corn forage, sorghum forage.

(27) Sugarcane, cane sorghum.

[36 FR 22540, Nov. 25, 1971, as amended at 39 FR 28286, Aug. 6, 1974; 39 FR 28977, Aug. 13, 1974; 40 FR 6972, Feb. 18, 1975; 45 FR 82928, Dec. 17, 1980; 48 FR 29860, June 29, 1983; 60 FR 26635, May 17, 1995; 73 FR 75600, Dec. 12, 2008]

§ 180.35 Tests for potentiation.

Experiments have shown that certain cholinesterase-inhibiting pesticides when fed together to test animals are more toxic than the sum of their individual toxicities when fed separately. One substance potentiates the toxicity of the other. Important toxicological interactions also have been observed between pesticides and other substances. Wherever there is reason to believe that a pesticide chemical for which a tolerance is proposed may interact with other pesticide chemicals or other substances to which man is exposed, it may be necessary to require special experimental data regarding potentiation capacities to evaluate the safety of the proposed tolerance. This necessarily will be determined on a case-by-case basis.

§ 180.40 Tolerances for crop groups.

(a) Group or subgroup tolerances may be established as a result of:

(1) A petition from a person who has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) On the initiative of the Administrator.

(3) A petition by an interested person.

(b) The tables in § 180.41 are to be used in conjunction with this section for the establishment of crop group tolerances. Each table in § 180.41 lists a group of raw agricultural commodities that are considered to be related for the purposes of this section. Refer also to § 180.1(h) for a listing of commodities for which established tolerances may be applied to certain other related and similar commodities.

(c) When there is an established or proposed tolerance for all of the representative commodities for a specific group or subgroup of related commodities, a tolerance may be established for all commodities in the associated group or subgroup. Tolerances may be established for a crop group or, alternatively, tolerances may be established for one or more of the subgroups of a crop group.

(d) The representative crops are given as an indication of the minimum residue chemistry data base acceptable to the Agency for the purposes of establishing a group tolerance. The Agency may, at its discretion, allow group tolerances when data on suitable substitutes for the representative crops are available (e.g., limes instead of lemons).

(e) Since a group tolerance reflects maximum residues likely to occur on all individual crops within a group, the proposed or registered patterns of use for all crops in the group or subgroup must be similar before a group tolerance is established. The pattern of use consists of the amount of pesticide applied, the number of times applied, the timing of the first application, the interval between applications, and the interval between the last application and harvest. The pattern of use will also include the type of application; for example, soil or foliar application, or application by ground or aerial equipment.

(f) When the crop grouping contains commodities or byproducts that are utilized for animal feed, any needed tolerance or exemption from a tolerance for the pesticide in meat, milk, poultry and/or eggs must be established before a tolerance will be granted for the group as a whole. The representative crops include all crops in the group that could be processed such that residues may concentrate in processed food and/or feed. Processing data will be required prior to establishment of a group tolerance. Tolerances will not be granted on a group basis as to processed foods prepared from crops covered by the group tolerance.

(g) If maximum residues (tolerances) for the representative crops vary by more than a factor of 5 from the maximum value observed for any crop in the group, a group or subgroup tolerance will ordinarily not be established.

In this case individual crop tolerances, rather than group tolerances, will normally be established.

(h) Alternatively, a commodity with a residue level significantly higher or lower than the other commodities in a group may be excluded from the group tolerance (e.g., cereal grains, except corn). In this case an individual tolerance at the appropriate level for the unique commodity would be established, if necessary. The alternative approach of excluding a commodity with a significantly higher or lower residue level will not be used to establish a tolerance for a commodity subgroup. Most subgroups have only two representative commodities; to exclude one such commodity and its related residue data would likely provide insufficient residue information to support the remainder of the subgroup. Residue data from crops additional to those representative crops in a grouping may be required for systemic pesticides.

(i) The commodities included in the groups will be updated periodically either at the initiative of the Agency or at the request of an interested party. Persons interested in updating this section should contact the Registration Division of the Office of Pesticide Programs.

(j) When EPA amends a crop group in a manner that expands or contracts the commodities that are covered by the group, EPA will initially retain the pre-existing as well as the revised crop group in the CFR. The revised crop group will have the same number as the pre-existing crop group; however, the revised crop group number will be followed by a hyphen and the final two digits of the year in which it was established (e.g., if Crop Group 1 is amended in 2007, the revised group will be designated as Crop Group 1-07). If the pre-existing crop group had crop subgroups, these subgroups will be numbered in a similar fashion in the revised crop group. The name of the revised crop group will not be changed from the pre-existing crop group unless the revision so changes the composition of the crop group that the pre-existing name is no longer accurate. Once a revised crop group is established, EPA will no longer establish tolerances under the pre-existing crop group. At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group. Once all of the tolerances for the pre-existing crop group have been updated, the pre-existing crop group will be removed from the CFR.

(k) Establishment of a tolerance does not substitute for the additional need to register the pesticide under a companion law, the Federal Insecticide, Fungicide, and Rodenticide Act. The Registration Division of the Office of Pesticide Programs should be contacted concerning procedures for registration of new uses of a pesticide.

[60 FR 26635, May 17, 1995, as amended at 70 FR 33363, June 8, 2005; 72 FR 69155, Dec. 7, 2007]

§ 180.41 Crop group tables.

(a) The tables in this section are to be used in conjunction with § 180.40 to establish crop group tolerances.

(b) Commodities not listed are not considered as included in the groups for the purposes of this paragraph, and individual tolerances must be established. Miscellaneous commodities intentionally not included in any group include asparagus, avocado, banana, fig, globe artichoke, hops, mango, okra, papaya, pawpaw, peanut, persimmon, pineapple, water chestnut, and watercress.

(c) Each group is identified by a group name and consists of a list of representative commodities followed by a list of all commodity members for the group. If the group includes subgroups, each subgroup lists the subgroup name, the representative commodity or commodities, and the member commodities for the subgroup. Subgroups, which are a subset of their associated crop group, are established for some but not all crops groups.

(1) *Crop Group 1:* Root and Tuber Vegetables Group.

(i) *Representative commodities.* Carrot, potato, radish, and sugar beet.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 1 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 1: ROOT AND TUBER VEGETABLES

Commodities	Related crop subgroups
Arracacha (*Arracacia xanthorrhiza*)	1C, 1D
Arrowroot (*Maranta arundinacea*)	1C, 1D
Artichoke, Chinese (*Stachys affinis*)	1C, 1D
Artichoke, Jerusalem (*Helianthus tuberosus*)	1C, 1D
Beet, garden (*Beta vulgaris*)	1A, 1B
Beet, sugar (*Beta vulgaris*)	1A
Burdock, edible (*Arctium lappa*)	1A, 1B
Canna, edible (Queensland arrowroot) (*Canna indica*)	1C, 1D
Carrot (*Daucus carota*)	1A, 1B
Cassava, bitter and sweet (*Manihot esculenta*)	1C, 1D
Celeriac (celery root) (*Apium graveolens* var. *rapaceum*)	1A, 1B
Chayote (root) (*Sechium edule*)	1C, 1D
Chervil, turnip-rooted (*Chaerophyllum bulbosum*)	1A, 1B
Chicory (*Cichorium intybus*)	1A, 1B
Chufa (*Cyperus esculentus*)	1C, 1D
Dasheen (taro) (*Colocasia esculenta*)	1C, 1D
Ginger (*Zingiber officinale*)	1C, 1D
Ginseng (*Panax quinquefolius*)	1A, 1B
Horseradish (*Armoracia rusticana*)	1A, 1B
Leren (*Calathea allouia*)	1C, 1D
Parsley, turnip-rooted (*Petroselinum crispum* var. *tuberosum*)	1A, 1B
Parsnip (*Pastinaca sativa*)	1A, 1B
Potato (*Solanum tuberosum*)	1C
Radish (*Raphanus sativus*)	1A, 1B
Radish, oriental (daikon) (*Raphanus sativus* subvar. *longipinnatus*)	1A, 1B
Rutabaga (*Brassica campestris* var. *napobrassica*)	1A, 1B
Salsify (oyster plant) (*Tragopogon porrifolius*)	1A, 1B
Salsify, black (*Scorzonera hispanica*)	1A, 1B
Salsify, Spanish (*Scolymus hispanicus*)	1A, 1B
Skirret (*Sium sisarum*)	1A, 1B
Sweet potato (*Ipomoea batatas*)	1C, 1D
Tanier (cocoyam) (*Xanthosoma sagittifolium*)	1C, 1D
Turmeric (*Curcuma longa*)	1C, 1D
Turnip (*Brassica rapa* var. *rapa*)	1A, 1B
Yam bean (jicama, manoic pea) (*Pachyrhizus* spp.)	1C, 1D
Yam, true (*Dioscorea* spp.)	1C, 1D

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 1, specifies the representative commodity(ies) for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 1 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 1A. Root vegetables subgroup.	
Carrot, radish, and sugar beet.	Beet, garden; beet, sugar; burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip-rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip.
Crop Subgroup 1B. Root vegetables (except sugar beet) subgroup.	
Carrot and radish.	Beet, garden; burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip-rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip.
Crop Subgroup 1C. Tuberous and corm vegetables subgroup.	
Potato.	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen; ginger; leren; potato; sweet potato; tanier; turmeric; yam bean; yam, true.
Crop Subgroup 1D. Tuberous and corm vegetables (except potato) subgroup.	
Sweet potato.	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen; ginger; leren; sweet potato; tanier; turmeric; yam bean; yam, true.

(2) *Crop Group 2.* Leaves of Root and Tuber Vegetables (Human Food or Animal Feed) Group (Human Food or Animal Feed) Group.

(i) *Representative commodities.* Turnip and garden beet or sugar beet.

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 2:

CROP GROUP 2: LEAVES OF ROOT AND TUBER VEGETABLES (HUMAN FOOD OR ANIMAL FEED) GROUP—COMMODITIES

Beet, garden (*Beta vulgaris*)
Beet, sugar (*Beta vulgaris*)
Burdock, edible (*Arctium lappa*)
Carrot (*Daucus carota*)
Cassava, bitter and sweet (*Manihot esculenta*)
Celeriac (celery root) (*Apium graveolens* var. *rapaceum*)
Chervil, turnip-rooted (*Chaerophyllum bulbosum*)
Chicory (*Cichorium intybus*)
Dasheen (taro) (*Colocasia esculenta*)
Parsnip (*Pastinaca sativa*)
Radish (*Raphanus sativus*)
Radish, oriental (daikon) (*Raphanus sativus* subvar. *longipinnatus*)
Rutabaga (*Brassica campestris* var. *napobrassica*)
Salsify, black (*Scorzonera hispanica*)
Sweet potato (*Ipomoea batatas*)
Tanier (cocoyam) (*Xanthosoma sagittifolium*)
Turnip (*Brassica rapa* var. *rapa*)
Yam, true (*Dioscorea* spp.)

(3) *Crop Group 3.* Bulb Vegetables (*Allium* spp.) Group.

(i) *Representative commodities.* Onion, green; and onion, dry bulb.

(ii) *Commodities.* The following is a list of all the commodities in Crop Group 3.

CROP GROUP 3: BULB VEGETABLE (*Allium* SPP.) GROUP—COMMODITIES

Garlic, bulb (*Allium sativum*)
Garlic, great headed, (elephant) (*Allium ampeloprasum* var. *ampeloprasum*)
Leek (*Allium ampeloprasum*, *A. porrum, A. tricoccum*)
Onion, dry bulb and green (*Allium cepa, A. fistulosum*)
Onion, Welsh, (*Allium fistulosum*)
Shallot (*Allium cepa* var. *cepa*)

(4) *Crop Group 3-07.* Bulb Vegetable Group. (i) *Representative Commodities.* Onion, bulb and onion, green.

(ii) *Table.* The following Table 1 lists all the commodities listed in Crop Group 3-07 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 3-07: BULB VEGETABLE GROUP

Commodities	Related crop subgroups
Chive, fresh leaves (*Allium schoenoprasum L.*)	3-07B
Chive, Chinese, fresh leaves (*Allium tuberosum* Rottler ex Spreng)	3-07B
Daylily, bulb (*Hemerocallis fulva* (L.) L. var. *fulva*)	3-07A
Elegans hosta (*Hosta Sieboldiana (Hook.) Engl*)	3-07B
Fritillaria, bulb (*Fritillaria L. fritillary*)	3-07A
Fritillaria, leaves (*Fritillaria L. fritillary*)	3-07B
Garlic, bulb (*Allium sativum* L. var. *sativum*) (*A. sativum* Common Garlic Group)	3-07A
Garlic, great headed, bulb (*Allium ampeloprasum* L. var. *ampeloprasum*) (*A. ampeloprasum* Great Headed Garlic Group)	3-07A
Garlic, Serpent, bulb (*Allium sativum* var. *ophioscorodon* or *A. sativum* Ophioscorodon Group)	3-07A
Kurrat (*Allium kurrat Schweinf. Ex. K. Krause* or *A. ampeloprasum* Kurrat Group)	3-07B
Lady's leek (*Allium cernuum* Roth)	3-07B
Leek *Allium porrum* L. (syn: *A. ampeloprasum L.* var. *porrum* (L.) J. Gay) (*A.ampeloprasum* Leek Group)	3-07B
Leek, wild (*Allium tricoccum* Aiton)	3-07B
Lily, bulb (*Lilium* spp. (*Lilium Leichtlinii* var. *maximowiczii, Lilium lancifolium*))	3-07A
Onion, Beltsville bunching (*Allium* x *proliferum* (Moench) Schrad.) (syn: *Allium fistulosum* L. x *A. cepa* L.)	3-07B
Onion, bulb (*Allium cepa* L. var. *cepa*) (*A. cepa* Common Onion Group)	3-07A
Onion, Chinese, bulb (*Allium chinense* G. Don.) (syn: *A. bakeri* Regel)	3-07A
Onion, fresh (*Allium fistulosum* L. var. *caespitosum* Makino)	3-07B
Onion, green (*Allium cepa* L. var. *cepa*) (*A. cepa* Common Onion Group)	3-07B
Onion, macrostem (*Allium macrostemom* Bunge)	3-07B
Onion, pearl (*Allium porrum* var. *sectivum* or *A. ampeloprasum* Pearl Onion Group)	3-07A
Onion, potato, bulb (*Allium cepa* L. var. *aggregatum* G. Don.) (*A. cepa* Aggregatum Group)	3-07A
Onion, tree, tops (*Allium x proliferum* (Moench) Schrad. ex Willd.) (syn: *A. cepa* var. *proliferum* (Moench) Regel; *A. cepa* L. var. *bulbiferum* L.H. Bailey; *A. cepa* L. var. *viviparum* (Metz.) Alef.)	3-07B
Onion, Welsh, tops (*Allium fistulosum* L.)	3-07B
Shallot, bulb (*Allium cepa* var. *aggregatum* G. Don.)	3-07A
Shallot, fresh leaves (*Allium cepa* var. *aggregatum* G. Don.)	3-07B
Cultivars, varieties, and/or hybrids of these.	

(iii) *Table.* The following Table 2 identifies the crop subgroups for Crop Group 3-07, specifies the representative commodities for each subgroup and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 3-07: SUBGROUP LISTING

Representative commodities	Commodities
Crop subgroup 3-07A. Onion, bulb, subgroup.	
Onion, bulb.	Daylily, bulb; fritillaria, bulb; garlic, bulb; garlic, great-headed, bulb; garlic, serpent, bulb; lily, bulb; onion, bulb; onion, Chinese, bulb; onion, pearl; onion, potato, bulb; shallot, bulb; cultivars, varieties, and/or hybrids of these.
Crop subgroup 3-07B. Onion, green, subgroup.	
Onion, green.	Chive, fresh leaves; chive, Chinese, fresh leaves; elegans hosta; fritillaria, leaves; kurrat; lady's leek; leek; leek, wild; Onion, Beltsville bunching; onion, fresh; onion, green; onion, macrostem; onion, tree, tops; onion, Welsh, tops; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these.

(5) *Crop Group 4.* Leafy Vegetables (Except *Brassica* Vegetables) Group.

(i) *Representative commodities.* Celery, head lettuce, leaf lettuce, and spinach (*Spinacia oleracea*).

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 4 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 4: LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES) GROUP

Commodities	Related crop subgroups
Amaranth (leafy amaranth, Chinese spinach, tampala) (*Amaranthus* spp.)	4A
Arugula (Roquette) (*Eruca sativa*)	4A
Cardoon (*Cynara cardunculus*)	4B
Celery (*Apium graveolens* var. *dulce*)	4B
Celery, Chinese (*Apium graveolens* var. *secalinum*)	4B
Celtuce (*Lactuca sativa* var. *angustana*)	4B
Chervil (*Anthriscus cerefolium*)	4A
Chrysanthemum, edible-leaved (*Chrysanthemum coronarium* var. *coronarium*)	4A
Chrysanthemum, garland (*Chrysanthemum coronarium* var. *spatiosum*)	4A
Corn salad (*Valerianella locusta*)	4A
Cress, garden (*Lepidium sativum*)	4A
Cress, upland (yellow rocket, winter cress) (*Barbarea vulgaris*)	4A
Dandelion (*Taraxacum officinale*)	4A
Dock (sorrel) (*Rumex* spp.)	4A
Endive (escarole) (*Cichorium endivia*)	4A
Fennel, Florence (finochio) (*Foeniculum vulgare* Azoricum Group)	4B
Lettuce, head and leaf (*Lactuca sativa*)	4A
Orach (*Atriplex hortensis*)	4A
Parsley (*Petroselinum crispum*)	4A
Purslane, garden (*Portulaca oleracea*)	4A
Purslane, winter (*Montia perfoliata*)	4A
Radicchio (red chicory) (*Cichorium intybus*)	4A
Rhubarb (*Rheum rhabarbarum*)	4B
Spinach (*Spinacia oleracea*)	4A
Spinach, New Zealand (*Tetragonia tetragonioides, T. expansa*)	4A
Spinach, vine (Malabar spinach, Indian spinach) (*Basella alba*)	4A
Swiss chard (*Beta vulgaris* var. *cicla*)	4B

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 4, specifies the representative commodities for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 4 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 4A. Leafy greens subgroup.	
Head lettuce and leaf lettuce, and spinach (*Spinacia oleracea*).	Amaranth; arugula; chervil; chrysanthemum, edible-leaved; chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion; dock; endive; lettuce; orach; parsley; purslane, garden; purslane, winter; radicchio (red chicory); spinach; spinach, New Zealand; spinach, vine.

TABLE 2—CROP GROUP 4 SUBGROUP LISTING—Continued

Representative commodities	Commodities
Crop Subgroup 4B. Leaf petioles subgroup.	
Celery.	Cardoon; celery; celery, Chinese; celtuce; fennel, Florence; rhubarb; Swiss chard.

(6) *Crop Group 5. Brassica* (Cole) Leafy Vegetables Group.

(i) *Representative commodities.* Broccoli or cauliflower; cabbage; and mustard greens.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 5 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 5: *Brassica* (COLE) LEAFY VEGETABLES

Commodities	Related crop subgroups
Broccoli (*Brassica oleracea* var. *botrytis*)	5A
Broccoli, Chinese (gai lon) (*Brassica alboglabra*)	5A
Broccoli raab (rapini) (*Brassica campestris*)	5B
Brussels sprouts (*Brassica oleracea* var. *gemmifera*)	5A
Cabbage (*Brassica oleracea*)	5A
Cabbage, Chinese (bok choy) (*Brassica chinensis*)	5B
Cabbage, Chinese (napa) (*Brassica pekinensis*)	5A
Cabbage, Chinese mustard (gai choy) (*Brassica campestris*)	5A
Cauliflower (*Brassica oleracea* var. *botrytis*)	5A
Cavalo broccolo (*Brassica oleracea* var. *botrytis*)	5A
Collards (*Brassica oleracea* var. *acephala*)	5B
Kale (*Brassica oleracea* var. *acephala*)	5B
Kohlrabi (*Brassica oleracea* var. *gongylodes*)	5A
Mizuna (*Brassica rapa* Japonica Group)	5B
Mustard greens (*Brassica juncea*)	5B
Mustard spinach (*Brassica rapa* Perviridis Group)	5B
Rape greens (*Brassica napus*)	5B

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 5, specifies the representative commodity(ies) for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 5 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 5A. Head and stem *Brassica* subgroup	
Broccoli or cauliflower; and cabbage	Broccoli; broccoli, Chinese; brussels sprouts; cabbage; cabbage, Chinese (napa); cabbage, Chinese mustard; cauliflower; cavalo broccolo; kohlrabi
Crop Subgroup 5B. Leafy *Brassica* greens subgroup.	
Mustard greens	Broccoli raab; cabbage, Chinese (bok choy); collards; kale; mizuna; mustard greens; mustard spinach; rape greens

(7) *Crop Group 6.* Legume Vegetables (Succulent or Dried) Group.

(i) *Representative commodities.* Bean (*Phaseolus* spp.; one succulent cultivar and one dried cultivar); pea (*Pisum* spp.; one succulent cultivar and one dried cultivar); and soybean.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 6 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 6: LEGUME VEGETABLES (SUCCULENT OR DRIED)

Commodities	Related crop subgroups
Bean (*Lupinus* spp.) (includes grain lupin, sweet lupin, white lupin, and white sweet lupin)	6C
Bean (*Phaseolus* spp.) (includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean)	6A, 6B, 6C
Bean (*Vigna* spp.) (includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean)	6A, 6B, 6C
Broad bean (fava bean) (*Vicia faba*)	6B, 6C
Chickpea (garbanzo bean) (*Cicer arietinum*)	6C
Guar (*Cyamopsis tetragonoloba*)	6C
Jackbean (*Canavalia ensiformis*)	6A
Lablab bean (hyacinth bean) (*Lablab purpureus*)	6C
Lentil (*Lens esculenta*)	6C
Pea (*Pisum* spp.) (includes dwarf pea, edible-pod pea, English pea, field pea, garden pea, green pea, snow pea, sugar snap pea)	6A, 6B, 6C
Pigeon pea (*Cajanus cajan*)	6A, 6B, 6C
Soybean (*Glycine max*)	N/A
Soybean (immature seed) (*Glycine max*)	6A
Sword bean (*Canavalia gladiata*)	6A

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 6, specifies the representative commodities for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 6 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 6A. Edible-podded legume vegetables subgroup.	
Any one succulent cultivar of edible-podded bean (*Phaseolus* spp.) and any one succulent cultivar of edible-podded pea (*Pisum* spp.)..	Bean (*Phaseolus* spp.) (includes runner bean, snap bean, wax bean); bean (*Vigna* spp.) (includes asparagus bean, Chinese longbean, moth bean, yardlong bean); jackbean; pea (*Pisum* spp.) (includes dwarf pea, edible-pod pea, snow pea, sugar snap pea); pigeon pea; soybean (immature seed); sword bean.
Crop Subgroup 6B. Succulent shelled pea and bean subgroup.	
Any succulent shelled cultivar of bean (*Phaseolus* spp.) and garden pea (*Pisum* spp.)..	Bean (*Phaseolus* spp.) (includes lima bean (green)); broad bean (succulent); bean (*Vigna* spp.) (includes blackeyed pea, cowpea, southern pea); pea (*Pisum* spp.) (includes English pea, garden pea, green pea); pigeon pea.
Crop Subgroup 6C. Dried shelled pea and bean (except soybean) subgroup	
Any one dried cultivar of bean (*Phaseolus* spp.); and any one dried cultivar of pea (*Pisum* spp.).	Dried cultivars of bean (*Lupinus* spp.) (includes grain lupin, sweet lupin, white lupin, and white sweet lupin); (*Phaseolus* spp.) (includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean; tepary bean; bean (*Vigna* spp.) (includes adzuki bean, blackeyed pea, catjang, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean); broad bean (dry); chickpea; guar; lablab bean; lentil; pea (*Pisum* spp.) (includes field pea); pigeon pea.

(8) *Crop Group 7.* Foliage of Legume Vegetables Group.

(i) *Representative commodities.* Any cultivar of bean (*Phaseolus* spp.), field pea (*Pisum* spp.), and soybean.

(ii) *Table.* The following table 1 lists the commodities included in Crop Group 7.

TABLE 1—CROP GROUP 7: FOLIAGE OF LEGUME VEGETABLES GROUP

Representative commodities	Commodities
Any cultivar of bean (*Phaseolus* spp.) and field pea (*Pisum* spp.), and soybean (*Glycine max*).	Plant parts of any legume vegetable included in the legume vegetables that will be used as animal feed.

(iii) *Table.* The following table 2 identifies the crop subgroup for Crop Group 7 and specifies the representative commodities for the subgroup, and lists all the commodities included in the subgroup.

TABLE 2—CROP GROUP 7 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 7A. Foliage of legume vegetables (except soybeans) subgroup	
Any cultivar of bean (*Phaseolus* spp.), and field pea (*Pisum* spp.).	Plant parts of any legume vegetable (except soybeans) included in the legume vegetables group that will be used as animal feed.

(9) *Crop Group 8.* Fruiting Vegetables (Except Cucurbits) Group.

(i) *Representative commodities.* Tomato, bell pepper, and one cultivar of non-bell pepper.

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 8:

CROP GROUP 8: FRUITING VEGETABLES (EXCEPT CUCURBITS)—COMMODITIES

Eggplant (*Solanum melongena*)
Groundcherry (*Physalis* spp.)
Pepino (*Solanum muricatum*)
Pepper (*Capsicum* spp.) (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper)
Tomatillo (*Physalis ixocarpa*)
Tomato (*Lycopersicon esculentum*)

(10) *Crop Group 9.* Cucurbit Vegetables Group.

(i) *Representative commodities.* Cucumber, muskmelon, and summer squash.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 9 and identifies the related subgroups.

TABLE 1—CROP GROUP 9: CUCURBIT VEGETABLES

Commodities	Related crop subgroups
Chayote (fruit) (*Sechium edule*)	9B
Chinese waxgourd (Chinese preserving melon) (*Benincasa hispida*)	9B
Citron melon (*Citrullus lanatus* var. *citroides*)	9A
Cucumber (*Cucumis sativus*)	9B
Gherkin (*Cucumis anguria*)	9B
Gourd, edible (*Lagenaria* spp.) (includes hyotan, cucuzza); (*Luffa acutangula, L. cylindrica*) (includes hechima, Chinese okra)	9B
Momordica spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber)	9B
Muskmelon (hybrids and/or cultivars of *Cucumis melo*) (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon)	9A
Pumpkin (*Cucurbita* spp.)	9B
Squash, summer (*Cucurbita pepo* var. *melopepo*) (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini)	9B
Squash, winter (*Cucurbita maxima; C. moschata*) (includes butternut squash, calabaza, hubbard squash); (*C. mixta; C. pepo*) (includes acorn squash, spaghetti squash)	9B
Watermelon (includes hybrids and/or varieties of *Citrullus lanatus*)	9A

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 9, specifies the representative commodities for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 9 SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 9A. Melon subgroup	
Cantaloupes	Citron melon; muskmelon; watermelon
Crop Subgroup 9B. Squash/cucumber subgroup	
One cultivar of summer squash and cucumber.	Chayote (fruit); Chinese waxgourd; cucumber; gherkin; gourd, edible; *Momordica* spp.; pumpkin; squash, summer; squash, winter.

(11) *Crop Group 10.* Citrus Fruits (*Citrus* spp., *Fortunella* spp.) Group.

(i) *Representative commodities.* Sweet orange; lemon and grapefruit.

(ii) *Commodities.* The following is a list of all the commodities in Crop Group 10:

CROP GROUP 10: CITRUS FRUITS (CITRUS SPP., FORTUNELLA SPP.) GROUP—COMMODITIES

Calamondin (*Citrus mitis×Citrofortunella mitis*)
Citrus citron (*Citrus medica*)
Citrus hybrids (*Citrus* spp.) (includes chironja, tangelo, tangor)
Grapefruit (*Citrus paradisi*)
Kumquat (*Fortunella* spp.)
Lemon (*Citrus jambhiri, Citrus limon*)
Lime (*Citrus aurantiifolia*)
Mandarin (tangerine) (*Citrus reticulata*)
Orange, sour (*Citrus aurantium*)
Orange, sweet (*Citrus sinensis*)
Pummelo (*Citrus grandis, Citrus maxima*)
Satsuma mandarin (*Citrus unshiu*)

(12) *Crop Group 11:* Pome Fruits Group.

(i) *Representative commodities.* Apple and pear.

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 11:

CROP GROUP 11: POME FRUITS GROUP—COMMODITIES

Apple (*Malus domestica*)
Crabapple (*Malus* spp.)
Loquat (*Eriobotrya japonica*)
Mayhaw (*Crataegus aestivalis, C. opaca,* and *C. rufula*)
Pear (*Pyrus communis*)
Pear, oriental (*Pyrus pyrifolia*)
Quince (*Cydonia oblonga*)

(13) *Crop Group 12.* Stone Fruits Group.

(i) *Representative commodities.* Sweet cherry or tart cherry; peach; and plum or fresh prune (*Prunus domestica, Prunus* spp.)

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 12:

CROP GROUP 12: STONE FRUITS GROUP—COMMODITIES

Apricot (*Prunus armeniaca*)
Cherry, sweet (*Prunus avium*),
Cherry, tart (*Prunus cerasus*)
Nectarine (*Prunus persica*)
Peach (*Prunus persica*)
Plum (*Prunus domestica, Prunus* spp.)
Plum, Chickasaw (*Prunus angustifolia*)
Plum, Damson (*Prunus domestica* spp. *insititia*)
Plum, Japanese (*Prunus salicina*)
Plumcot (*Prunus. armeniaca×P. domestica*)
Prune (fresh) (*Prunus domestica, Prunus* spp.)

(14) *Crop Group 13.* Berries Group.

(i) *Representative commodities.* Any one blackberry or any one raspberry; and blueberry.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 13 and identifies the related subgroups.

TABLE 1—CROP GROUP 13: BERRIES GROUP

Commodities	Related crop subgroups
Blackberry (*Rubus eubatus*) (including bingleberry, black satin berry, boysenberry, Cherokee blackberry, Chesterberry, Cheyenne blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, Himalayaberry, hullberry, Lavacaberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, nectarberry, olallieberry, Oregon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, youngberry, and varieties and/or hybrids of these)	13A
Blueberry (*Vaccinium* spp.)	13B
Currant (*Ribes* spp.)	13B
Elderberry (*Sambucus* spp.)	13B
Gooseberry (*Ribes* spp.)	13B
Huckleberry (*Gaylussacia* spp.)	13B
Loganberry (*Rubus loganobaccus*)	13A
Raspberry, black and red (*Rubus occidentalis, Rubus strigosus, Rubus idaeus*)	13A

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 13, specifies the representative commodities for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 13 SUBGROUPS LISTING

Representative commodities	Commodities
Crop Subgroup 13A. Caneberry (blackberry and raspberry) subgroup.	
Any one blackberry or any one raspberry.	Blackberry; loganberry; red and black raspberry; cultivars and/or hybrids of these.
Crop Subgroup 13B. Bushberry subgroup..	
Blueberry, highbush.	Blueberry, highbush and lowbush; currant; elderberry; gooseberry; huckleberry.

(15) *Crop Group 13-07*. Berry and Small Fruit Crop Group

(i) *Representative commodities*. Any one blackberry or any one raspberry; highbush blueberry; elderberry or mulberry; grape; fuzzy kiwifruit, and strawberry.

(ii) *Table*. The following Table 1 lists all the commodities listed in Crop Group 13-07 and identifies the related crop subgroups.

TABLE 1—CROP GROUP 13-07: BERRY AND SMALL FRUIT CROP GROUP

Commodities	Related crop subgroups
Amur river grape (*Vitis amurensis Rupr*)	13-07D, 13-07E, 13-07F
Aronia berry (*Aronia* spp.)	13-07B
Bayberry (*Myrica* spp.)	13-07C
Bearberry (*Arctostaphylos uva-ursi*)	13-07G, 13-07H
Bilberry (*Vaccinium myrtillus L.)*	13-07G, 13-07H
Blackberry (*Rubus* spp.) (including Andean blackberry, arctic blackberry, bingleberry, black satin berry, boysenberry, brombeere, California blackberry, Chesterberry, Cherokee blackberry, Cheyenne blackberry, common blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, evergreen blackberry, Himalayaberry, hullberry, lavacaberry, loganberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, mora, mures deronce, nectarberry, Northern dewberry, olallieberry, Oregon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, Southern dewberry, tayberry, youngberry, zarzamora, and cultivars, varieties and/or hybrids of these.)	13-07A
Blueberry, highbush (*Vaccinium* spp.)	13-07B
Blueberry, lowbush (*Vaccinium angustifolium* Aiton)	13-07B
Buffalo currant (*Ribes aureum* Pursh)	13-07B
Buffaloberry (*Shepherdia argentea* (Pursh) Nutt.)	13-07C
Che (*Cudrania tricuspidata* Bur. Ex Lavallee)	13-07C
Chilean guava (*Myrtus ugni* Mol.)	13-07B
Chokecherry (*Prunus virginiana* L.)	13-07C
Cloudberry (*Rubus chamaemorus* L.)	13-07G, 13-07H
Cranberry (*Vaccinium macrocarpon* Aiton)	13-07G, 13-07H
Currant, black (*Ribes nigrum* L.)	13-07B
Currant, red (*Ribes rubrum* L.)	13-07B
Elderberry (*Sambucus* spp.)	13-07B, 13-07C
European barberry (*Berberis vulgaris* L.)	13-07B
Gooseberry (*Ribes* spp.)	13-07B, 13-07D, 13-07E, 13-07F
Grape (Vitis spp.)	13-07D, 13-07F
Highbush cranberry (*Viburnum opulus* L. var. *Americanum* Aiton)	13-07B
Honeysuckle, edible (*Lonicera caerula L*. var. *emphyllocalyx* Nakai, *Lonicera caerula L* var . *edulis Turcz. ex herder*)	13-07B
Huckleberry (*Gaylussacia* spp.)	13-07B
Jostaberry (*Ribes x nidigrolaria* Rud. Bauer and A. Bauer)	13-07B
Juneberry (Saskatoon berry) (*Amelanchier* spp.)	13-07B, 13-07C
Kiwifruit, fuzzy (*Actinidia deliciosa* A. Chev.) (C.F. Liang and A.R. Fergusons, *Actinida chinensis* Planch.)	13-07D, 13-07E
Kiwifruit, hardy (*Actinidia arguta* (Siebold and Zucc.) Planch. ex Miq)	13-07D, 13-07E, 13-07F
Lingonberry (*Vaccinium vitis-idaea* L.)	13-07B, 13-07G 13-07H
Maypop (*Passiflora incarnata* L.)	13-07E, 13-07F
Mountain pepper berries (*Tasmannia lanceolata*)(Poir.) A.C.Sm.	13-07C
Mulberry (*Morus* spp.)	13-07C
Muntries (*Kunzea pomifera* F. Muell.)	13-07G, 13-07H
Native currant (*Acrotriche depressa* R. BR.)	13-07B
Partridgeberry (*Mitchella repens* L.)	13-07G, 13-07H
Phalsa (*Grewia subinaequalis* DC.)	13-07C
Pincherry (*Prunus pensylvanica* L.f.)	13-07C
Raspberry, black and red (*Rubus* spp.)	13-07A
Riberry (*Syzygium luehmannii*)	13-07C
Salal (*Gaultheria shallon* Pursh.)	13-07B, 13-07C

TABLE 1—CROP GROUP 13-07: BERRY AND SMALL FRUIT CROP GROUP—Continued

Commodities	Related crop subgroups
Schisandra berry (Schisandra chinensis (Turcz.) Baill.)	13-07D, 13-07E, 13-07F
Sea buckthorn (*Hippophae rhamnoides* L.)	13-07B
Serviceberry (*Sorbus* spp.)	13-07C
Strawberry (*Fragaria x ananassa* Duchesne)	13-07G
Wild raspberry (*Rubus muelleri* Lefevre ex P.J. Mull)	13-07A
Cultivars, varieties, and/or hybrids of these.	

(iii) *Table.* The following Table 2 identifies the crop subgroups for Crop Group 13-07, specifies the representative commodities for each subgroup and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 13-07: SUBGROUP LISTING

Representative commodities	Commodities
Crop Subgroup 13-07A. Caneberry subgroup	
Any one blackberry or any one raspberry..	Blackberry; loganberry; raspberry, red and black; wild raspberry; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 13-07B. Bushberry subgroup.	
Blueberry, highbush.	Aronia berry; blueberry, highbush; blueberry, lowbush; buffalo currant; Chilean guava; currant, black; currant, red; elderberry; European, barberry; gooseberry; cranberry, highbush; honeysuckle, edible; huckleberry; jostaberry; Juneberry; lingonberry; native currant; salal; sea buckthorn; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 13-07C. Large shrub/tree berry subgroup.	
Elderberry or mulberry.	Bayberry; buffaloberry; che; chokecherry; elderberry; Juneberry; mountain pepper berries; mulberry; phalsa; pincherry; riberry; salal; serviceberry; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 13-07D. Small fruit vine climbing subgroup.	
Grape and fuzzy kiwifruit.	Amur river grape; gooseberry; grape; kiwifruit, fuzzy; kiwifruit, hardy; Maypop; schisandra berry; cultivars, varieties, and /or hybrids of these.
Crop Subgroup 13-07E. Small fruit vine climbing subgroup, except grape.	
Fuzzy kiwifruit.	Amur river grape; gooseberry; kiwifruit, fuzzy; kiwifruit, hardy; Maypop; schisandra berry; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 13-07F. Small fruit vine climbing subgroup except fuzzy kiwifruit.	
Grape.	Amur river grape; gooseberry; grape; kiwifruit, hardy; Maypop; schisandra berry; cultivars varieties, and/or hybrids of these.
Crop Subgroup 13-07G. Low growing berry subgroup.	
Strawberry.	Bearberry; bilberry; blueberry, lowbush; cloudberry; cranberry; lingonberry; muntries; partridgeberry; strawberry; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 13-07H. Low growing berry subgroup, except strawberry.	
Cranberry	Bearberry; bilberry; blueberry, lowbush; cloudberry; cranberry; lingonberry; muntries; partridgeberry; cultivars, varieties, and/or cultivars of these.

(16) *Crop Group 14.* Tree Nuts Group.

(i) *Representative commodities.* Almond and pecan.

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 14:

CROP GROUP 14: TREE NUTS—COMMODITIES

Almond (*Prunus dulcis*)
Beech nut (*Fagus* spp.)
Brazil nut (*Bertholletia excelsa*)
Butternut (*Juglans cinerea*)
Cashew (*Anacardium occidentale*)
Chestnut (*Castanea* spp.)
Chinquapin (*Castanea pumila*)
Filbert (hazelnut) (*Corylus* spp.)
Hickory nut (*Carya* spp.)
Macadamia nut (bush nut) (*Macadamia* spp.)
Pecan (*Carya illinoensis*)
Walnut, black and English (Persian) (*Juglans* spp.)

(17) *Crop Group 15.* Cereal Grains Group.

(i) *Representative commodities.* Corn (fresh sweet corn and dried field corn), rice, sorghum, and wheat.

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 15:

CROP GROUP 15: CEREAL GRAINS—COMMODITIES

Barley (*Hordeum* spp.)
Buckwheat (*Fagopyrum esculentum*)
Corn (*Zea mays*)
Millet, pearl (*Pennisetum glaucum*)
Millet, proso (*Panicum milliaceum*)
Oats (*Avena* spp.)
Popcorn (*Zea mays* var. *everta*)
Rice (*Oryza sativa*)
Rye (*Secale cereale*)
Sorghum (milo) (*Sorghum* spp.)
Teosinte (*Euchlaena mexicana*)
Triticale (*Triticum-Secale* hybrids)
Wheat (*Triticum* spp.)
Wild rice (*Zizania aquatica*)

(18) *Crop Group 16.* Forage, Fodder and Straw of Cereal Grains Group.

(i) *Representative commodities.* Corn, wheat, and any other cereal grain crop.

(ii) *Commodities.* The commodities included in Crop Group 16 are: Forage, fodder, and straw of all commodities included in the group cereal grains group.

(19) *Crop Group 17.* Grass Forage, Fodder, and Hay Group.

(i) *Representative commodities.* Bermuda grass; bluegrass; and bromegrass or fescue.

(ii) *Commodities.* The commodities included in Crop Group 17 are: Any grass, *Gramineae* family (either green or cured) except sugarcane and those included in the cereal grains group, that will be fed to or grazed by livestock, all pasture and range grasses and grasses grown for hay or silage.

(20) *Crop Group 18.* Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group.

(i) *Representative commodities.* Alfalfa and clover (*Trifolium* spp.)

(ii) *Commodities.* The following is a list of all the commodities included in Crop Group 18:

CROP GROUP 18: NONGRASS ANIMAL FEEDS (FORAGE, FODDER, STRAW, AND HAY) GROUP—COMMODITIES

Alfalfa (*Medicago sativa* subsp. *sativa*)
Bean, velvet (*Mucuna pruriens* var. *utilis*)
Clover (*Trifolium* spp., *Melilotus* spp.)
Kudzu (*Pueraria lobata*)
Lespedeza (*Lespedeza* spp.)
Lupin (*Lupinus* spp.)
Sainfoin (*Onobrychis viciifolia*);
Trefoil (*Lotus* spp.)
Vetch (*Vicia* spp.)
Vetch, crown (*Coronilla varia*)
Vetch, milk (*Astragalus* spp).

(21) *Crop Group 19.* Herbs and Spices Group.

(i) *Representative commodities.* Basil (fresh and dried); black pepper; chive; and celery seed or dill seed.

(ii) *Table.* The following table 1 lists all the commodities included in Crop Group 19 and identifies the related subgroups.

TABLE 1—CROP GROUP 19: HERBS AND SPICES GROUP

Commodities	Related crop subgroups
Allspice (*Pimenta dioica*)	19B
Angelica (*Angelica archangelica*)	19A
Anise (anise seed) (*Pimpinella anisum*)	19B
Anise, star (*Illicium verum*)	19B
Annatto (seed)	19B
Balm (lemon balm) (*Melissa officinalis*)	19A
Basil (*Ocimum basilicum*)	19A
Borage (*Borago officinalis*)	19A
Burnet (*Sanguisorba minor*)	19A
Camomile (*Anthemis nobilis*)	19A
Caper buds (*Capparis spinosa*)	19B
Caraway (*Carum carvi*)	19B
Caraway, black (*Nigella sativa*)	19B
Cardamom (*Elettaria cardamomum*)	19B
Cassia bark (*Cinnamomum aromaticum*)	19B
Cassia buds (*Cinnamomum aromaticum*)	19B
Catnip (*Nepeta cataria*)	19A
Celery seed (*Apicum graveolens*)	19B
Chervil (dried) (*Anthriscus cerefolium*)	19A
Chive (*Allium schoenoprasum*)	19A
Chive, Chinese (*Allium tuberosum*)	19A
Cinnamon (*Cinnamomum verum*)	19B
Clary (*Salvia sclarea*)	19A
Clove buds (*Eugenia caryophyllata*)	19B
Coriander (cilantro or Chinese parsley) (leaf) (*Coriandrum sativum*)	19A
Coriander (cilantro) (seed) (*Coriandrum sativum*)	19B
Costmary (*Chrysanthemum balsamita*)	19A
Culantro (leaf) (*Eryngium foetidum*)	19A
Culantro (seed) (*Eryngium foetidum*)	19B
Cumin (*Cuminum cyminum*)	19B
Curry (leaf) (*Murraya koenigii*)	19A
Dill (dillweed) (*Anethum graveolens*)	19A
Dill (seed) (*Anethum graveolens*)	19B
Fennel (common) (*Foeniculum vulgare*)	19B
Fennel, Florence (seed) (*Foeniculum vulgare* Azoricum Group)	19B
Fenugreek (*Trigonella foenumgraecum*)	19B
Grains of paradise (*Aframomum melegueta*)	19B
Horehound (*Marrubium vulgare*)	19A
Hyssop (*Hyssopus officinalis*)	19A
Juniper berry (*Juniperus communis*)	19B
Lavender (*Lavandula officinalis*)	19A
Lemongrass (*Cymbopogon citratus*)	19A
Lovage (leaf) (*Levisticum officinale*)	19A
Lovage (seed) (*Levisticum officinale*)	19B
Mace (*Myristica fragrans*)	19B

TABLE 1—CROP GROUP 19: HERBS AND SPICES GROUP—Continued

Commodities	Related crop sub-groups
Marigold (*Calendula officinalis*)	19A
Marjoram (*Origanum spp.*) (includes sweet or annual marjoram, wild marjoram or oregano, and pot marjoram)	19A
Mustard (seed) (*Brassica* juncea, *B.* hirta, *B.* nigra)	19B
Nasturtium (*Tropaeolum majus*)	19A
Nutmeg (*Myristica fragrans*)	19B
Parsley (dried) (*Petroselinum crispum*)	19A
Pennyroyal (*Mentha pulegium*)	19A
Pepper, black (*Piper nigrum*)	19B
Pepper, white	19B
Poppy (seed) (*Papaver somniferum*)	19B
Rosemary (*Rosemarinus officinalis*)	19A
Rue (*Ruta graveolens*)	19A
Saffron (*Crocus sativus*)	19B
Sage (*Salvia officinalis*)	19A
Savory, summer and winter (*Satureja spp.*)	19A

TABLE 1—CROP GROUP 19: HERBS AND SPICES GROUP—Continued

Commodities	Related crop sub-groups
Sweet bay (bay leaf) (*Laurus nobilis*)	19A
Tansy (*Tanacetum vulgare*)	19A
Tarragon (*Artemisia dracunculus*)	19A
Thyme (*Thymus spp.*)	19A
Vanilla (*Vanilla planifolia*)	19B
Wintergreen (*Gaultheria procumbens*)	19A
Woodruff (*Galium odorata*)	19A
Wormwood (*Artemisia absinthium*)	19A

(iii) *Table.* The following table 2 identifies the crop subgroups for Crop Group 19, specifies the representative commodities for each subgroup, and lists all the commodities included in each subgroup.

TABLE 2—CROP GROUP 19 SUBGROUPS

Representative commodities	Commodities
Crop Subgroup 19A. Herb subgroup.	
Basil (fresh and dried) and chive.	Angelica; balm; basil; borage; burnet; camomile; catnip; chervil (dried); chive; chive, Chinese, clary; coriander (leaf); costmary; culantro (leaf); curry (leaf); dillweed; horehound; hyssop; lavender; lemongrass; lovage (leaf); marigold; marjoram (*Origanum* spp.); nasturtium; parsley (dried); pennyroyal; rosemary; rue; sage; savory, summer and winter; sweet bay; tansy; tarragon; thyme; wintergreen; woodruff; and wormwood.
Crop Subgroup 19B. Spice subgroup.	
Black pepper; and celery seed or dill seed.	Allspice; anise (seed); anise, star; annatto (seed); caper (buds); caraway; caraway, black; cardamom; cassia (buds); celery (seed); cinnamon; clove (buds); coriander (seed); culantro (seed); cumin; dill (seed); fennel, common; fennel, Florence (seed); fenugreek; grains of paradise; juniper (berry); lovage (seed); mace; mustard (seed); nutmeg; pepper, black; pepper, white; poppy (seed); saffron; and vanilla.

(22) *Crop Group 21.* Edible fungi Group.

(i) *Representative commodities.* White button mushroom and any one oyster mushroom or any Shiitake mushroom.

(ii) *Table.* The following is a list of all the commodities in Crop Group 21. There are no related subgroups.

CROP GROUP 21—EDIBLE FUNGI GROUP—COMMODITIES

Blewitt (*Lepista nuda*)
Bunashimeji (*Hypsizygus marrmoreus*)
Chinese mushroom (*Volvariella volvacea*) (Bull.) Singer
Enoki (*Flammulina velutipes*) (Curt.) Singer
Hime-Matsutake (*Agaricus blazei*) Murill
Hirmeola (*Auricularia auricular*)
Maitake (*Grifola frondosa*)
Morel (*Morchella spp.*)
Nameko (*Pholiota nameko*)
Net Bearing (*Dictyophora*)
Oyster mushroom (*Pleurotus spp.*)
Pom Pom (*Hericium erinaceus*)
Reishi mushroom (*Ganoderma lucidum* (Leyss. Fr.) Karst.)
Rodman's agaricus (*Agaricus bitorquis*) (Quel.) Saccardo
Shiitake mushroom (*Lentinula edodes* (Berk.) Pegl.)
Shimeji (*Tricholoma conglobatum*)
Stropharia (*Stropharia spp.*)
Truffle (*Tuber spp.*)
White button mushroom (*Agaricus bisporous* (Lange) Imbach)
White Jelly Fungi (*Tremella fuciformis*)

[60 FR 26635, May 17, 1995, as amended at 72 FR 69156, 69157, Dec. 7, 2007; 73 FR 52, Jan. 2, 2008]

Subpart C—Specific Tolerances

EDITORIAL NOTE: Nomenclature changes to subpart C appear at 67 FR 41803–41808, June 19, 2002; 67 FR 42393–42397, June 21, 2002; 68 FR 39430–39435, July 1, 2003; 71 FR 74804–74812, Dec. 13, 2006; 72 FR 53137–53151, Sept. 18, 2007; 72 FR 61536, Oct. 31, 2007; and 73 FR 60155–60157, Oct. 10, 2008.

§ 180.101 Specific tolerances; general provisions.

(a) The tolerances established for pesticide chemicals in this subpart C apply to residues resulting from their application prior to harvest or slaughter, unless otherwise stated. Tolerances are expressed in terms of parts by weight of the pesticide chemical per one million parts by weight of the raw agricultural commodity.

(b) The poisonous and deleterious substances for which tolerances are established by the regulations in this subpart C are named by their common names wherever practicable, otherwise by their chemical names.

(c) The analytical methods to be used for determining whether pesticide residues, including negligible residues, in or on raw agricultural commodities are in compliance with the tolerances established in this part 180 are identified among the methods contained or referenced in the Food and Drug Administration's ''Pesticide Analytical Manual'' which is available from the Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, DC 20204.

§ 180.103 Captan; tolerances for residues.

(a)(1) *General.* Tolerances are established for residues of the fungicide, captan (N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide) in or on the following commodities:

Commodity	Parts per million
Almond	0.25
Almond, hulls	75.0
Animal feed, nongrass, group 18	0.05
Apple	25.0
Apricot	10.0
Blueberry	20.0
Caneberry, subgroup 13A	25.0
Cherry, sweet	50.0
Cherry, tart	50.0
Cotton, undelinted seed	0.05
Dill, seed	0.05
Flax, seed	0.05
Grape	25.0
Grain, cereal, forage, fodder and straw, group 16	0.05
Grain, cereal, group 15	0.05
Grass, forage	0.05
Grass, hay	0.05
Nectarine	25.0
Okra	0.05
Peach	15.0
Peanut	0.05
Peanut, hay	0.05
Pear	25.0
Plum, prune, fresh	10.0
Rapeseed, forage	0.05
Rapeseed, seed	0.05
Safflower, seed	0.05
Sesame, seed	0.05
Strawberry	20.0
Sunflower, seed	0.05
Vegetable, brassica leafy, group 5	0.05
Vegetable, bulb, group 3	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, foliage of legume, group 7	0.05
Vegetable, fruiting, group 8	0.05
Vegetable, leafy, except brassica, group 4	0.05
Vegetable, leaves of root and tuber, group 2	0.05
Vegetable, legume, group 6	0.05
Vegetable, root and tuber, group 1	0.05

(2) Tolerances are established for the combined residues of the fungicide, captan (N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide) and its metabolite 1,2,3,6-tetrahydrophthalimide (THPI), measured at THPI, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.15
Cattle, meat	0.20
Cattle, meat byproducts	0.30
Goat, fat	0.15
Goat, meat	0.20
Goat, meat byproducts	0.30
Hog, fat	0.15
Hog, meat	0.20
Hog, meat byproducts	0.30
Horse, fat	0.15
Horse, meat	0.20
Horse, meat byproducts	0.30
Milk	0.10
Sheep, fat	0.15
Sheep, meat	0.20
Sheep, meat byproducts	0.30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 52016, Sept. 12, 2007]

§ 180.106 Diuron; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide diuron, 3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline in or on food commodities, as follows:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	2.0
Apple	0.1
Artichoke, globe	1
Asparagus	7
Banana	0.1
Berry group 13	0.1
Cattle, fat	1
Cattle, meat	1
Cattle, meat byproducts	1
Citrus, oil	3.0
Corn, field, grain	0.1
Corn, pop, grain	0.1
Cotton, undelinted seed	0.2
Fish – freshwater finfish, farm raised	2.0
Fruit, citrus, group 10, except lemon	0.05
Goat, fat	1
Goat, meat	1
Goat, meat byproducts	1
Grain, aspirated fractions	5.0
Grape	0.05
Grass, forage, except bermudagrass	2
Grass, hay, except bermudagrass	2
Hazelnut	0.1
Hog, fat	1
Hog, meat	1
Hog, meat byproducts	1
Horse, fat	1
Horse, meat	1
Horse, meat byproducts	1
Lemon	0.5
Nut, macadamia	0.05
Olive	1
Papaya	0.5
Peach	0.1
Pear	1
Pea, field, seed	0.1
Pea, field, vines	2
Pea, field, hay	2
Pecan	0.05
Peppermint, tops	1.5
Pineapple	0.1
Pineapple, process residue	0.4
Sheep, fat	1
Sheep, meat	1
Sheep, meat byproducts	1
Sorghum, grain, forage	2
Sorghum, grain, grain	0.5
Sorghum, grain, stover	2
Spearmint, tops	1.5
Sugarcane, cane	0.2
Sugarcane, molasses	0.7
Walnut	0.05
Wheat, bran	0.7
Wheat, forage	2
Wheat, grain	0.5
Wheat, hay	2
Wheat, straw	1.5

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide diuron and its metabolites convertible to 3,4-dichloroaniline in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation date
Catfish	2.0	06/30/08

(c) *Tolerances with regional registrations.* Tolerances with a regional registration as defined in § 180.1(n) are established for the combined residues of the herbicide diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline) in or on the raw agricultural commodities:

Commodity	Parts per million
Barley, bran	0.7
Barley, grain	0.2
Barley, hay	2
Barley, straw	1.5
Cactus	0.05
Clover, forage	0.1
Clover, hay	1.0
Oat, forage	2
Oat, grain	0.1
Oat, hay	2
Oat, straw	1.5
Trefoil, forage	0.1
Trefoil, hay	1.5
Vetch, forage	0.1
Vetch, hay	1.5

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 2164, Jan. 14, 1998, as amended at 63 FR 57072, Oct. 26, 1998; 64 FR 41305, July 30, 1999; 66 FR 28671, May 24, 2001; 67 FR 46883, July 17, 2002; 69 FR 71717, Dec. 10, 2004; 72 FR 32540, June 13, 2007; 72 FR 35666, June 29, 2007; 73 FR 54958, Sept. 24, 2008]

§ 180.108 Acephate; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of acephate *per se* (*O,S*-dimethyl acetylphosphoramidothioate) in or on the following food commodities [1]:

Commodity [1]	Parts per million
Bean, dry, seed	3.0
Bean, succulent	3.0
Brussels sprouts	3.0

Commodity [1]	Parts per million
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Cauliflower	2.0
Celery	10
Cotton, hulls	1.0
Cotton, meal	1.0
Cotton, undelinted seed	0.5
Cranberry	0.5
Egg	0.1
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.1
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.1
Lettuce, head	10
Milk	0.1
Peanut	0.2
Pepper	4.0
Peppermint, tops	27
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Sheep, fat	0.1
Sheep, meat	0.1
Sheep, meat byproducts	0.1
Spearmint, tops	27
Soybean, seed	1.0

[1]Residues of the acephate metabolite, methamidophos, are regulated under 40 CFR 180.315

(2) A food tolerance of 0.02 ppm is established for residues of acephate *per se* (*O,S*-dimethyl acetylphosphoramidothioate) as follows:

(i) In or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments.

(ii) The acephate may be present as a residue from applications of acephate in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries in accordance with the following prescribed conditions:

(A) Application shall be limited solely to spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and served. Spray concentration shall be limited to a maximum of 1.0 percent active ingredient. For crack and crevice treatments, equipment capable of delivering a pin-stream of insecticide shall be used. For spot treatments, a coarse, low-pressure spray shall be used to avoid atomization or splashing of the spray. Contamination of food or food-contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* Tolerances with regional registration, as defined in § 180.1(m), are established for residues of acephate *per se* (*O,S*-dimethyl acetylphosphoramidothioate) in or on the following food commodities:

Commodity	Parts per million
Nut, macadamia	0.05

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 13542, Mar. 20, 1998, as amended at 67 FR 49615, July 31, 2002; 73 FR 5108, Jan. 29, 2008]

§ 180.110 Maneb; tolerances for residues.

(a) *General.* Tolerances for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, are established in or on raw agricultural commodities in the following table:

Commodity	Parts per million	Expiration/ Revocation Date
Almond	0.1	None
Apple	2	None
Apricot	10	None
Banana (not more than 0.5 part per million) shall be in the pulp after peel is removed and discarded (preharvest application only)	4	None
Bean, dry, seed	7	None
Bean, succulent	10	None
Beet, sugar, tops	45	None
Broccoli	10	None
Brussels sprouts	10	None
Cabbage	10	None
Cabbage, chinese	10	None
Carrot, roots	7	None
Cauliflower	10	None
Celery	5	None
Collards	10	None
Corn, sweet, kernel plus cob with husks removed	5	None
Cranberry	7	None
Cucumber	4	None

Commodity	Parts per million	Expiration/ Revocation Date
Eggplant	7	None
Endive	10	None
Fig	7	None
Grape	7	None
Kale	10	None
Kohlrabi	10	None
Lettuce	10	None
Melon	4	None
Mustard greens	10	None
Nectarine	10	None
Onion	7	None
Papaya	10	None
Peach	10	None
Pepper	7	None
Potato	0.1	None
Pumpkin	7	None
Squash, summer	4	None
Squash, winter	4	None
Tomato	4	None
Turnip, greens	10	None
Turnip, roots	7	None

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenethiourea in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Walnut	0.05	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 49924, Sept. 24, 1997, as amended at 63 FR 57072, Oct. 26, 1998; 64 FR 13103, Mar. 17, 1999; 64 FR 72284, Dec. 27, 1999; 66 FR 64773, Dec. 14, 2001; 68 FR 37764, June 25, 2003; 70 FR 37696, June 30, 2005; 70 FR 75739, Dec. 21, 2005; 74 FR 636, Jan. 7, 2009]

§ 180.111 Malathion; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide malathion (*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate) in or on the following food commodities:

Commodity	Parts per million
Alfalfa	135
Almond, hulls	50
Almond, postharvest	8
Apple	8
Apricot	8
Asparagus	8
Avocado	8
Barley, grain, postharvest	8
Bean	8
Beet (including tops)	8
Beet, sugar, roots	1
Beet, sugar, tops	8
Blackberry	8
Blueberry	8
Boysenberry	8
Carrot, roots	8
Cattle, fat (PRE-S)	4
Cattle, meat byproducts [1] (PRE-S)	4
Cattle, meat [1] (PRE-S)	4
Chayote, fruit	8
Chayote, roots	8
Cherry	8
Chestnut	1
Clover	135
Corn, forage	8
Corn, grain, postharvest	8
Corn, sweet, kernel plus cob with husks removed	2
Cotton, undelinted seed	2
Cowpea, forage	135
Cowpea, hay	135
Cranberry	8
Cucumber	8
Currant	8
Date, dried fruit	8
Dewberry	8
Eggplant	8
Egg (from application to poultry)	0.1
Fig	8
Flax, seed	0.1
Garlic	8
Goat, fat (PRE-S)	4
Goat, meat byproducts [1] (PRE-S)	4
Goat, meat [1] (PRE-S)	4
Gooseberry	8
Grapefruit	8
Grape	8
Grass, forage	135
Grass, hay	135
Guava	8
Hazelnut	1
Hog, fat (PRE-S)	4
Hog, meat byproducts [1] (PRE-S)	4
Hog, meat [1] (PRE-S)	4
Hop, dried cones	1
Horseradish	8
Horse, fat (PRE-S)	4
Horse, meat byproducts [1] (PRE-S)	4
Horse, meat [1] (PRE-S)	4
Kumquat	8
Leek	8
Lemon	8
Lentil, seed	8
Lespedeza, hay	135
Lime	8
Loganberry	8
Lupin, seed	8
Mango	8
Melon	8
Milk, fat (from application to dairy cows)	0.5
Mushroom	8
Nectarine	8
Nut, macadamia	1

Commodity	Parts per million
Oat, grain, postharvest	8
Okra	8
Onion (including green onion)	8
Orange, sweet	8
Papaya	1
Parsnip	8
Passionfruit	8
Pea	8
Pea, field, hay	8
Pea, field, vines	8
Peach	8
Peanut, hay	135
Peanut, postharvest	8
Pear	8
Pecan	8
Pepper	8
Peppermint, tops	8
Pineapple	8
Plum	8
Potato	8
Poultry, fat (PRE-S)	4
Poultry, meat byproducts [1] (PRE-S)	4
Poultry, meat [1] (PRE-S)	4
Plum, prune	8
Pumpkin	8
Quince	8
Radish	8
Raspberry	8
Rice, grain, postharvest	8
Rice, wild	8
Rutabagas	8
Rye, grain, postharvest	8
Safflower, seed	0.2
Salsify (including tops)	8
Shallot, bulb	8
Sheep, fat (PRE-S)	4
Sheep, meat byproducts [1] (PRE-S)	4
Sheep, meat [1] (PRE-S)	4
Sorghum, forage	8
Sorghum, grain, grain, postharvest	8
Soybean (dry and succulent)	8
Soybean, forage	135
Soybean, hay	135
Spearmint, tops	8
Squash, summer and winter	8
Strawberry	8
Sunflower, seed (Post-H)	8
Sweet potato, roots	1
Tangerine	8
Tomato	8
Trefoil, forage	135
Trefoil, hay	135
Turnip (including tops)	8
Vegetable, brassica, leafy, group 5	8
Vegetables, leafy, except brassica, group 4	8
Vetch, hay	135
Walnut	8
Wheat, grain, postharvest	8

[1] The tolerance level shall not be exceeded in any cut of meat or in any meat byproducts from cattle, goat, hog, horse, poultry, or sheep.

(2) Malathion may be safely used in accordance with the following conditions:

(i) It is incorporated into paper trays in amounts not exceeding 100 milligrams per square foot.

(ii) Treated paper trays are intended for use only in the drying of grape (raisins).

(iii) Total residues of malathion resulting from drying of grape on treated trays and from application to grape before harvest shall not exceed 12 parts per million on processed ready-to-eat raisins.

(3) Residues of malathion in safflower, refined oil from application to the growing safflower plant shall not exceed 0.6 parts per million.

(4) Malathion may be safely used for the control of insects during the drying of grape (raisins) in compliance with paragraph (a)(2) of this section by incorporation into paper trays in amounts not exceeding 100 milligrams per square foot.

(5) Malathion (*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate) may be safely used in feed in accordance with the following conditions.

(i) A tolerance of 50 parts per million is established for residues of malathion in citrus, dried pulp for cattle feed, when present as the result of the application of the pesticide to bagged citrus pulp during storage. Whether or not tolerances for residues of malathion on the fresh fruit have been established under section 408 of the Act, the total residue of malathion in the citrus, dried pulp shall not exceed 50 parts per million.

(ii) A tolerance of 10 parts per million is established for malathion in nonmedicated cattle feed concentrate blocks resulting from its application as a pesticide to paper used in packaging the nonmedicated cattle feed concentrate blocks.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 22974, May 30, 1978, as amended at 43 FR 45584, Oct. 3, 1978; 44 FR 38844, July 3, 1979; 45 FR 76145, Nov. 18, 1980; 47 FR 42738, Sept. 29, 1982; 47 FR 55226, Dec. 8, 1982; 52 FR 45183, Nov. 25, 1987; 62 FR 66023, 66025, Dec. 17, 1997; 65 FR 33694, May 24, 2000; 72 FR 35665, June 29, 2007; 73 FR 54959, Sept. 24, 2008]

§ 180.114 Ferbam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide

ferbam (ferric dimethyldithiocarbamate), calculated as carbon disulfide, in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Apple	4.0 [1]	None
Bean	7.0 [1]	10/27/07
Cabbage	7.0 [1]	10/27/07
Cherry	4.0 [1]	None
Cranberry	4.0 [1]	None
Fruit, citrus, group 10	4.0 [1]	None
Grape	4.0 [1]	None
Lettuce	7.0 [1]	10/27/07
Nectarine	4.0 [1]	None
Peach	4.0 [1]	None
Pear	4.0 [1]	None
Raspberry	7.0 [1]	10/27/07

[1] Some of these tolerances were established on the basis of data acquired at the public hearings held in 1950 (formerly § 180.101) and the remainder were established on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Pub. L. 518, 83d Congress (68 Stat. 511)

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(m), are established for residues of the fungicide ferbam (ferric dimethyldithiocarbamate), calculated as carbon disulfide, in or on the following food commodities:

Commodity	Parts per million
Mango	4.0 [1]

[1] This tolerance was established on the basis of data acquired at the public hearings held in 1950 (formerly § 180.101) and the remainder was established on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Pub. L. 518, 83d Congress (68 Stat. 511)

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 57072, Oct. 26, 1998, as amended at 72 FR 53453, Sept. 19, 2007]

§ 180.116 Ziram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide ziram (zinc dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, in or on the following food commodities:

Commodity	Parts per million
Almond	0.1 [1]
Apple	7.0 [1]
Apricot	7.0 [1]
Blackberry	7.0 [1]
Blueberry	7.0 [1]
Cherry, sweet	7.0 [1]
Cherry, tart	7.0 [1]
Grape	7.0
Huckleberry	7.0
Peach	7.0
Pear	7.0 [1]
Pecan	0.1
Quince	7.0 [1]
Strawberry	7.0
Tomato	7.0 [1]

[1] Some of these tolerances were established on the basis of data acquired at the public hearings held in 1950 (formerly § 180.101) and the remainder were established on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Public Law 518, 83d Congress (68 Stat. 511).

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39437, July 1, 2003, as amended at 71 FR 54432, Sept. 15, 2006; 73 FR 54959, Sept. 24, 2008]

§ 180.117 S-Ethyl dipropylthiocarbamate; tolerances for residues.

Tolerances are established for negligible residues (N) of the herbicide S-ethyl dipropylthiocarbamate in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.1(N)
Asparagus	0.1(N)
Castorbean, seed	0.1(N)
Cotton, forage	0.1(N)
Cotton, undelinted seed	0.1(N)
Flax, seed	0.1(N)
Fruit, citrus	0.1(N)
Fruit, small	0.1(N)
Grain, crop	0.1(N)
Grass, forage	0.1(N)
Legume, forage	0.1(N)
Nut	0.1(N)
Pineapple	0.1(N)
Safflower, seed	0.1(N)
Strawberry	0.1(N)
Sunflower, seed	0.1(N)
Vegetable, fruiting	0.1(N)
Vegetable, leafy	0.1(N)
Vegetable, root	0.1(N)
Vegetable, seed and pod	0.1(N)

[42 FR 9178, Feb. 15, 1977]

§ 180.121 Methyl parathion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide parathion *O, O*-Dimethyl-*O*-p-nitrophenyl thiophosphate (the methyl

homolog of parathion) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	1.25	None
Alfalfa, hay	5.0	None
Almond	0.1	None
Almond, hulls	3.0	None
Barley	1.0	None
Bean, dry, seed	1.0	1/24/09
Beet, sugar, roots	0.1	1/24/09
Beet, sugar, tops	0.1	1/24/09
Cabbage	1.0	1/24/09
Corn	1.0	None
Corn, field, forage	1.0	None
Corn, sweet, forage	1.0	None
Cotton, undelinted seed	0.75	None
Grass, forage	1.0	None
Hop, dried cones	1.0	1/24/09
Oat	1.0	None
Onion	1.0	None
Peanut	1.0	None
Pea, dry, seed	1.0	1/24/09
Pea, field, vines	1.0	None
Pecan	0.1	1/24/09
Potato	0.1	None
Rapeseed, seed	0.2	None
Rice, grain	1.0	None
Soybean, hay	1.0	None
Soybean, seed	0.1	None
Sunflower, seed	0.2	None
Sweet potato, roots	0.1	None
Walnut	0.1	None
Wheat	1.0	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

(e) *Revoked tolerances subject to the channel of trade provisions.* The following table lists commodities for which methyl parathion use was unlawful after December 31, 1999, and the revoked tolerances. Commodities with residues of methyl parathion resulting from lawful use are subject to the channels of trade provisions of section 408(1)(5) of the FFDCA.

Commodity	Parts per million
Apple	1
Artichoke, globe	1
Beet, garden, tops	1
Beet, garden, roots	1
Broccoli	1
Brussels sprouts	1
Carrot, roots	1
Cauliflower	1
Celery	1
Cherry	1
Collards	1
Grape	1
Kale	1
Kohlrabi	1
Lettuce	1
Mustard greens	1
Nectarine	1
Peach	1
Pear	1
Plum, prune, fresh	1
Rutabaga, roots	1
Rutabaga tops	1
Spinach	1
Tomato	1
Trefoil, forage	1.25
Trefoil, hay	5
Turnip, greens	1
Turnip, roots	1
Vegetable, brassica, leafy, group 5	1
Vetch	1

[66 FR 1245, Jan. 5, 2001, as amended at 66 FR 38955, July 26, 2001; 67 FR 38603, June 5, 2002; 72 FR 35666, June 29, 2007; 73 FR 54959, Sept. 24, 2008]

§ 180.122 Parathion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide parathion (*O, O*-Diethyl-*O*-p-nitrophenyl thiophosphate) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	1.25	12/31/05
Alfalfa, hay	5.0	12/31/05
Barley	1.0	12/31/05
Corn	1.0	12/31/05
Corn, forage	1.0	12/31/05
Cotton, undelinted seed	0.75	12/31/05
Rapeseed, seed	0.2	12/31/05
Sorghum, forage	3.0	12/31/05
Sorghum, grain, grain	0.1	12/31/05
Sorghum, grain, stover	3.0	12/31/05
Soybean	0.1	12/31/05
Soybean, hay	1.0	12/31/05
Sunflower, seed	0.2	12/31/05
Wheat	1.0	12/31/05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 38603, June 5, 2002]

§ 180.123 Inorganic bromide residues resulting from fumigation with methyl bromide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of inorganic bromides (calculated as Br) in or on the

following food commodities which have been fumigated with the antimicrobial agent and insecticide methyl bromide after harvest (with the exception of strawberry):

Commodity	Parts per million
Alfalfa, hay, postharvest	50.0
Almond, postharvest	200.0
Apple, postharvest	5.0
Apricot, postharvest	20.0
Artichoke, jerusalem, postharvest	30.0
Asparagus, postharvest	100.0
Avocado, postharvest	75.0
Barley, grain, postharvest	50.0
Bean, lima, postharvest	50.0
Bean, postharvest	50.0
Bean, snap, succulent, postharvest	50.0
Bean, succulent, postharvest	50.0
Beet, garden, roots, postharvest	30.0
Beet, sugar, roots, postharvest	30.0
Blueberry, postharvest	20.0
Butternut, postharvest	200.0
Cabbage, postharvest	50.0
Cantaloupe, postharvest	20.0
Carrot, roots, postharvest	30.0
Cashew, postharvest	200.0
Cherry, sweet, postharvest	20.0
Cherry, tart, postharvest	20
Chestnut, postharvest	200.0
Cippolini, bulb, postharvest	50.0
Citron, citrus, postharvest	30.0
Cacao bean, roasted bean, postharvest	50.0
Coconut, copra, postharvest	100.0
Coffee, bean, green, postharvest	75.0
Corn, field, grain, postharvest	50.0
Corn, pop, postharvest	240.0
Corn, sweet, kernel plus cob with husks removed, postharvest	50.0
Cotton, undelinted seed, postharvest	200.0
Cucumber, postharvest	30.0
Cumin, seed, postharvest	100.0
Eggplant, postharvest	20.0
Garlic, postharvest	50.0
Ginger, postharvest	100.0
Grapefruit, postharvest	30.0
Grape, postharvest	20.0
Hazelnut, postharvest	200.0
Horseradish, postharvest	30.0
Kumquat, postharvest	30.0
Lemon, postharvest	30.0
Lime, postharvest	30.0
Mango, postharvest	20.0
Melon, honeydew, postharvest	20.0
Muskmelon, postharvest	20.0
Nectarine, postharvest	20.0
Nut, brazil, postharvest	200.0
Nut, hickory, postharvest	200.0
Nut, macadamia, postharvest	200.0
Oat, postharvest	50.0
Okra, postharvest	30.0
Onion, bulb, postharvest	20.0
Onion, green, postharvest	20.0
Orange, postharvest	30.0
Papaya, postharvest	20.0
Parsnip, roots, postharvest	30.0
Peach, postharvest	20.0
Peanut, postharvest	200.0
Pear, postharvest	5.0
Pea, blackeyed, postharvest	50.0
Pea, postharvest	50.0
Pecan, postharvest	200.0
Pepper, postharvest	30.0
Pimento, postharvest	30.0
Pineapple, postharvest	20.0
Pistachio, postharvest	200.0
Plum, postharvest	20.0
Pomegranate, postharvest	100.0
Potato, postharvest	75.0
Pumpkin, postharvest	20.0
Quince, postharvest	5.0
Radish, postharvest	30.0
Rice, grain, postharvest	50.0
Rutabaga, roots, postharvest	30.0
Rutabaga, tops, postharvest	30.0
Rye, grain, postharvest	50.0
Salsify, roots, postharvest	30.0
Sorghum, grain, grain, postharvest	50.0
Soybean, postharvest	200.0
Squash, summer, postharvest	30.0
Squash, winter, postharvest	20.0
Squash, zucchini, postharvest	20.0
Strawberry, postharvest	60.0
Sweet potato, postharvest	75.0
Tangerine, postharvest	30.0
Timothy, hay, postharvest	50.0
Tomato, postharvest	20.0
Turnip, roots, postharvest	30.0
Walnut, postharvest	200.0
Watermelon, postharvest	20.0
Wheat	50.0

(2) Inorganic bromide may be present as a residue in certain processed food in accordance with the following conditions:

(i) When inorganic bromide residues are present as a result of fumigation of the processed food with methyl bromide or from such fumigation in addition to the authorized use of methyl bromide on the source raw agricultural commodity, as provided for in this part, the total residues of inorganic bromides (calculated as Br) shall not exceed the following levels:

(A) 400 parts per million in or on egg, dried and herb, processed and spice.

(B) 325 parts per million in or on cheese, parmesan and cheese, roquefort cheese.

(C) 250 parts per million in or on tomato, concentrated products and fig, dried fruit.

(D) 125 parts per million in or on processed food other than those listed above.

(ii) When inorganic bromide residues are present in malt beverage, fermented in accordance with 21 CFR 172.730(a)(2), the amount shall not exceed 25 parts per million (calculated as Br).

(iii) Where tolerances are established on both the raw agricultural commodities and processed food made therefrom, the total residues of inorganic bromides in or on the processed food shall not be greater than those designated in paragraph (a)(2) of this section, unless a higher level is established elsewhere in this part.

(3) Tolerances are established for residues of inorganic bromides (calculated as Br) as follows:

(i) 400 parts per million for residues in or on dog food, resulting from fumigation with methyl bromide.

(ii) 125 parts per million for residues in or on processed commodities for animal feedstuffs from barley, corn, grain sorghum, oat, rice, rye and wheat, resulting directly from fumigation with methyl bromide or from carryover and concentration of residues of inorganic bromides from fumigation of the grains with methyl bromide.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(n), is established for residues of inorganic bromides (calculated as Br) in or on the following food commodity grown in soil fumigated with methyl bromide.

Commodity	Parts per million
Ginger, postharvest	100

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74812, Dec. 13, 2006]

§ 180.123a Inorganic bromide residues in peanut hay and peanut hulls; statement of policy.

(a) Investigations by the Food and Drug Administration show that peanut hay and peanut shells have been used as feed for meat and dairy animals. While many growers now harvest peanuts with combines and leave the hay on the ground to be incorporated into the soil, some growers follow the practice of curing peanuts on the vines in a stack and save the hay for animal feed. Peanut shells or hulls have been used to a minor extent as roughage for cattle feed. It has been established that the feeding to cattle of peanut hay and peanut hulls containing residues of inorganic bromides will contribute considerable residues of inorganic bromides to the meat and milk.

(b) There are no tolerances for inorganic bromides in meat and milk to cover residues from use of such peanut hulls as animal feed. Peanut hulls containing residues of inorganic bromides from the use of methyl bromide are unsuitable as an ingredient in the feed of meat and dairy animals and should not be represented, sold, or used for that purpose.

[58 FR 65555, Dec. 15, 1993]

§ 180.127 Piperonyl butoxide; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the insecticide piperonyl butoxide [(butyl carbityl)(6-propyl piperonyl)ether] are established in or on the following food commodities:

Commodity	Parts per million
Almond, postharvest	8
Apple, postharvest	8
Barley, postharvest	20
Bean, postharvest	8
Birdseed, mixtures, postharvest	20
Blackberry, postharvest	8
Blueberry, postharvest	8
Boysenberry, postharvest	8
Buckwheat, grain, postharvest	20
Cattle, fat	0.1
Cattle, meat byproducts	0.1
Cattle, meat	0.1
Cherry, sweet, postharvest	8
Cherry, tart, postharvest	8
Cacoa bean, roasted bean, postharvest	8
Coconut, copra, postharvest	8
Corn, field, grain, postharvest	20
Corn, pop, postharvest	20
Cotton, undelinted seed, postharvest	8
Crabapple, postharvest	8
Currant, postharvest	8
Dewberry, postharvest	8
Egg	1
Fig, postharvest	8
Flax, seed, postharvest	8
Goat, fat	0.1
Goat, meat byproducts	0.1
Goat, meat	0.1
Gooseberry, postharvest	8
Grape, postharvest	8
Guava, postharvest	8
Hog, fat	0.1
Hog, meat byproducts	0.1
Hog, meat	0.1
Horse, fat	0.1
Horse, meat byproducts	0.1
Horse, meat	0.1
Loganberry, postharvest	8
Mango, postharvest	8
Milk, fat	0.25
Muskmelon, postharvest	8
Oat, postharvest	8

Commodity	Parts per million
Orange, postharvest	8
Peach, postharvest	8
Peanut, postharvest	8
Pea, postharvest	8
Pear, postharvest	8
Pineapple, postharvest	8
Plum, prune, fresh, postharvest	8
Potato, postharvest	0.25
Poultry, fat	3
Poultry, meat byproducts	3
Poultry, meat	3
Raspberry, postharvest	8
Rice, postharvest	20
Rye, postharvest	20
Sheep, fat	0.1
Sheep, meat byproducts	0.1
Sheep, meat	0.1
Sorghum, grain, postharvest	8
Sweet potato, postharvest	0.25
Tomato, postharvest	8
Walnut, postharvest	8
Wheat, postharvest	20

(2) Piperonyl butoxide may be safely used in accordance with the following prescribed conditions:

(i) It is used or intended for use in combination with pyrethrins for control of insects:

(A) In cereal grain mills and in storage areas for milled cereal grain products, whereby the amount of piperonyl butoxide is at least equal to but not more than 10 times the amount of pyrethrins in the formulation.

(B) On the outer ply of multiwall paper bags of 50 pounds or more capacity in amounts not exceeding 60 milligrams per square foot, whereby the amount of piperonyl butoxide is equal to 10 times the amount of pyrethrins in the formulation. Such treated bags are to be used only for food, dried.

(C) On cotton bags of 50 pounds or more capacity in amounts not exceeding 55 milligrams per square foot of cloth, whereby the amount of piperonyl butoxide is equal to 10 times the amount of pyrethrins in the formulation. Such treated bags are constructed with waxed paper liners and are to be used only for food, dried that contain 4 percent fat or less.

(D) In two-ply bags consisting of cellophane/polyolefin sheets bound together by an adhesive layer when it is incorporated in the adhesive. The treated sheets shall contain not more than 50 milligrams of piperonyl butoxide per square foot (538 milligrams per square meter). Such treated bags are to be used only for packaging plum, prune, dried; grape, raisin; and other fruit, dried and are to have a maximum ratio of 3.12 milligrams of piperonyl butoxide per ounce of fruit (0.10 milligram of piperonyl butoxide per gram of product).

(E) In food processing and food storage areas: Provided, That the food is removed or covered prior to such use.

(ii) It is used or intended for use in combination with pyrethrins and N-octylbicycloheptene dicarboximide for insect control in accordance with 21 CFR 178.3730.

(iii) A tolerance of 10 parts per million is established for residues of piperonyl butoxide in or on:

(A) Grain, cereal, milled fractions when present therein as a result of its use in cereal grain mills and in storage areas for milled cereal grain products.

(B) Food, dried when present as a result of migration from its use on the outer ply of multiwall paper bags of 50 pounds or more capacity.

(C) Food treated in accordance with 21 CFR 178.3730.

(D) Food, dried that contain 4 percent fat, or less, when present as a result of migration from its use on the cloth of cotton bags of 50 pounds or more capacity constructed with waxed paper liners.

(E) Food treated in accordance with paragraph (a)(2)(i)(D) and (E) of this section.

(iv) To assure safe use of the pesticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(v) Where tolerances are established on both raw agricultural commodities and processed food made therefrom, the total residues of piperonyl butoxide in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

(3) Piperonyl butoxide may be safely used in accordance with the following prescribed conditions:

(i) It is used or intended for use in combination with pyrethrins for control of insects:

(A) On the outer ply of multiwall paper bags of 50 pounds or more capacity in amounts not exceeding 60 milligrams per square foot.

(B) On cotton bags of 50 pounds or more capacity in amounts not exceeding 55 milligrams per square foot of cloth. Such treated bags are constructed with waxed paper liners and are to be used only for feed, dried that contain 4 percent fat or less.

(ii) It is used in combination with pyrethrins, whereby the amount of piperonyl butoxide is equal to 10 times the amount of pyrethrins in the formulation. Such treated bags are to be used only for feed, dried.

(iii) A tolerance of 10 parts per million is established for residues of piperonyl butoxide when present as the result of migration:

(A) In or on feed, dried from its use on the outer ply of multiwall paper bags of 50 pounds or more capacity.

(B) In or on feed, dried that contain 4 percent fat, or less, from its use on cotton bags of 50 pounds or more capacity constructed with waxed paper liners.

(iv) To assure safe use of the pesticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency.

(v) Where tolerances are established on both the raw agricultural commodities and food, processed made therefrom, the total residues of piperonyl butoxide in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74813, Dec. 13, 2006]

§ 180.128 Pyrethrins; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the insecticide pyrethrins ((1S)-2-methyl-4-oxo-3-(2Z)-2,4-pentadienylcyclopenten-1-yl (1R,3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate (pyrethrin 1), (1S)-2-methyl-4-oxo-3-(2Z)-2,4-pentadienyl-2-cyclopenten-1-yl (1R,3R)-3-[(1E)-3-methoxy-2-methyl-3-oxo-1-propenyl]-2,2-dimethylcyclopropanecarboxylate (pyrethrin 2), (1S)-3-(2Z)-2-butenyl-2-methyl-4-oxo-2-cyclopenten-1-yl (1R,3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate (cinerin 1), (1S)-3-(2Z)-2-butenyl-2-methyl-4-oxo-2-cyclopenten-1-yl (1R,3R)-3-[(1E)-3-methoxy-2-methyl-3-oxo-1-propenyl]-2,2-dimethylcyclopropanecarboxylate (cinerin 2), (1S)-2-methyl-4-oxo-3-(2Z)-2-pentenyl-2-cyclopenten-1-yl (1R, 3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate (jasmolin 1), and (1S)-2-methyl-4-oxo-3-(2Z)-pentenyl-2-cyclopenten-1-yl (1R,3R)-3-[(1E)-3-methoxy-2-methyl-3-oxo-1-propenyl]-2,2-dimethylcyclopropanecarboxylate (jasmolin 2)), the insecticidally active principles of Chrysanthemum cinerariaefolium, which are measured as cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 are not to exceed the following:

Commodity	Parts per million
Almond, postharvest	1.0
Apple, postharvest	1.0
Barley, grain, postharvest	3.0
Bean, succulent, postharvest	1.0
Birdseed, mixtures, postharvest	3.0
Blackberry, postharvest	1.0
Blueberry, postharvest	1.0
Boysenberry, postharvest	1.0
Buckwheat, grain, postharvest	3.0
Cacao bean, roasted bean, postharvest	1.0
Cattle, fat	1.0
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cherry, sweet, postharvest	1.0
Cherry, tart, postharvest	1.0
Coconut, copra, postharvest	1.0
Corn, field, grain, postharvest	3.0
Corn, pop, grain, postharvest	3.0
Cotton, undelinted seed, postharvest	1.0
Crabapple, postharvest	1.0
Currant, postharvest	1.0
Dewberry, postharvest	1.0
Fig, postharvest	1.0
Flax, seed, postharvest	1.0
Goat, fat	1.0
Goat, meat	0.05
Goat, meat byproducts	0.05
Gooseberry, postharvest	1.0
Grape, postharvest	1.0
Guava, postharvest	1.0
Hog, fat	1.0
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	1.0
Horse, meat	0.05
Horse, meat byproducts	0.05
Loganberry, postharvest	1.0
Mango, postharvest	1.0
Milk, fat (reflecting negligible residues in milk)	0.05
Muskmelon, postharvest	1.0
Oat, grain, postharvest	1.0
Orange, postharvest	1.0
Pea, dry, seed, postharvest	1.0
Peach, postharvest	1.0

Commodity	Parts per million
Peanut, postharvest	1.0
Pear, postharvest	1.0
Pineapple, postharvest	1.0
Plum, prune, fresh, postharvest	1.0
Potato, postharvest	0.05
Raspberry, postharvest	1.0
Rice, grain, postharvest	3.0
Rye, grain, postharvest	3.0
Sheep, fat	1.0
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain, postharvest	1.0
Sweet potato, postharvest	0.05
Tomato, postharvest	1.0
Walnut, postharvest	1.0
Wheat, grain, postharvest	3.0

(2) A tolerance of 1.0 ppm is established for residues of the insecticide pyrethrins in or on milled fractions derived from grain, cereal when present as a result of its use in cereal grain mills and in storage areas for milled cereal grain products.

(3) A tolerance of 1.0 ppm is established for residues of the insecticide pyrethrins in or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served. Food must be removed or covered prior to use.

(4) Where tolerances are established on both the raw agricultural commodities and processed foods made therefrom, the total residues of pyrethrins in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74814, Dec. 13, 2006, as amended at 73 FR 5108, Jan. 29, 2008]

§ 180.129 o-Phenylphenol and its sodium salt; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the fungicide o-phenylphenol and sodium o-phenylphenate, each expressed as o-phenylphenol, from postharvest application of either in or on the following food commodities:

Commodity	Parts per million
Apple	25
Cantaloupe (NMT 10 ppm in edible portion)	125
Carrot, roots	20
Cherry	5
Citrus fruits	10
Cucumber	10
Lemon	10
Nectarine	5
Orange	10
Pepper, bell	10
Peach	20
Pear	25.0
Pineapple	10
Plum, prune, fresh	20
Sweet potato, roots	15
Tomato	10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54960, Sept. 24, 2008]

§ 180.130 Hydrogen Cyanide; tolerances for residues.

(a) *General.* A tolerance for residues of the insecticide hydrogen cyanide from postharvest fumigation as a result of application of sodium cyanide is established as follows: 50 parts per million in or on Fruit, citrus.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 39077, July 21, 1999]

§ 180.132 Thiram; tolerances for residues.

(a) *General.* Tolerances for residues of the fungicide thiram (tetramethyl thiuram disulfide) in or on raw agricultural commodities are established as follows:

Commodity	Parts per million
Apple	7.0
Peach	7.0
Strawberry	7.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 49615, July 31, 2002]

§ 180.133 Lindane; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide lindane (gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane) in or on raw agricultural commodities as follows:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, fat	7.0	10/02/09
Goat, fat	7.0	10/02/09
Hog, fat	4.0	10/02/09
Horse, fat	7.0	10/02/09
Sheep, fat	7.0	10/02/09

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39438, July 1, 2003, as amended at 70 FR 55286, Sept. 21, 2005; 72 FR 53454, Sept. 19, 2007]

§ 180.136 Basic copper carbonate; tolerance for residues.

The tolerance for residues of the fungicide basic copper carbonate in or on pear from postharvest use of the chemical is 3 parts per million of combined copper.

§ 180.142 2,4-D; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, plant regulator, and fungicide 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on the following food commodities:

Commodity	Parts per million
Almond hulls	0.1
Asparagus	5.0
Barley, bran	4.0
Barley, grain	2.0
Barley, straw	50
Berry, group 13	0.2
Cattle, fat	0.3
Cattle, kidney	4.0
Cattle, meat	0.3
Cattle, meat byproducts, except kidney	0.3
Corn, field, forage	6.0
Corn, field, grain	0.05
Corn, field, stover	50
Corn, pop, grain	0.05
Corn, pop, stover	50
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	50
Fish	0.1
Fruit, citrus, group 10	3.0
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.05
Goat, fat	0.3
Goat, kidney	4.0
Goat, meat	0.3
Goat, meat byproducts, except kidney	0.3
Grain, aspirated fractions	40
Grape	0.05
Grass, forage	360
Grass, hay	300
Hop, dried cones	0.2
Horse, fat	0.3
Horse, kidney	4.0
Horse, meat	0.3
Horse, meat byproducts, except kidney	0.3
Millet, forage	25
Millet, grain	2.0
Millet, straw	50
Milk	0.05
Nut, tree, group 14	0.2
Oat, forage	25
Oat, grain	2.0
Oat, straw	50
Pistachio	0.05
Potato	0.4
Rice, grain	0.5
Rice, hulls	2.0
Rice, straw	10
Rye, bran	4.0
Rye, forage	25
Rye, grain	2.0
Rye, straw	50
Sheep, fat	0.3
Sheep, kidney	4.0
Sheep, meat	0.3
Sheep, meat byproducts, except kidney	0.3
Shellfish	1.0
Sorghum, grain, forage	0.2
Sorghum, grain, grain	0.2
Sorghum, grain, stover	0.2
Soybean, forage	0.02
Soybean, hay	2.0
Soybean, seed	0.02
Strawberry	0.05
Sugarcane, cane	0.05
Sugarcane, molasses	0.2
Vegetable, leaves of root and tuber, group 2	0.1
Vegetable, root and tuber, except potato, group 1	0.1
Wheat, bran	4.0
Wheat, forage	25
Wheat, grain	2.0
Wheat, straw	50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m), are established for residues of the herbicide, plant regulator, and fungicide 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined

as the acid, in or on the following food commodities:

Commodity	Parts per million
Rice, wild, grain	0.05

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide, plant regulator, and fungicide 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on the following food commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18	0.2
Avocado	0.05
Cotton, undelinted seed	0.05
Dill, seed	0.05
Okra	0.05
Vegetable, brassica leafy, group 5	0.4
Vegetable, bulb, group 3	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, foliage of legume, group 7	0.2
Vegetable, fruiting, group 8	0.05
Vegetable, leafy, except brassica, group 4	0.4
Vegetable, legume, group 6	0.05

[72 FR 52017, Sept. 12, 2007, as amended at 73 FR 53737, Sept. 17, 2008]

§ 180.144 Cyhexatin; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the pesticide cyhexatin (tricyclohexylhydroxystannane; CAS Reg. No. 13121–70–5) and its organotin metabolites (calculated as cyhexatin) in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Orange, juice	0.1	6/13/09

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33708, May 24, 2000, as amended at 70 FR 55272, Sept. 21, 2005]

§ 180.145 Fluorine compounds; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in or on the following agricultural commodities:

Commodity	Parts per million
Apricot	7
Blackberry	7
Blueberry	7
Boysenberry	7
Broccoli	7
Brussels sprouts	7
Cabbage	7
Cauliflower	7
Collards	7
Cranberry	7
Cucumber	7
Dewberry	7
Eggplant	7
Fruit, citrus	7
Grape	7
Kale	7
Kohlrabi	7
Lettuce, head	7
Lettuce, leaf	7
Loganberry	7
Melon	7
Nectarine	7
Peach	7
Pepper	7
Plum, prune, fresh	7
Pumpkin	7
Raspberry	7
Squash, summer	7
Squash, winter	7
Strawberry	7
Tomato	7
Youngberry	7

(2) Time-limited tolerances are established for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in or on the commodities as follows:

Commodity	Parts per million	Expiration/ revocation date
Potato	2.0	11/21/01
Potato, processed potato waste	22.0	11/21/01

(3) Tolerances are established for residues of fluoride in or on the following commodities from the postharvest fumigation with sulfuryl fluoride for the control of insects:

Commodity	Parts per million
All processed food commodities not otherwise listed	70
Barley, bran, postharvest	45.0
Barley, flour, postharvest	45.0
Barley, grain, postharvest	15.0
Barley, pearled barley, postharvest	45.0
Cattle, meat, dried	40
Cheese	5.0

Commodity	Parts per million
Cacao bean, roasted bean, postharvest	20
Coconut, postharvest	40
Coffee, bean, green, postharvest	15
Corn, field, flour, postharvest	35.0
Corn, field, grain, postharvest	10.0
Corn, field, grits, postharvest	10.0
Corn, field, meal, postharvest	30.0
Corn, pop, grain, postharvest	10.0
Cotton, undelinted seed, postharvest	70
Egg, dried	900
Fruit, dried, except grape, raisin, postharvest	3.0
Ginger, postharvest	70
Grain, aspirated fractions, postharvest	55.0
Grape, raisin, postharvest	7.0
Hog, meat	20
Herbs and spices group 19, postharvest	70
Milk, powdered	5.0
Millet, grain, postharvest	40.0
Nut, pine, postharvest	20
Nut, tree, Group 14, postharvest	10.0
Oat, flour, postharvest	75.0
Oat, grain, postharvest	25.0
Oat, groats/rolled oats	75.0
Peanut, postharvest	15
Pistachio, postharvest	10.0
Rice, bran, postharvest	31.0
Rice, flour, postharvest	45
Rice, grain, postharvest	12.0
Rice, hulls, postharvest	35.0
Rice, polished rice, postharvest	25.0
Rice, wild, grain, postharvest	25.0
Sorghum, grain, postharvest	40.0
Triticale, grain, postharvest	40.0
Vegetable, legume, group 6, postharvest	70
Wheat, bran, postharvest	40.0
Wheat, flour, postharvest	125.0
Wheat, germ, postharvest	130.0
Wheat, grain, postharvest	40.0
Wheat, milled byproducts, postharvest	130.0
Wheat, shorts, postharvest	40.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined by § 180.1(n), are established for the combined residues of the insecticidal fluorine compounds, cryolite and synthetic cryolite (sodium aluminum fluoride), in or on the following raw agricultural commodities:

Commodity	Parts per million
Kiwifruit	15

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74815, Dec. 13, 2006]

§ 180.149 Mineral oil; tolerances for residues.

(a) *General.* (1) For the purposes of this section, the insecticide mineral oil is defined as the refined petroleum fraction having the following characteristics:

(i) Minimum flashpoint of 300 °F.

(ii) Gravity of 27 to 34 by the American Petroleum Institute standard method.

(iii) Pour point of 30 °F maximum.

(iv) Color 2 maximum by standards of the American Society for Testing Materials.

(v) Boiling point between 480 °F and 960 °F.

(vi) Viscosity at 100 °F of 100 to 200 seconds Saybolt.

(vii) Unsulfonated residue of 90 percent minimum.

(viii) No sulfur compounds according to the United States Pharmacopeia test under Liquid Petrolatum.

(2) Tolerances for residues of mineral oil as specified in paragraph (a)(1) of this section are established in or on the following food commodities:

Commodity	Parts per million
Corn, grain, postharvest	200
Sorghum, grain, grain, postharvest	200

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39438, July 1, 2003]

§ 180.151 Ethylene oxide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the antimicrobial agent and insecticide ethylene oxide, when used as a postharvest fumigant in or on the following food commodities:

Commodity	Parts per million
Coconut, copra	50
Spices, whole	50
Walnut, black	50

(2) Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices and other processed natural seasoning materials, except mixtures to which salt has been added, in accordance with the following prescribed conditions:

(i) Ethylene oxide, either alone or admixed with carbon dioxide or dichlorodifluoromethane, shall be used in amounts not to exceed that required to accomplish the intended technical effects. If used with dichlorodifluoromethane, the dichlorodifluoromethane shall conform with the requirements prescribed by 21 CFR 173.355 of this chapter.

(ii) To assure safe use of the fumigant, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label or labeling.

(iii) Residues of ethylene oxide in ground spices from both postharvest application to whole spices and application to the ground spices shall not exceed the established tolerance of 50 parts per million for residues in whole spices in paragraph (a)(1) of this section.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33695, May 24, 2000]

§ 180.153 Diazinon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide diazinon, *O,O*-diethyl *O*-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl]phosphorothioate (CAS No. 333–41–5), in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	3.0
Apple	0.50
Apricot	0.20
Bean, lima	0.50
Bean, snap, succulent	0.50
Beet, garden, roots	0.75
Beet, garden, tops	0.70
Blueberry	0.50
Caneberry subgroup 13-07A	0.75
Carrot, roots	0.75
Cattle, fat	0.50
Cherry, sweet	0.20
Cherry, tart	0.20
Cranberry	0.50
Endive	0.70
Fig	0.50
Ginseng	0.75
Grape[2]	0.75
Hazelnut	0.50
Kiwifruit[1]	0.75
Lettuce	0.70
Melon	0.75
Mushroom	0.75[2]
Nectarine	0.20
Onion, bulb	0.75
Onion, green	0.75
Pea, succulent	0.50
Peach	0.20
Pear	0.50
Pineapple	0.50
Plum, prune, fresh	0.20
Radish	0.50
Rutabaga	0.75
Spinach	0.70
Strawberry	0.50
Tomato	0.75
Vegetable, brassica, leafy, group 5	0.70
Watercress	0.05

[1]There are no domestic registrations for kiwifruit as of March 6, 2002.

[2]The expiration/revocation date for this tolerance is 9/10/2010.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m), are established for residues of the insecticide diazinon, *O, O*-diethyl *O*-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl]-phosphorothioate (CAS No. 333–41–5), in or on the following food commodities:

Commodity	Parts per million
Almond	0.50
Banana	0.20
Celery	0.70
Cucumber	0.75
Parsley, leaves	0.75
Parsnip	0.50
Pepper	0.5
Potato	0.10
Squash, summer	0.50
Squash, winter	0.75
Sweet potato, roots	0.10
Swiss chard	0.70
Turnip, roots	0.50
Turnip, tops	0.75

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 42738, Sept. 29, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.153, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.154 *O,O*-Dimethyl *S*-[(4-oxo-1,2,3-benzotriazin-3(4*H*)-yl)methyl]phosphorodithioate; tolerances for residues.

(a) *General.* Tolerances for residues of the insecticide *O,O*-dimethyl *S*-[(4-oxo-

1,2,3-benzotriazin-3(4*H*)-yl)methyl]phosphorodithioate in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	2.0	None
Alfalfa, hay	5.0	None
Almond	0.2	None
Almond, hulls	5.0	None
Apple	1.5	None
Bean, snap, succulent	2.0	None
Blackberry	2.0	None
Blueberry	5.0	None
Boysenberry	2.0	None
Broccoli	2.0	None
Brussels sprouts	2.0	None
Cabbage	2.0	None
Cauliflower	2.0	None
Celery	2.0	None
Cherry	2.0	None
Clover, forage	2.0	None
Clover, hay	5.0	None
Cotton, undelinted seed	0.5	None
Crabapple	1.5	None
Cranberry	0.5	None
Cucumber	2.0	None
Eggplant	0.3	None
Fruit, citrus, group 10	2.0	None
Grape	4.0	None
Hazelnut	0.3	None
Loganberry	2.0	None
Melon	2.0	None
Onion	2.0	None
Parsley, leaves	5.0	None
Parsley, turnip rooted, roots	2.0	None
Peach	2.0	None
Pear	1.5	None
Pecan	0.3	None
Pepper	0.3	None
Pistachio	0.3	None
Plum, prune	2.0	None
Potato	0.2	None
Quince	1.5	None
Raspberry	2.0	None
Spinach	2.0	None
Strawberry	2.0	None
Sugarcane, cane	0.3	6/30/00
Tomato, postharvest	2.0	None
Trefoil, forage	2.0	None
Trefoil, hay	5.0	None
Walnut	0.3	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 38752, June 22, 2000]

§ 180.155 1-Naphthaleneacetic acid; tolerances for residues.

(a) Tolerances are established for residues of the plant growth regulator 1-naphthaleneacetic acid in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	1
Cherry, sweet	0.1
Olive	0.1(N)
Orange, sweet	0.1
Pear	1
Pineapple (from the application of the sodium salt to the growing crop)	0.05
Quince	1
Tangerine	0.1

(b) Tolerances are established for residues of the ethyl ester of 1-naphthaleneacetic acid in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	1
Pear	1
Olive	0.1

[46 FR 23238, Apr. 24, 1981, as amended at 47 FR 33692, Aug. 4, 1982; 48 FR 20054, May 4, 1983]

§ 180.157 Methyl 3-[(dimethoxyphosphinyl) oxy]butenoate, alpha and beta isomers; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide methyl 3-[(dimethoxyphosphinyl)oxy]butenoate, alpha and beta isomers, in or on the following raw agricultural commodities:

Commodity	Parts per million
Broccoli	1.0
Cabbage	1.0
Cauliflower	1.0
Celery	1.0
Cucumber	0.2
Grape	0.5
Lettuce	0.5
Melon (determined on the edible portion with rind removed)	0.5
Pea	0.25
Pepper	0.25
Spinach	1.0
Squash, summer	0.25
Strawberry	1.0
Tomato	0.2
Watermelon	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 41822, Aug. 2, 1999]

§ 180.163 1,1-Bis(4-chlorophenyl)-2,2,2-trichloroethanol; tolerances for residues.

(a) *General.* (1) Tolerances for the combined residues of the insecticide dicofol, 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol in or on raw agricultural commodities are established as follows:

Commodity	Parts per million
Apple, wet pomace	38.0
Bean, dry, seed	0.5
Bean, succulent	3.0
Butternut	0.1
Caneberry subgroup 13A	5.0
Chestnut	0.1
Citrus, dried pulp	12.0
Citrus oil	200.0
Cotton, refined oil	0.5
Cotton, undelinted seed	0.1
Fruit, citrus, group 10	6.0
Fruit, pome, group 11	10.0
Fruit, stone, group 12	5.0
Grape	5.0
Grape, raisin	20.0
Hazelnut	0.1
Hop, dried cones	65.0
Nut, hickory	0.1
Nut, macadamia	0.1
Pecan	0.1
Peppermint, oil	30.0
Peppermint, tops	25.0
Spearmint, oil	30.0
Spearmint, tops	25.0
Strawberry	10.0
Tea, dried	50.0
Tea, plucked leaves	30.0
Vegetable, cucurbit, group 9	2.0
Vegetable, fruiting, group 8	2.0
Walnut	0.1

(2) Tolerances for the combined residues of the insecticide dicofol, 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol, 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol, 1,1-bis(4-chlorophenyl)-2,2-dichloroethanol, and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethanol in or on raw agricultural commodities are established as follows:

Commodity	Parts per million
Cattle, fat	50.0
Cattle, liver	5.0
Cattle, meat	3.0
Cattle, meat byproducts, except liver	3.0
Egg	0.05
Goat, fat	50.0
Goat, liver	5.0
Goat, meat	3.0
Goat, meat byproducts, except liver	3.0
Hog, fat	50.0
Hog, liver	5.0
Hog, meat	3.0
Hog, meat byproducts, except liver	3.0
Horse, fat	50.0
Horse, liver	5.0
Horse, meat	3.0
Horse, meat byproducts, except liver	3.0
Milk, fat (reflecting 0.75 ppm in whole milk)	22.0
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Sheep, fat	50.0
Sheep, liver	5.0
Sheep, meat	3.0
Sheep, meat byproducts, except liver	3.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34826, June 26, 1998, as amended at 72 FR 35665, June 29, 2007; 72 FR 41928, Aug. 1, 2007]

§ 180.169 Carbaryl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide carbaryl, 1-naphthyl *N*-methylcarbamate *per se*, in or on the following food commodities:

Commodity	Parts per million	Expiration/revocation date
Alfalfa, forage	50	None
Alfalfa, hay	75	None
Almond, hulls	50	None
Apple, wet pomace	15	None
Asparagus	15	None
Banana	5.0	None
Beet, sugar, roots	0.5	None
Beet, sugar, tops	25	None
Bushberry subgroup 13-07B	3.0	None
Cabbage	21	None
Cactus, fruit	5.0	None
Cactus, pads	12	None
Caneberry subgroup 13-07A	12.0	None
Citrus, oil	20	None
Clover, forage	50	None
Clover, hay	70	None
Corn, field, forage	30	None
Corn, field, grain	0.02	None
Corn, field, stover	20	None
Corn, pop, grain	0.02	None
Corn, pop, stover	20	None
Corn, sweet, forage	185	None
Corn, sweet, kernel plus cob with husks removed	0.1	None
Corn, sweet, stover	215	None
Cotton, undelinted seed	5.0	10/31/09
Cranberry	3.0	None
Dandelion, leaves	22	None
Endive	10	None
Flax, seed	0.5	None

Commodity	Parts per million	Expiration/ revocation date
Fruit, citrus, group 10	10	None
Fruit, pome, group 11	12	None
Fruit, stone, group 12	10	None
Grain, aspirated fractions	70	None
Grape	10	None
Grape, raisin	12	None
Grass, forage	100	None
Grass, hay	15	None
Leaf petiole subgroup 4B	3.0	None
Lettuce	10	None
Millet, proso, grain	1.0	None
Millet, proso, straw	20	None
Nut, tree group 14, except walnut	0.1	None
Okra	4.0	None
Olive	10	None
Oyster	0.25	None
Parsley, leaves	22	None
Pea and bean, dried shelled, except soybean, subgroup 6C	1.0	None
Peanut	0.05	None
Peanut, hay	20	None
Pineapple	2.0	None
Pistachio	0.1	None
Rice, grain	15	None
Rice, hulls	30	None
Rice, straw	60	None
Sorghum grain, forage	30	None
Sorghum grain, grain	10	None
Sorghum grain, stover	30	None
Soybean, forage	15	None
Soybean, hay	15	None
Soybean, seed	0.5	None
Spinach	22	None
Strawberry	4.0	None
Sunflower, seed	0.5	None
Sweet potato, roots	0.2	None
Trefoil, forage	15	None
Trefoil, hay	25	None
Vegetable, brassica, leafy, group 5, except cabbage	10	None
Vegetable, cucurbit, group 9	3.0	None
Vegetable, foliage of legume, subgroup 7A, except soybean	60	None
Vegetable, fruiting, group 8	5.0	None
Vegetable, leaves of root and tuber, group 2, except sugar beet tops	75	None
Vegetable, legume, edible podded, subgroup 6A	10	None
Vegetable, root and tuber, group 1, except sugar beet and sweet potato	2.0	None
Walnut	1.0	None
Wheat, forage	30	None
Wheat, grain	1.0	None
Wheat, hay	30	None
Wheat, straw	20	None

(2) Tolerances are established for residues of the insecticide carbaryl, 1-naphthyl *N*-methylcarbamate, including its metabolites: 1-naphthol (naphthyl-sulfate); 5,6-dihydrodihydroxycarbaryl; and 5,6-dihydrodihydroxy naphthol, calculated as 1-naphthyl *N*-methylcarbamate and the free and conjugated residues of carbaryl: 5,6-dihydro-5,6-dihydroxy carbaryl and 5-methoxy-6-hydroxy carbaryl, in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
Cattle, fat	0.5	None
Cattle, meat	1.0	None
Cattle, meat byproducts	3.0	None
Egg	0.5	10/31/09
Goat, fat	0.5	None
Goat, meat	1.0	None
Goat, meat byproducts	3.0	None
Hog, fat	0.5	None
Hog, meat	1.0	None
Hog, meat byproducts	3.0	None
Horse, fat	0.5	None
Horse, meat	1.0	None
Horse, meat byproducts	3.0	None
Milk	1.0	None
Poultry, fat	5.0	10/31/09
Poultry, meat	5.0	10/31/09
Sheep, fat	0.5	None
Sheep, meat	1.0	None
Sheep, meat byproducts	3.0	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(m), are established for residues of the insecticide carbaryl, 1-naphthyl *N*-methylcarbamate *per se*, in or on the following food commodities:

Commodity	Parts per million
Dillweed, fresh leaves	0.2

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33695, May 24, 2000, as amended at 66 FR 38955, July 26, 2001; 67 FR 49615, July 31, 2002; 70 FR 44492, Aug. 3, 2005; 73 FR 52611, Sept. 10, 2008; 74 FR 10490, Mar. 11, 2009]

§ 180.172 Dodine; tolerances for residues.

(a) *General.* Tolerances are established for the fungicide dodine (n-dodecylguanidine acetate) in or on the following food commodities:

Commodity	Parts per million
Apple	5.0
Apple, wet pomace	15.0
Banana	0.50
Cherry, sweet	3.0
Cherry, tart	3.0
Peach	5.0
Peanut	0.013
Pear	5.0
Pecan	0.3
Strawberry	5.0
Walnut	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 52017, Sept. 12, 2007, as amended at 73 FR 45634, Aug. 6, 2008]

§ 180.173 Ethion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide ethion (*O,O,O′,O′*-tetraethyl *S,S′*-methylene bisphosphorodithioate) including its oxygen analog (*S*-[[(diethoxyphosphinothioyl)thio] methyl] *O,O*- diethyl phosphorothioate) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, fat	0.2	10/1/08
Cattle, meat	0.2	10/1/08
Cattle, meat byproducts	0.2	10/1/08
Citrus, dried pulp	25.0	10/1/08
Fruit, citrus, group 10	5.0	10/1/08
Goat, fat	0.2	10/1/08
Goat, meat	0.2	10/1/08
Goat, meat byproducts	0.2	10/1/08
Hog, fat	0.2	10/1/08
Hog, meat	0.2	10/1/08
Hog, meat byproducts	0.2	10/1/08
Horse, fat	0.2	10/1/08
Horse, meat	0.2	10/1/08
Horse, meat byproducts	0.2	10/1/08
Milk, fat, reflecting negligible residues in milk	0.5	10/1/08
Sheep, fat	0.2	10/1/08
Sheep, meat	0.2	10/1/08
Sheep, meat byproducts	0.2	10/1/08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.*[Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 42739, Sept. 29, 1982, as amended at 63 FR 2165, Jan. 14, 1998; 63 FR 57073, Oct. 26, 1998; 67 FR 49615, July 31, 2002; 69 FR 43924, July 23, 2004]

§ 180.175 Maleic hydrazide; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the herbicide and plant regulator maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Onion, bulb	15.0
Potato	50.0

(2) A food additive known as maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) may be present in potato, chips when used in accordance with the following conditions:

(i) The food additive is present as a result of the application of a pesticide formulation containing maleic hydrazide to the growing potato plant in accordance with directions registered by the U.S. Environmental Protection Agency.

(ii) The label of the pesticide formulation containing the food additive conforms to labeling registered by the U.S. Environmental Protection Agency.

(iii) The food additive is present in an amount not to exceed 160 parts per million by weight of the finished food.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 64293, Dec. 5, 1997, as amended at 64 FR 11792, Mar. 10, 1999; 67 FR 35048, May 17, 2002]

§ 180.176 Mancozeb; tolerances for residues.

(a) *General.* Tolerances for residues of a fungicide which is a coordination product of zinc ion and maneb (manganous ethylene-bisdithiocarbamate) containing 20 percent manganese, 2.5 percent zinc, and 77.5 percent ethylenebisdithiocarbamate (the whole product calculated as zinc ethylenebisdithiocarbamate), are established as follows:

Commodity	Parts per million
Apple	7
Asparagus (negligible residue)	0.1
Banana	4.0
Banana, pulp	0.5
Barley, grain	5
Barley, milled feed fractions	20
Barley, straw	25
Beet, sugar, roots	2
Beet, sugar, tops	65
Carrot, roots	2
Celery	5
Corn, field, grain	0.1

Commodity	Parts per million
Corn, forage	5
Corn, pop, grain	0.5
Corn, stover	5
Corn, sweet, kernel plus cob with husks removed	0.5
Cotton, undelinted seed	0.5
Crabapple	10
Cranberry	7
Cucumber	4
Fennel	10
Grape	7
Kidney	0.5
Liver	0.5
Melon	4
Oat, bran	20
Oat, grain	5
Oat, milled feed fractions	20
Oat, straw	25
Onion, bulb	0.5
Papaya (whole fruit with no residue present in the edible pulp after the peel is removed and discarded)	10
Peanut	0.5
Peanut, hay	65
Pear	10
Quince	10
Rye, bran	20
Rye, grain	5
Rye, straw	25
Squash, summer	4
Tomato	4
Wheat, grain	5
Wheat, milled byproducts	20
Wheat, straw	25

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for combined residues of the fungicide mancozeb, calculated as zinc ethylenebisdithiocarbamate and it's metabolite ETU in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Ginseng	2.0	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33708, May 24, 2000, as amended at 65 FR 49924, Aug. 16, 2000; 66 FR 64773, Dec. 14, 2001; 68 FR 2247, Jan. 16, 2003; 69 FR 29458, May 24, 2004; 71 FR 76199, Dec. 20, 2006]

§ 180.178 Ethoxyquin; tolerances for residues.

(a) *General.* A tolerance is established for residues of the plant regulator ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) from preharvest or postharvest use in or on the following commodity:

Commodity	Parts per million
Pear	3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 57073, Oct. 26, 1998]

§ 180.180 Orthoarsenic acid; tolerance for residues.

(a) *General.* A tolerance that expires on July 1, 1995, for combined As_2O_3 is established for residues of the defoliant orthoarsenic acid in or on the following food commodity:

Commodity	Parts per million
Cotton, undelinted seed	4

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003]

§ 180.181 Chlorpropham; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the plant regulator and herbicide chlorpropham (isopropyl m-chlorocarbanilate (CIPC) in or on the following food commodities:

Commodity	Parts per million
Potato	30
Potato, wet peel	40

(2) Tolerances are established for the combined residues of the plant regulator and herbicide chlorpropham (isopropyl m-chlorocarbanilate (CIPC) and its metabolite 4-hydroxychlorpropham-O-sulfonic acid (4-HSA) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.20
Cattle, kidney	0.30
Cattle, meat	0.06
Cattle, meat byproducts except kidney	0.06
Goat, fat	0.20
Goat, kidney	0.30
Goat, meat	0.06
Goat, meat byproducts except kidney	0.06
Hog, fat	0.20
Hog, kidney	0.30
Hog, meat	0.06
Hog, meat byproducts except kidney	0.06
Horse, fat	0.20
Horse, kidney	0.30
Horse, meat	0.06
Horse, meat byproducts except kidney	0.06
Milk	0.30
Sheep, fat	0.20
Sheep, kidney	0.30
Sheep, meat	0.06
Sheep, meat byproducts except kidney	0.06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 52487, Nov. 13, 1978, as amended at 63 FR 57073, Oct. 26, 1998; 72 FR 37653, July 11, 2007]

§ 180.182 Endosulfan; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the insecticide endosulfan, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide (alpha and beta isomers), and its metabolite endosulfan sulfate, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide, in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	0.3
Alfalfa, hay	1.0
Almond	0.3
Almond, hulls	1.0
Apple	1.0
Apple, wet pomace	5.0
Apricot	2.0
Barley, grain	0.3
Barley, straw	0.4
Bean	2.0
Blueberry	0.3
Broccoli	3.0
Brussels sprouts	2.0
Cabbage	4.0
Carrot, roots	0.2
Cattle, fat	13.0
Cattle, liver	5.0
Cattle, meat	2.0
Cattle, meat byproducts, except liver	1.0
Cauliflower	2.0
Celery	8.0
Cherry, sweet	2.0
Cherry, tart	2.0
Collards	2.0
Corn, sweet, forage	12.0
Corn, sweet, kernel plus cob with husks removed	0.2
Corn, sweet, stover	14.0
Cotton, gin byproducts	30.0
Cotton, undelinted seed	1.0
Eggplant	1.0
Goat, fat	13.0
Goat, liver	5.0
Goat, meat	2.0
Goat, meat byproducts, except liver	1.0
Grape	2.0
Hazelnut	0.2
Hog, fat	13.0
Hog, liver	5.0
Hog, meat	2.0
Hog, meat byproducts, except liver	1.0
Horse, fat	13.0
Horse, liver	5.0
Horse, meat	2.0
Horse, meat byproducts, except liver	1.0
Kale	2.0
Lettuce, head	11.0
Lettuce, leaf	6.0
Milk, fat	2.0
Mustard greens	2.0
Mustard, seed	0.2
Nectarine	2.0
Nut, macadamia	0.2
Oat, grain	0.3
Oat, straw	0.4
Pea, succulent	2.0
Peach	2.0
Pear	2.0
Pecan	0.2
Pepper	2.0
Pineapple	1.0
Pineapple, process residue	20.0
Plum	2.0
Plum, prune	2.0
Potato	0.2
Rapeseed, seed	0.2
Rye, grain	0.3
Rye, straw	0.3
Sheep, fat	13.0
Sheep, liver	5.0
Sheep, meat	2.0
Sheep, meat byproducts, except liver	1.0
Spinach	2.0
Strawberry	2.0
Sugarcane, cane	0.5
Sweet potato, roots	0.15
Tomato	1.0
Turnip, roots	0.2
Turnip, tops	2.0
Vegetable, cucurbit, group 9	1.0
Walnut	0.2
Watercress	2.0
Wheat, grain	0.3
Wheat, straw	0.4

(2) A tolerances of 24 parts per million (ppm) is established for the combined residues of the insecticide endosulfan, 6,7,8,9,10,10-hexachloro-

1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide (alpha and beta isomers), and its metabolite endosulfan sulfate, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide, in or on dried tea (reflecting less than 0.1 ppm residues in beverage tea) resulting from application of the insecticide to growing tea.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33696, May 24, 2000, as amended at 71 FR 54433, Sept. 15, 2006]

§ 180.183 *O,O*-Diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide *O,O*-diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate and its cholinesterase-inhibiting metabolites, calculated as demeton, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.75
Barley, straw	5.0
Bean, lima	0.75
Bean, snap, succulent	0.75
Broccoli	0.75
Brussels sprouts	0.75
Cabbage	0.75
Cauliflower	0.75
Coffee, bean	0.3
Cotton, undelinted seed	0.75
Lettuce	0.75
Peanut	0.75
Pea, dry, seed	0.75
Pea, field, vines	5.0
Pea, succulent	0.75
Pepper	0.1
Potato	0.75
Spinach	0.75
Tomato	0.75
Wheat, hay	5.0
Wheat, grain	0.3
Wheat, straw	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of *O,O*-diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate and its cholinesterase-inhibiting metabolites, calculated as demeton, in or on the following raw agricultural commodities:

Commodity	Parts per million
Asparagus	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 2165, Jan. 14, 1998, as amended at 63 FR 57073, Oct. 26, 1998; 66 FR 38955, July 26, 2001; 67 FR 41806, June 19, 2002; 67 FR 49615, July 31, 2002; 70 FR 44492, Aug. 3, 2005; 73 FR 54960, Sept. 24, 2008]

§ 180.184 Linuron; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following food commodities:

Commodity	Parts per million
Asparagus	7.0
Carrot, roots	1.0
Cattle, fat	0.2
Cattle, kidney	2.0
Cattle, liver	2.0
Cattle, meat	0.1
Cattle, meat byproducts except kidney and liver	0.1
Celeriac	1.0
Corn, field, forage	1.0
Corn, field, grain	0.1
Corn, field, stover	6.0
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.25
Corn, sweet, stover	6.0
Cotton, gin byproducts	5.0
Cotton, undelinted seed	0.25
Goat, fat	0.2
Goat, kidney	2.0
Goat, liver	2.0
Goat, meat	0.1
Goat, meat byproducts except kidney and liver	0.1
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.1
Horse, fat	0.2
Horse, kidney	2.0
Horse, liver	2.0
Horse, meat	0.1
Horse, meat byproducts except kidney and liver	0.1
Milk	0.05
Parsnip, roots	0.05
Parsnip, tops	0.05
Rhubarb	0.5
Sheep, fat	0.2
Sheep, kidney	2.0
Sheep, liver	2.0
Sheep, meat	0.1
Sheep, meat byproducts except kidney and liver	0.1
Sorghum, grain, forage	1.0

Commodity	Parts per million
Sorghum, grain, grain	0.25
Sorghum, grain, stover	1.0
Soybean, seed	1.0
Soybean, vegetable	1.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerance expires and is revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Lentil	0.1	12/31/2011

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(m), are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following food commodities:

Commodity	Parts per million
Celery	0.5
Parsley, leaves	0.25
Potato	0.2
Wheat, forage	0.5
Wheat, grain	0.05
Wheat, hay	0.5
Wheat, straw	2.0

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 41822, Aug. 2, 1999, as amended at 72 FR 37653, July 11, 2007; 73 FR 51727, Sept. 5, 2008]

§ 180.185 DCPA; tolerances for residues.

(a) *General.* Tolerances for the combined residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyltetrachloroterephthalate (MTP) and tetrachloroterephthalic acid (TCP) (calculated as dimethyl tetrachloroterephthalate) are established in or on the following food commodities:

Commodity	Parts per million
Cantaloupe	1.0
Garlic	1.0
Ginseng	2.0
Horseradish	2.0
Muskmelon	1.0
Onion, bulb	1.0
Onion, green	1.0
Strawberry	2.0
Tomato	1.0
Vegetable, brassica, leafy, group 5	5.0
Watermelon	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m), are established for the combined inadvertent residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyl tetrachloroterephthalate acid (MTP) and terachlorophthalic acid (TCP) (calculated as DCPA) in or on the following food commodities:

Commodity	Parts per million
Radish, roots	2.0
Radish, tops	15.0

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined indirect or inadvertent residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyl tetrachloroterephthalate acid (MTP) and terachlorophthalic acid (TCP) (calculated as DCPA) in or on the following food commodities:

Commodity	Parts per million
Basil, dried leaves	20.0
Basil, fresh leaves	5.0
Bean, dry	2.0
Bean, mung, seed	2.0
Bean, snap, succulent	2.0
Celeriac	2.0
Chicory, roots	2.0
Chicory, tops	5.0
Chive	5.0
Coriander, leaves	5.0
Corn, field, forage	0.4
Corn, field, grain	0.05
Corn, field, stover	0.4
Corn, pop, forage	0.4
Corn, pop, grain	0.05

Commodity	Parts per million
Corn, pop, stover	0.4
Corn, sweet, forage	0.4
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.4
Cotton, undelinted seed	0.2
Cucumber	1.0
Dill	5.0
Eggplant	1.0
Lettuce	2.0
Marjoram	5.0
Parsley, dried leaves	20.0
Parsley, leaves	5.0
Pea, blackeyed, seed	2.0
Pepper	2.0
Pimento	2.0
Potato	2.0
Radicchio	5.0
Radish, oriental, roots	2.0
Radish, oriental, tops	2.0
Rutabaga	2.0
Soybean	2.0
Squash, summer	1.0
Squash, winter	1.0
Sweet potato	2.0
Turnip, roots	2.0
Turnip, tops	5.0
Yam, true, tuber	2.0

[72 FR 52018, Sept. 12, 2007, as amended at 73 FR 53737, Sept. 17, 2008; 73 FR 80302, Dec. 31, 2008; 74 FR 14744, Apr. 1, 2009]

§ 180.189 Coumaphos; tolerances for residues.

(a) *General.* Tolerances for residues of the insecticide coumaphos (*O,O*-diethyl *O*-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphorothioate and its oxygen analog (*O,O*-diethyl *O*-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) in or on food commodities as follows:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, meat	1.0
Cattle, meat byproducts	1.0
Goat, fat	1.0
Goat, meat	1.0
Goat, meat byproducts	1.0
Hog, fat	1.0
Hog, meat	1.0
Hog, meat byproducts	1.0
Honey	0.15
Honeycomb	45.0
Horse, fat	1.0
Horse, meat	1.0
Horse, meat byproducts	1.0
Milk, fat (=n in whole milk)	0.5
Sheep, fat	1.0
Sheep, meat	1.0
Sheep, meat byproducts	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 39077, July 21, 1999, as amended at 65 FR 49936, Aug. 16, 2000; 67 FR 46883, July 17, 2002; 69 FR 29458, May 24, 2004; 72 FR 28876, May 23, 2007]

§ 180.190 Diphenylamine; tolerances for residues.

(a) *General.* Tolerances for residues of the plant regulator diphenylamine are established in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	30.0
Apple from preharvest or postharvest use, including use of impregnated wraps	10.0
Cattle, fat	0.01
Cattle, liver	0.1
Cattle, meat byproducts, except liver	0.01
Cattle, meat	0.01
Goat, fat	0.01
Goat, liver	0.1
Goat, meat byproducts, except liver	0.01
Goat, meat	0.01
Horse, fat	0.01
Horse, liver	0.1
Horse, meat byproducts, except liver	0.01
Horse, meat	0.01
Milk	0.01
Pear (post harvest)	5.0
Sheep, fat	0.01
Sheep, liver	0.1
Sheep, meat byproducts, except liver	0.01
Sheep, meat	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* A time-limited tolerance is established for the indirect or inadvertent residues of diphenylamine in or on the following commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Pear	10	12/1/01

[64 FR 25848, May 13, 1999, as amended at 66 FR 63198, Dec. 5, 2001; 72 FR 16283, Apr. 4, 2007]

§ 180.191 Folpet; tolerances for residues.

(a) *General.* Tolerances are established for the fungicide folpet (*N*-(trichloromethylthio)phthalimide) in

or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple [1]	5.0
Cranberry [1]	15.0
Cucumber [1]	2.0
Grape [1]	50.0
Grape, raisin [1]	80.0
Hop, dried cones	120.0
Lettuce [1]	50.0
Melon [1]	3.0
Onion, bulb [1]	2.0
Strawberry [1]	5.0
Tomato [1]	25.0

[1] No U.S. registrations.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations as defined in § 180.1(m) are established for the fungicide folpet (*N*-(trichloromethylthio)phthalimide) in or on the following raw agricultural commodity:

Commodity	Parts per million
Avocado	25.0

(d) *Indirect or inadvertent residues.* [Reserved]

[61 FR 37222, July 17, 1996, as amended at 68 FR 10388, Mar. 5, 2003; 69 FR 52192, Aug. 25, 2004; 72 FR 41928, Aug. 1, 2007]

§ 180.198 Trichlorfon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide trichlorfon (dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat [1]	0.5
Cattle, meat [1]	0.2
Cattle, meat byproducts [1]	0.1

[1] There are no U.S. registrations for cattle commodities as of June 24, 1999.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 54578, Sept. 26, 2007]

§ 180.200 Dicloran; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide 2,6-dichloro-4-nitroaniline in or on the following raw agricultural commodities. Unless otherwise specified, these tolerances prescribed in this paragraph provide for residues from preharvest application only.

Commodity	Parts per million
Apricot, postharvest	20
Bean, snap, succulent	20
Carrot, roots, postharvest	10
Celery	15
Cherry, sweet, postharvest	20
Cucumber	5
Endive	10
Garlic	5
Grape	10
Lettuce	10
Nectarine, postharvest	20
Onion	10
Peach, postharvest	20
Plum, prune, fresh, postharvest	15
Potato	0.25
Rhubarb	10
Sweet potato, postharvest	10
Tomato	5

(2) Unless otherwise specified, these tolerances prescribed in this section provide for residues from preharvest application only.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[46 FR 27938, May 22, 1981, as amended at 63 FR 162, Jan. 5, 1998; 63 FR 57073, Oct. 26, 1998; 64 FR 13096, Mar. 17, 1999; 67 FR 35048, May 17, 2002]

§ 180.202 *p*-Chlorophenoxyacetic acid; tolerances for residues.

(a) *General.* A tolerance is established for the combined residues of the plant regulator *p*-chlorophenoxyacetic acid and its metabolite *p*-chlorophenol to inhibit embryonic root development in or on the following food commodity:

Commodity	Parts per million
Bean, mung, sprouts	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003, as amended at 71 FR 56398, Sept. 27, 2006]

§ 180.204 Dimethoate; tolerances for residues.

(a) *General.* Tolerances are established for total residues of the insecticide dimethoate (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate) including its oxygen analog (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate) in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	2.0
Alfalfa, hay	2.0
Bean, dry, seed	2.0
Bean, lima	2.0
Bean, snap, succulent	2.0
Blueberry [1]	1.0
Broccoli	2.0
Cattle, meat byproducts	0.02
Cauliflower	2.0
Celery	2.0
Citrus, dried pulp	5.0
Corn, field, forage	1.0
Corn, field, grain	0.1
Corn, field, stover	1.0
Corn, pop, grain	0.1
Corn, pop, stover	1.0
Corn, sweet, forage	1.0
Cotton, undelinted seed	0.1
Egg	0.02
Endive	2.0
Goat, meat byproducts	0.02
Grapefruit	2.0
Hog, meat byproducts	0.02
Horse, meat byproducts	0.02
Kale	2.0
Lemon	2.0
Lettuce, leaf	2.0
Melon	1.0
Milk	0.002
Mustard greens	2.0
Orange	2.0
Pea	2.0
Pear	2.0
Pecan	0.1
Pepper	2.0
Potato	0.2
Poultry, meat byproducts	0.02
Safflower, seed	0.1
Sheep, meat byproducts	0.02
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.1
Sorghum, grain, stover	0.1
Soybean, forage	2.0
Soybean, hay	2.0
Soybean, seed	0.05
Swiss chard	2.0
Tangerine	2.0
Tomato	2.0
Turnip, roots	0.2
Turnip, tops	2.0
Wheat, forage	2.0
Wheat, grain	0.04
Wheat, hay	2.0
Wheat, straw	2.0

[1] There are U.S. registrations as of August 16, 1996.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m), are established for total residues of dimethoate including its oxygen analog in or on the following food commodities:

Commodity	Parts per million
Asparagus	0.15
Brussels sprouts	5.0
Cherry, sweet	2.0
Cherry, tart	2.0

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33697, May 24, 2000, as amended at 69 FR 6567, Feb. 11, 2004; 73 FR 53737, Sept. 17, 2008]

§ 180.205 Paraquat; tolerances for residues.

(a) *General.* Tolerances are established for residues of the desiccant, defoliant, and herbicide paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) derived from application of either the bis(methyl sulfate) or the dichloride salt (both calculated as the cation) in or on the following food commodities:

Commodity	Parts per million
Acerola	0.05
Almond, hulls	0.5
Animal feed, nongrass, group 18, forage	75.0
Animal feed, nongrass, group 18, hay	210.0
Artichoke, globe	0.05
Asparagus	0.5
Avocado	0.05
Banana	0.05
Barley, grain	0.05
Barley, hay	3.5
Barley, straw	1.0
Beet, sugar, roots	0.5
Beet, sugar, tops	0.05
Berry group 13	0.05
Cacao bean, bean	0.05
Carrot, roots	0.05
Cattle, fat	0.05
Cattle, kidney	0.5
Cattle, meat	0.05
Cattle, meat byproducts, except kidney	0.05
Coffee, bean, green	0.05

Commodity	Parts per million
Corn, field, forage	3.0
Corn, field, grain	0.1
Corn, field, stover	10.0
Corn, pop, grain	0.1
Corn, pop, stover	10.0
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, gin byproducts	110.0
Cotton, undelinted seed	3.5
Cowpea, forage	0.1
Cowpea, hay	0.4
Cranberry	0.05
Egg	0.01
Endive	0.05
Fig	0.05
Fruit, citrus, group 10	0.05
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.05
Ginger	0.1
Goat, fat	0.05
Goat, kidney	0.5
Goat, meat	0.05
Goat, meat byproducts, except kidney	0.05
Grain, aspirated fractions	65.0
Grape	0.05
Grass, forage	90.0
Grass, hay	40.0
Guar, seed	0.5
Guava	0.05
Hog, fat	0.05
Hog, kidney	0.5
Hog, meat	0.05
Hog, meat byproducts, except kidney	0.05
Hop, dried cones	0.5
Horse, fat	0.05
Horse, kidney	0.5
Horse, meat	0.05
Horse, meat byproducts, except kidney	0.05
Kiwifruit	0.05
Lentil, seed	0.3
Lettuce	0.05
Milk	0.01
Mint, hay	0.5
Nut, tree, group 14	0.05
Okra	0.05
Olive	0.05
Onion, bulb	0.1
Onion, green	0.05
Papaya	0.05
Passionfruit	0.2
Pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean	0.3
Pea and bean, succulent shelled, subgroup 6B	0.05
Pea, field, hay	0.8
Pea, field, vines	0.2
Peanut	0.05
Peanut, hay	0.5
Persimmon	0.05
Pineapple	0.05
Pineapple, process residue	0.25
Pistachio	0.05
Potato	0.5
Rhubarb	0.05
Rice, grain	0.05
Rice, straw	0.06
Safflower, seed	0.05
Sheep, fat	0.05
Sheep, kidney	0.5
Sheep, meat	0.05
Sheep, meat byproducts, except kidney	0.05
Sorghum, forage, forage	0.1
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.05
Soybean, forage	0.4
Soybean, hay	10.0
Soybean, hulls	4.5
Soybean, seed	0.7
Strawberry	0.25
Sugarcane, cane	0.5
Sugarcane, molasses	3.0
Sunflower, seed	2.0
Turnip, greens	0.05
Turnip, roots	0.05
Vegetable, brassica, leafy, group 5	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.05
Vegetable, legume, edible podded, subgroup 6A	0.05
Wheat, forage	0.5
Wheat, grain	1.1
Wheat, hay	3.5
Wheat, straw	50.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration as defined in § 180.1(n), are established for residues of the pesticide paraquat (1,1′-dimethyl-4,4′ bipyridinium ion) derived from application of either the bis(methyl sulfate) or the dichloride salt (both calculated as the cation) in or on the following food commodities:

Commodity	Parts per million
Cassava	0.05
Pea, pigeon, seed	0.05
Tanier	0.05
Taro, corm	0.1
Tyfon	0.05
Yam, true, tuber	0.05

(d) *Indirect or inadvertent residues.* [Reserved]

[46 FR 51614, Oct. 21, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.205, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.206 Phorate; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide phorate (*O,O*-diethyl *S* (ethylthio) methyl]phosphorodithioate), phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone in or on the following food commodities:

Commodity	Parts per million
Bean, dry, seed	0.05
Bean, succulent	0.05
Beet, sugar, roots	0.3
Beet, sugar, tops	3.0
Coffee, green bean [1]	0.02
Corn, field, forage	0.5
Corn, field, grain	0.05
Corn, sweet, forage	0.5
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, undelinted seed	0.05
Hop, dried cones	2.0
Peanut	0.1
Potato	0.2
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.1
Soybean, seed	0.05
Sugarcane, cane	0.05
Wheat, forage	1.5
Wheat, grain	0.05
Wheat, hay	1.5
Wheat, straw	0.05

[1] There are no U.S. registrations as of September 1, 1993 for the use of phorate on the growing crop, coffee.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[58 FR 62038, Nov. 24, 1993, as amended at 63 FR 2165, Jan. 14, 1998; 63 FR 57074, Oct. 26, 1998; 66 FR 50833, Oct. 5, 2001; 67 FR 49616, July 31, 2002; 71 FR 74816, Dec. 13, 2006; 73 FR 53738, Sept. 17, 2008]

§ 180.207 Trifluralin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide and plant growth regulator trifluralin, alpha, alpha, alpha-trifluoro-2,6-dinitro-*N*,*N*-dipropyl-*p*-toluidine, in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	2.0
Almond, hulls	0.05
Asparagus	0.05
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Bean, mung, sprouts	2.0
Carrot, roots	1.0
Celery	0.05
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Endive	0.05
Flax, seed	0.05
Fruit, citrus, group 10	0.05
Fruit, stone, group 12	0.05
Grape	0.05
Hop, dried cones	0.05
Mustard, seed	0.05
Nut, tree, group 14	0.05
Okra	0.05
Peanut	0.05
Peanut, hay	0.05
Peppermint, oil	2.0
Peppermint, tops	0.05
Rapeseed, seed	0.05
Safflower, seed	0.05
Sorghum, grain, forage	0.05
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.05
Spearmint, oil	2.0
Spearmint, tops	0.05
Sugarcane, cane	0.05
Sunflower, seed	0.05
Vegetable, brassica, leafy group 5	0.05
Vegetable, bulb, group 3	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, foliage of legume, group 7	0.05
Vegetable, fruiting, group 8	0.05
Vegetable, leaves of root and tuber, group 2	0.05
Vegetable, legume, group 6	0.05
Vegetable, root and tuber, group 1, except carrot	0.05
Wheat, grain	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 42619, June 25, 1980, as amended at 45 FR 56346, Aug. 25, 1980; 45 FR 86493, Dec. 31, 1980; 46 FR 37250, July 20, 1981; 47 FR 13524, Mar. 31, 1982; 47 FR 20309, May 12, 1982; 63 FR 57074, Oct. 26, 1998; 64 FR 39082, July 21, 1999; 70 FR 21643, Apr. 27, 2005; 71 FR 54433, Sept. 15, 2006]

§ 180.208 Benfluralin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide benfluralin, *N*-butyl-*N*-ethyl-αααα-trifluoro-2,6-dinitro-*p*-toluidine, in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.05
Clover, forage	0.05
Clover, hay	0.05
Lettuce	0.05
Trefoil, forage	0.05
Trefoil, hay	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003, as amended at 73 FR 52613, Sept. 10, 2008]

§ 180.209 Terbacil; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide terbacil, (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], calculated as terbacil, in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	1.0
Alfalfa, hay	2.0
Apple	0.3
Asparagus	0.4
Blueberry	0.2
Caneberry subgroup 13A	0.2
Peach	0.2
Peppermint, tops	2.0
Spearmint, tops	2.0
Strawberry	0.1
Sugarcane, cane	0.4
Watermelon	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 30818, May 31, 2006]

§ 180.210 Bromacil; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide bromacil (5-bromo-3-*sec*-butyl-6-methyluracil) in or on the following food commodities:

Commodity	Parts per million
Fruit, citrus	0.1
Pineapple	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003]

§ 180.211 Propachlor; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide propachlor (2-chloro-N-isopropylacetanilide) and its metabolites containing the N-isopropylaniline moiety, calculated as 2-chloro-N-isopropylacetanilide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.2
Cattle, meat	0.02
Cattle, meat byproducts, except kidney	0.05
Corn, field, forage	3.0
Corn, field, grain	0.2
Corn, field, stover	1.0
Corn, sweet, forage	3.0
Goat, fat	0.05
Goat, kidney	0.2
Goat, meat	0.02
Goat, meat byproducts, except kidney	0.05
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.05
Horse, kidney	0.2
Horse, meat	0.02
Horse, meat byproducts, except kidney	0.05
Milk	0.02
Sheep, fat	0.05
Sheep, kidney	0.2
Sheep, meat	0.02
Sheep, meat byproducts, except kidney	0.05
Sorghum, forage, forage	8.0
Sorghum, grain, forage	8.0
Sorghum, grain, grain	0.25
Sorghum, grain, stover	12.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 25959, June 16, 1982, as amended at 47 FR 28381, June 30, 1982; 47 FR 28626, July 1, 1982; 47 FR 46701, Oct. 20, 1982; 63 FR 57074, Oct. 26, 1998; 72 FR 53454, Sept. 19, 2007]

§ 180.212 *S*-Ethyl cyclohexylethylthiocarbamate; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide *S*-ethyl cyclohexylethylthiocarbamate in or on the following food commodities:

Commodity	Parts per million
Beet, garden, roots	0.05(N)
Beet, garden, tops	0.05(N)
Beet, sugar, roots	0.05(N)
Beet, sugar, tops	0.05(N)
Spinach	0.05(N)

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003]

§ 180.213 Simazine; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide simazine (2-chloro-4,6-bis(ethylamino)-s-triazine) and its two chlorinated degradates (2-amino-4-chloro-6-ethylamino-s-triazine and 2,4-diamino-6-chloro-s-triazine), the total residue to be measured in or on the following food commodities:

Commodity	Parts per million
Almond	0.25
Almond, hulls	0.25
Apple	0.20
Avocado	0.20
Blackberry	0.20
Blueberry	0.20
Cattle, meat	0.03
Cattle, meat byproducts	0.03
Cherry	0.25
Corn, field, forage	0.20
Corn, field, grain	0.20
Corn, field, stover	0.25
Corn, pop, grain	0.20
Corn, pop, stover	0.25
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husks removed	0.25
Corn, sweet, stover	0.25
Cranberry	0.25
Currant	0.25
Egg	0.03
Goat, meat	0.03
Goat, meat byproducts	0.03
Grape	0.20
Grapefruit	0.25
Hazelnut	0.20
Horse, meat	0.03
Horse, meat byproducts	0.03
Lemon	0.25
Loganberry	0.20
Milk	0.03
Nut, macadamia	0.25
Olive	0.20
Orange	0.25
Peach	0.20
Pear	0.25
Pecan	0.20
Plum	0.20
Raspberry	0.20
Sheep, meat	0.03
Sheep, meat byproducts	0.03
Strawberry	0.25
Walnut	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 2165, Jan. 14, 1998, as amended at 63 FR 57074, Oct. 26, 1998; 72 FR 35665, June 29, 2007; 72 FR 53454, Sept. 19, 2007]

§ 180.214 Fenthion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide fenthion (*O,O*- dimethyl *O*-[4-(methylthio)-*m*- tolyl] phosphorothioate) and its cholinesterase-inhibiting metabolites in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, fat	0.1	4/1/06
Cattle, meat	0.1	4/1/06
Cattle, meat byproducts	0.1	4/1/06
Hog, fat	0.1	4/1/03
Hog, meat	0.1	4/1/03
Hog, meat byproducts	0.1	4/1/03
Milk	0.01	4/1/03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 86492, Dec. 31, 1980, as amended at 63 FR 57074, Oct. 26, 1998; 66 FR 50833, Oct. 5, 2001; 67 FR 49616, July 31, 2002]

§ 180.215 Naled; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide naled (1,2-dibromo-2,2-dichloro-ethyl dimethyl phosphate) and its conversion product 2,2-dichlorovinyl dimethyl phosphate, expressed as naled, resulting from the application of the pesticide to growing crops or from direct application to livestock and poultry, in

or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.5
Almond	0.5
Bean, dry, seed	0.5
Bean, succulent	0.5
Beet, sugar, roots	0.5
Beet, sugar, tops	0.5
Broccoli	1
Brussels sprouts	1
Cabbage	1
Cauliflower	1
Celery	3
Collards	3
Cotton, undelinted seed	0.5
Cucumber	0.5
Eggplant	0.5
Grapefruit	3
Grape	0.5
Grass, forage	10
Hop, dried cones	0.5
Kale	3
Legume, forage	10
Lemon	3
Lettuce	1
Melon	0.5
Orange, sweet	3
Peach	0.5
Pea, succulent	0.5
Pepper	0.5
Pumpkin	0.5
Safflower, seed	0.5
Spinach	3
Squash, summer	0.5
Squash, winter	0.5
Strawberry	1
Swiss chard	3
Tangerine	3
Tomato	0.5
Turnip, greens	3
Walnut	0.5

(2) A tolerance of 0.5 part per million is established for the pesticide naled in or on all raw agricultural commodities, except those otherwise listed in this section, from use of the pesticide for area pest (mosquito and fly) control.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[42 FR 46304, Sept. 15, 1977, as amended at 54 FR 20125, May 10, 1989; 63 FR 57074, Oct. 26, 1998; 66 FR 50833, Oct. 5, 2001]

§ 180.217 Ammoniates for [ethylenebis-(dithiocarbamato)] zinc and ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides; tolerances for residues.

(a) *General.* Tolerances are established for residues of a fungicide that is a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides, calculated as zinc ethylenebisdithiocarbamate, in or on the following raw agricultural commodities as follows:

Commodity	Parts per million
Apple	2.0
Potato	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 57074, Oct. 26, 1998]

§ 180.220 Atrazine; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide atrazine (2-chloro-4-ethylamino-6-isopropylamino-s-triazine) and its chlorinated metabolites 2-amino-4-chloro-6-isopropylamino-s-triazine, 2-amino-4-chloro-6-ethylamino-s-triazine, and 2,4-diamino-6-chloro-s-triazine, in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Corn, field, forage	15
Corn, field, grain	0.20
Corn, field, stover	0.5
Corn, pop, forage	1.5
Corn, pop, grain	0.20
Corn, pop, stover	0.5
Corn, sweet, forage	15
Corn, sweet, kernel plus cob with husks removed	0.20
Corn, sweet, stover	2.0
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Grass, forage	4.0
Grass, hay	4.0
Guava	0.05
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Nut, macadamia	0.20
Sheep, fat	0.02
Sheep, meat	0.02

Commodity	Parts per million
Sheep, meat byproducts	0.02
Sorghum, forage, forage	15
Sorghum, grain forage	15
Sorghum, grain, grain	0.20
Sorghum, grain, stover	0.50
Sugarcane, cane	0.20
Wheat, forage	1.5
Wheat, grain	0.10
Wheat, hay	5.0
Wheat, straw	0.50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertant residues of atrazine, 2-chloro-4-ethylamino-6-isopropylamino-s-triazine, in or on the following raw agricultural commodity when present therein as a result of application of atrazine to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Vegetable, leafy, except brassica, group 4	0.25

[43 FR 29121, July 6, 1978, as amended at 44 FR 67116, Nov. 23, 1979; 47 FR 3771, Jan. 27, 1982; 47 FR 8012, Feb. 24, 1982; 63 FR 57075, Oct. 26, 1998; 67 FR 46893, July 17, 2002; 69 FR 6567, Feb. 11, 2004; 72 FR 35666, June 29, 2007; 72 FR 53454, Sept. 19, 2007; 73 FR 37852, July 2, 2008]

§ 180.221 *O*-Ethyl *S*-phenyl ethylphosphonodithioate; tolerances for residues.

(a) *General.* Time limited tolerances are established for residues of the insecticide *O*-Ethyl *S*-phenylethylphosphonodithioate, including its oxygen analog (*O*-ethyl *S*-phenyl ethylphosphonothioate, in or on the following food commodities:

Commodities	Parts per million	Expiration/ Revocation date
Asparagus	0.5	12/31/02
Banana	0.1	Do.
Beet, sugar, tops	0.1	Do.
Corn, field, forage	0.1	Do.
Corn, field, grain	0.1	Do.
Corn, field, stover	0.1	Do.
Corn, pop, grain	0.1	Do.
Corn, pop, stover	0.1	Do.
Corn, sweet, forage	0.1	Do.
Corn, sweet, kernel plus cob with husks removed	0.1	Do.
Corn, sweet, stover	0.1	Do.
Peanut	0.1	Do.
Peanut, hay	0.1	Do.
Pea, field, hay	0.1	Do.
Pea, field, vines	0.1	Do.
Peppermint, tops	0.1	Do.
Plantain	0.1	Do.
Sorghum, grain, forage	0.1	Do.
Sorghum, grain, grain	0.1	Do.
Sorghum, grain, stover	0.1	Do.
Soybean, forage	0.1	Do.
Soybean, hay	0.1	Do.
Spearmint, tops	0.1	Do.
Strawberry	0.1	Do.
Sugarcane, cane	0.1	Do.
Vegetable, fruiting, group 8	0.1	Do.
Vegetable, leafy	0.1	Do.
Vegetable, root crop	0.1	Do.
Vegetable, seed and pod	0.1	Do.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 39077, July 21, 1999]

§ 180.222 Prometryn; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide prometryn (2,4-bis(isopropylamino)-6-methylthio-*s*-triazine) in or on the following raw agricultural commodities:

Commodity	Parts per million
Carrot, roots [1]	0.1
Celery	0.5
Corn, grain	0.25
Cotton, undelinted seed	0.25
Pea, pigeon, seed	0.25

[1] There are no U.S. registrations as of April 10, 1998 for use on carrots.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional exemptions.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the herbicide prometryn (2,4-bis(isopropylamino-6-methylthio-*s*-triazine) in or on the following raw agricultural commodity:

Commodity	Parts per million
Dill	0.3
Parsley, leaves	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 29121, July 6, 1978, as amended at 45 FR 51782, Aug. 5, 1980; 54 FR 6918, Feb. 15, 1989; 60 FR 20434, Apr. 26, 1995; 63 FR 17692, Apr. 10, 1998; 63 FR 57075, Oct. 26, 1998; 64 FR 39082, July 21, 1999]

§ 180.225 Phosphine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of phosphine in or on the following raw agricultural commodities (RACs) resulting from postharvest fumigation for the control of insects with phosphine gas or phosphide compounds that produce phosphine gas.

Commodity	Parts per million
Almond	0.1
Avocado	0.01
Banana	0.01
Barley, grain	0.1
Cabbage, Chinese	0.01
Cacao bean, dried bean	0.1
Cashew	0.1
Citron, citrus	0.01
Coffee, bean, green	0.1
Corn, field, grain	0.1
Corn, pop, grain	0.1
Cotton, undelinted seed	0.1
Date, dried fruit	0.1
Dill, seed	0.01
Eggplant	0.01
Endive	0.01
Grapefruit	0.01
Hazelnut	0.1
Kumquat	0.01
Lemon	0.01
Lettuce	0.01
Lime	0.01
Mango	0.01
Millet, grain	0.1
Mushroom	0.01
Nut, brazil	0.1
Oat, grain	0.1
Okra	0.01
Orange, sweet	0.01
Papaya	0.01
Peanut	0.1
Pecan	0.1
Pepper	0.01
Persimmon	0.01
Pistachio	0.1
Rice, grain	0.1
Rye, grain	0.1
Safflower, seed	0.1
Salsify, tops	0.01
Sesame, seed	0.1
Sorghum, grain	0.1
Soybean, seed	0.1
Sunflower, seed	0.1
Sweet potato, roots	0.01
Tangelo	0.01
Tangerine	0.01
Tomato	0.01
Vegetable, legume, group 6, except soybean	0.01
Walnut	0.1
Wheat, grain	0.1

(2) Tolerances are established for residues of the fumigant in or on all RACs resulting from preharvest treatment of pest burrows in agricultural and noncrop land areas.

Commodity	Parts per million
All raw agricultural commodities resulting from preharvest treatment of pest burrows	0.01

(3) Residues resulting from fumigation of processed food:

Commodity	Parts per million
Processed food	0.01

(4) *Residues resulting from fumigation of animal feed*:

Commodity	Parts per million
Animal feed	0.1

(5) To assure safe use of this pesticide, it must be used in compliance with the labeling conforming to that registered by the U.S. Environmental Protection Agency (EPA) under FIFRA. Labeling shall bear a restriction to aerate the finished food/feed for 48 hours before it is offered to the consumer, unless EPA specifically determines that a different time period is appropriate. Where appropriate, a warning shall state that under no condition should any formulation containing aluminum or magnesium phosphide be used so that it will come in contact with any processed food, except processed brewer's rice, malt, and corn grits stored in breweries for use in the manufacture of beer.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[64 FR 72950, Dec. 29, 1999, as amended at 71 FR 74816, Dec. 13, 2006; 72 FR 41929, Aug. 1, 2007]

§ 180.226 Diquat; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the plant growth regulator and herbicide diquat, (6,7-dihydrodipyrido (1,2-a:2′1′-c)pyrazinediium) derived from application of the dibromide salt and calculated as the cation in or on the following food commodities:

Commodity	Parts per million
Alfalfa, seed	3.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Egg	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.02
Potato	0.1
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain	2.0
Soybean, seed	0.2

(2)(i) Tolerances are established for residues of the herbicide diquat (6,7-dihydrodipyrido (1,2-a:2,1-c) pyrazinediium) (calculated as the cation) derived from the application of the dibromide salt to ponds, lakes, reservoirs, marshes, drainage ditches, canals, streams, and rivers which are slow-moving or quiescent in programs of the Corps of Engineers or other Federal or State public agencies and to ponds, lakes and drainage ditches only where there is little or no outflow of water and which are totally under the control of the user, in or on the following food commodities:

Commodity	Parts per million
Avocado	0.2
Berry group 13	0.05
Cotton, undelinted seed	0.2
Cranberry	0.05
Fish	2.0
Fruit, citrus, group 10	0.05
Fruit, pome, group 11	0.02
Fruit, stone, group 12	0.02
Grain, cereal, forage, fodder and straw, group 16	0.02
Grain, cereal, group 15	0.02
Grape	0.05
Grass, forage, fodder and hay, group 17	0.2
Hop, dried cones	0.2
Nut, tree, group 14	0.02
Shellfish	20.0
Strawberry	0.05
Sugarcane, cane	0.2
Vegetable, brassica, leafy, group 5	0.05
Vegetable, cucurbit, group 9	0.02
Vegetable, foliage of legume, group 7	0.2
Vegetable, fruiting, group 8	0.05
Vegetable, leafy, except brassica, group 4	0.05
Vegetable, root and tuber, group 1	0.02
Vegetable, seed and pod	0.05

(ii) Where tolerances are established at higher levels from other uses of diquat on the subject crops, the higher tolerances applies also to residues of the aquatic uses cited in this paragraph.

(3) Tolerances are established for the plant growth regulator diquat [6,7-dihydrodipyrido (1,2-a:2¼,1¼-c) pyrazinediium] derived from application of the dibromide salt and calculated as the cation in or on the following food commodities:

Commodity	Parts per million
Banana	0.05
Coffee, bean, green	0.05
Soybean, hulls	0.6

(4) There are no U.S. registrations as of December 6, 1995.

(5) A tolerance of 0.5 part per million is established for residues of diquat in potato, granules/flakes and potato, chips.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33709, May 24, 2000, as amended at 72 FR 41929, Aug. 1, 2007]

§ 180.227 Dicamba; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*- anisic acid in or on the food commodities as follows:

Commodity	Parts per million
Barley, grain	6.0
Barley, hay	2.0
Barley, straw	15.0
Corn, field, forage	3.0
Corn, field, grain	0.1
Corn, field, stover	3.0
Corn, pop, grain	0.1
Corn, pop, stover	3.0
Corn, sweet, forage	0.50
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	0.50
Cotton, undelinted seed	0.2
Grass, forage, fodder and hay, group 17, forage	125.0
Grass, forage, fodder and hay, group 17, hay	200.0
Millet, proso, forage	90.0
Millet, proso, grain	2.0
Millet, proso, hay	40.0
Millet, proso, straw	30.0
Oat, forage	90.0
Oat, grain	2.0
Oat, hay	40.0
Oat, straw	30.0
Rye, forage	90.0
Rye, grain	2.0
Rye, straw	30.0
Sorghum, grain, forage	3.0
Sorghum, grain, grain	4.0
Sorghum, grain, stover	10.0
Sugarcane, cane	0.1
Sugarcane, molasses	2.0
Wheat, forage	90.0
Wheat, grain	2.0
Wheat, hay	40.0
Wheat, straw	30.0

(2) Tolerances are established for the combined residues of the herbicide dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite 3,6-dichloro-2-hydroxybenzoic acid in or on the food commodities as follows:

Commodity	Parts per million
Asparagus	4.0
Cattle, fat	0.3
Cattle, kidney	25.0
Cattle, meat	0.25
Cattle, meat byproducts, except kidney	3.0
Goat, fat	0.3
Goat, kidney	25.0
Goat, meat	0.25
Goat, meat byproducts, except kidney	3.0
Hog, fat	0.3
Hog, kidney	25.0
Hog, meat	0.25
Hog, meat byproducts, except kidney	3.0
Horse, fat	0.3
Horse, kidney	25.0
Horse, meat	0.25
Horse, meat byproducts, except kidney	3.0
Milk	0.2
Sheep, fat	0.3
Sheep, kidney	25.0
Sheep, meat	0.25
Sheep, meat byproducts, except kidney	3.0

(3) Tolerances are established for the combined residues of dicamba (3,6-dichloro-*o*-anisic and its metablites 3,6-dichloro-5-hydroxy-*o*-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid in or on the food commodities as follows:

Commodity	Parts per million
Grain, aspirated fractions	1000
Soybean, hulls	30.0
Soybean, seed	10.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33709, May 24, 2000, as amended at 72 FR 35665, June 29, 2007; 73 FR 17918, Apr. 2, 2008; 73 FR 54960, Sept. 24, 2008]

§ 180.228 *S*-Ethyl hexahydro-*1H*-azepine-1-carbothioate; tolerances for residues.

(a) *General.* Tolerances are established for the herbicide *S*-ethyl hexahydro-1*1H*-azepine-1-carbothioate in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Rice, grain	0.1	9/1/09
Rice, straw	0.1	9/1/09

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003, as amended at 69 FR 58083, Sept. 29, 2004]

§ 180.229 Fluometuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide fluometuron, *N*, *N*-dimethyl-*N'*-[3-(trifluoromethyl)phenyl]urea, and its metabolite, trifluoromethylaniline (TFMA) determined as TFMA, in or on the following food commodities:

Commodity	Parts per million
Cotton, gin byproducts	3.5
Cotton, undelinted seed	1.0

(2) Tolerances are established for the combined residues of the herbicide fluometuron, *N,N*-dimethyl-*N'*-[3-(trifluoromethyl)phenyl]urea, and its metabolites determined as TFMA and the hydroxylated metabolites: CGA-236431, 1-(4-hydroxy-3-trifluoromethylphenyl)urea; CGA-236432, 1-methyl-3-(4-hydroxy-3-trifluoromethylphenyl)urea; and CGA-13211, 1,1-dimethyl-3-(4-hydroxy-3-trifluoromethylphenyl)urea, in or on the following food commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.1
Egg	0.1
Goat, meat byproducts	0.1
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Milk	0.02
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Sheep, meat byproducts	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined residues of the herbicide fluometuron, *N, N*-dimethyl-*N'*-[3-(trifluoromethyl)phenyl]urea, and its metabolite, trifluoromethylaniline (TFMA) determined as TFMA, in or on the following food commodities.

Commodity	Parts per million
Grain, cereal, forage, fodder, and straw group 16, forage	3.0
Grain, cereal, forage, fodder, and straw, group 16, stover	6.0
Grain, cereal, group 15	0.5
Peanut	0.1
Peanut, hay	4.0
Peanut, meal	0.2
Soybean, forage	3.0
Soybean, hay	3.0
Soybean, seed	2.0
Rice, hulls	1.0
Wheat, milled byproducts	1.0

[73 FR 52613, Sept. 10, 2008]

§ 180.231 Dichlobenil; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide dichlobenil (2,6-dichlorobenzonitrile) and its metabolite 2,6-dichlorobenzamide in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	0.5
Bushberry subgroup 13–07B	0.15
Caneberry subgroup 13–07A	0.10
Cranberry	0.1
Fruit, stone, group 12	0.15
Grape	0.15
Hazelnut	0.1
Pear	0.5
Rhubarb	0.06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[36 FR 22540, Nov. 25, 1971, as amended at 63 FR 57075, Oct. 26, 1998; 66 FR 63198, Dec. 5, 2001; 73 FR 50570, Aug. 27, 2008]

§ 180.232 Butylate; tolerances for residues.

(a) *General.* Tolerances are established for the herbicide butylate in or on the following food commodities:

Commodity	Parts per million
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Corn, pop, forage	0.1
Corn, pop, grain	0.1
Corn, sweet, forage	0.1
Corn, sweet, kernel plus cob with husks removed	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39439, July 1, 2003]

§ 180.235 Dichlorvos; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the insecticide 2,2-dichlorovinyl dimethyl phosphate are established as follows:

Commodity	Parts per million
Cattle, fat	0.02(N)
Cattle, meat	0.02(N)
Cattle, meat byproducts	0.02(N)
Egg	0.05(N)

Commodity	Parts per million
Goat, fat	0.02(N)
Goat, meat	0.02(N)
Goat, meat byproducts	0.02(N)
Horse, fat	0.02(N)
Horse, meat	0.02(N)
Horse, meat byproducts	0.02(N)
Milk	0.02(N)
Mushroom (residues expressed as naled)	0.5
Poultry, fat	0.05(N)
Poultry, meat	0.05(N)
Poultry, meat byproducts	0.05(N)
Raw agricultural commodities, nonperishable, bulk stored regardless of fat content, postharvest	0.5
Raw agricultural commodities nonperishable, packaged or bagged, containing 6 percent fat or less, postharvest	0.5
Raw agricultural commodities, nonperishable, packaged or bagged, containing more than 6 percent fat, postharvest	2
Sheep, fat	0.02(N)
Sheep, meat	0.02(N)
Sheep, meat byproducts	0.02(N)
Tomato, postharvest (residues expressed as naled)	0.05

(2) The tolerance of 0.1 part per million prescribed by 21 CFR 556.180 for negligible residues of 2,2-dichlorovinyl dimethyl phosphate in the edible tissue of swine covers both its use as an anthelmintic in swine feed and as an insecticide applied directly to swine.

(3) Dichlorvos may be present as a residue from application as an insecticide on packaged or bagged nonperishable processed food (see: 21 CFR 170.3(j)) in an amount in such food not in excess of 0.5 part per million (ppm). To assure safe use of the insecticide, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency, and the usage employed shall conform with such label or labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 55223, Dec. 8, 1982, as amended at 55 FR 26440, June 28, 1990; 56 FR 29183, June 26, 1991; 63 FR 57075, Oct. 26, 1998; 65 FR 33697, May 24, 2000]

§ 180.236 Triphenyltin hydroxide; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide triphenyltin hydroxide (TPTH) and its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites, expressed in terms of parent TPTH, in or on the following raw agricultural commodities:

Commodity	Parts per million
Beet, sugar, roots	0.05
Beet, sugar, tops	10.0
Cattle, fat	0.2
Cattle, kidney	2.0
Cattle, liver	4.0
Cattle, meat	0.5
Goat, fat	0.2
Goat, kidney	2.0
Goat, liver	4.0
Goat, meat	0.5
Hog, fat	0.3
Hog, meat	0.06
Hog, meat byproducts	0.3
Horse, fat	0.2
Horse, kidney	2.0
Horse, liver	4.0
Horse, meat	0.5
Milk	0.06
Pecan	0.05
Potato	0.05
Sheep, fat	0.2
Sheep, kidney	2.0
Sheep, liver	4.0
Sheep, meat	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 41929, Aug. 1, 2007]

§ 180.239 Phosphamidon; tolerances for residues.

(a) *General.* Tolerances (expressed as phosphamidon) for residues of the insecticide phosphamidon (2-chloro-2-diethylcarbamoyl-1-methylvinyl dimethyl phosphate) including all of its related cholinesterase-inhibiting compounds in or on raw agricultural commodities are established as follows:

Commodity	Parts per million	Expiration/Revocation Date
Apple	1.0	12/31/02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 46893, July 17, 2002]

§ 180.241 Bensulide; tolerances for residues.

(a) *General.* Tolerances are established for the residues of S-(O,O-diisopropyl phosphorodithioate) of *N*-(2-mercaptoethyl) benzenesulfonamide including its oxygen analog *S*-(*O*,*O*-diisopropyl phosphorothioate) of *N*-(2-mercaptoethyl) benzenesulfonamide in or on the following food commodities:

Commodity	Parts per million
Onion, bulb	0.10
Vegetable, brassica, leafy group 5	0.15
Vegetable, cucurbits group 9	0.15
Vegetable, fruiting group 8	0.10
Vegetable, leafy except brassica group 4	0.15

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m), are established for the residues of *S*-(*O*,*O*-diisopropyl phosphorodithioate) of *N*-(2-mercaptoethyl) benzenesulfonamide including its oxygen analog *S*-(*O*,*O*-diisopropyl phosphorothioate) of *N*-(2-mercaptoethyl) benzenesulfonamide in or on the following food commodities:

Commodity	Parts per million
Carrot, roots	0.10

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39440, July 1, 2003, as amended at 73 FR 53738, Sept. 17, 2008]

§ 180.242 Thiabendazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite benzimidazole (free and conjugated) in or on the following food commodities:

Commodity	Parts per million
Apple, wet pomace	12.0
Avocado [1]	10.0
Banana, postharvest	3.0
Bean, dry, seed	0.1
Beet, sugar, dried pulp	3.5
Beet, sugar, roots	0.25
Beet, sugar, tops	10.0
Cantaloupe [1]	15.0
Carrot, roots, postharvest	10.0
Citrus, oil	15.0
Fruit, citrus, group 10, postharvest	10.0
Fruit, pome, group 11, postharvest	5.0
Mango	10.0
Mushroom	40.0
Papaya, postharvest	5.0
Potato, postharvest	10.0
Soybean	0.1
Strawberry [1]	5.0
Sweet potato (postharvest to sweet potato intended only for use as seed)	0.05
Wheat, grain	1.0
Wheat, straw	1.0

[1] There are no U.S. registrations on the indicated commodity.

(2) Tolerances are established for the combined residues of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolites 5-hydroxythiabendazole (free and conjugated) and benzimidazole in or on the following food commodities:

Commodity	Parts per million
Cattle, meat	0.1
Cattle, meat byproducts	0.4
Goat, meat byproducts	0.4
Hog, meat byproducts	0.3
Horse, meat byproducts	0.4
Milk	0.1
Sheep, meat byproducts	0.4

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite benzimidazole (free and conjugated), in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances will expire on the dates specified in the table.

Commodity	Parts per million	Expiration/ Revocation Date
Brussels sprout	0.05	12/31/09
Cabbage	0.05	12/31/09
Cauliflower	0.05	12/31/09
Lentil, seed	0.1	12/31/08

(c) *Tolerances with regional exemptions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[42 FR 32783, June 28, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.242, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and on GPO Access.

§ 180.243 Propazine; tolerances for residues.

Tolerances are established for negligible residues (N) of the herbicide propazine (2-chloro-4,6-bis(isopropylamino)-*s*-triazine in or on the following raw agricultural commodities:

Commodity	Parts per million
Sorghum, forage	0.25(N)
Sorghum, grain, grain	0.25(N)
Sorghum, grain, stover	0.25(N)
Sorghum, sweet	0.25(N)

[43 FR 29121, July 6, 1978]

§ 180.245 Streptomycin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide streptomycin in or on food commodities as follows:

Commodity	Parts per million
Bean, dry, seed	0.5
Bean, succulent	0.5
Fruit, pome, group 11	0.25

(2) Tolerances are established for residues of the fungicide streptomycin from treatment of seedling plants before transplanting in or on the following food commodities:

Commodity	Parts per million
Celery	0.25
Pepper	0.25
Tomato	0.25

(3) Tolerances are established for residues of the fungicide streptomycin from treatment of seed pieces in or on the following food commodity:

Commodity	Parts per million
Potato	0.25

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39440, July 1, 2003, as amended at 73 FR 54960, Sept. 24, 2008]

§ 180.249 Alachlor; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor in or on the following raw agricultural commodities.

Commodity	Parts per million
Beans, dry	0.1
Beans, succulent lima	0.1
Cattle, fat	0.02
Cattle, meat byproducts	0.02
Cattle, meat	0.02
Corn, field, forage	2.0
Corn, field, grain	0.2
Corn, field, pop	0.2
Corn, field, stover	2.0
Corn, pop, stover	2.0
Corn, sweet (K+CWHR)	0.05
Corn, sweet, stover	2.0
Cotton, gin byproducts	0.7
Cotton, undelinted seed	0.03
Cowpea, forage	5.0
Cowpea, hay	5.0
Egg	0.02
Goat, fat	0.02
Goat, meat byproducts	0.02
Goat, meat	0.02
Hog, fat	0.02
Hog meat byproducts	0.02
Hog, meat	0.02
Horse, fat	0.02
Horse, meat byproducts	0.02
Horse, meat	0.02
Milk	0.02
Peanut	0.5
Poultry, fat	0.02
Poultry, meat byproducts	0.02
Poultry, meat	0.02
Sheep, fat	0.02
Sheep, meat byproducts	0.02
Sheep, meat	0.02
Sorghum grain, forage	2.0
Sorghum, grain, grain	0.1
Sorghum, grain, stover	1.0
Soybeans, seed	1.0
Sunflower, meal	3.4
Sunflower, seed	2.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of alachlor (2-

chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor, in or on the following raw agricultural commodities when present therein as a result of the application of alachlor to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.4
Animal feed, nongrass, group 18, hay	1.2
Grain, cereal, forage, and straw, group 16 except corn, sorghum, rice, straw	0.8
Grain, cereal, forage, fodder and straw, group 16 except corn, sorghum, rice, forage	0.6
Grain, cereal, forage, fodder, and straw, group 16 except for corn, sorghum, rice, hay	0.8
Grain, cereal, group 15 except corn, sorghum, rice	0.05

[72 FR 54584, Sept. 26, 2007]

§ 180.252 Tetrachlorvinphos; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide tetrachlorvinphos, (*Z*)-2-chloro-1-(2,4,5- trichlorophenyl) vinyl dimethyl phosphate, and its metabolites, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol in/on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2	3/17/10
Cattle, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0	3/17/10
Cattle, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5	3/17/10
Cattle, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0	3/17/10
Cattle, meat by products, except kidney and liver	1.0	3/17/10
Egg (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.2	3/17/10
Hog, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2	3/17/10
Hog, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0	3/17/10
Hog, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5	3/17/10
Hog, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0	3/17/10
Hog, meat byproducts, except kidney and liver	1.0	3/17/10
Milk, fat (reflecting negligible residues in whole milk and of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.05	3/17/10
Poultry, fat (of which no more than 7.0 ppm is tetrachlorvinphos *per se*)	7.0	3/17/10
Poultry, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	2.0	3/17/10
Poultry, meat (of which no more than 3.0 ppm is tetrachlorvinphos *per se*)	3.0	3/17/10
Poultry, meat byproducts, except liver	2.0	3/17/10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 39053, July 21, 1999, as amended at 65 FR 33697, May 24, 2000; 67 FR 49616, July 31, 2002; 73 FR 53738, Sept. 17, 2008]

§ 180.253 Methomyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide methomyl (*S*-methyl *N*-[(methylcarbamoyl)oxy] thioacetimidate) in or on the food commodities as follows:

Commodity	Parts per million
Alfalfa	10
Apple	1
Asparagus	2
Avocado	2
Barley, grain	1
Barley, hay	10
Barley, straw	10
Bean, dry, seed	0.1(N)
Bean, forage	10
Bean, succulent	2
Beet, garden, tops	6
Bermudagrass, forage	10
Bermudagrass, hay	40
Blueberry	6
Broccoli	3
Brussels sprouts	2
Cabbage	5
Cabbage, chinese	5
Cauliflower	2
Celery	3
Collards	6
Corn, forage	10
Corn, grain (inc pop)	0.1(N)

Commodity	Parts per million
Corn, stover	10
Corn, sweet, kernel plus cob with husks removed	0.1(N)
Cotton, undelinted seed	0.1(N)
Cucurbits	0.2(N)
Dandelion, leaves	6
Endive	5
Grapefruit	2
Grape	5
Hop, dried cones [1]	12
Kale	6
Leek	3.0
Lemon	2
Lentil, seed	0.1
Lettuce	5
Mint, hay	2
Mustard greens	6
Nectarine	5
Oat, forage	10
Oat, grain	1
Oat, hay	10
Oat, straw	10
Onion, green	3
Orange, sweet	2
Parsley, leaves	6
Pea	5
Pea, field, vines	10
Peach	5
Peanut	0.1(N)
Pecan	0.1
Pepper	2
Pomegranate	0.2(N)
Rye, forage	10
Rye, grain	1
Rye, straw	10
Sorghum, forage	1
Sorghum, grain	0.2(N)
Soybean	0.2(N)
Soybean, forage	10
Spinach	6
Strawberry	2
Swiss chard	6
Tangerine	2
Tomato	1
Turnip, greens	6
Vegetable, brassica, leafy, group 5	6.0
Vegetable, fruiting	0.2(N)
Vegetables, leafy [exc. beet (tops), broccoli, Brussels sprouts, cabbage, cabbage, Chinese, cauliflower, celery, collards, dandelions, endive (escarole), kale, lettuce, mustard greens, parsley, spinach, Swiss chard, turnip, greens (tops), and watercress]	0.2(N)
Vegetable, root	0.2(N)
Watercress	6
Wheat, forage	10
Wheat, grain	1
Wheat, hay	10
Wheat, straw	10

[1]There are no U.S. registrations for use of methomyl on hop, dried cone, as of February 14, 1990.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of methomyl in or on the following food commodities:

Commodity	Parts per million
Pear	4

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33697, May 24, 2000, as amended at 72 FR 35666, June 29, 2007]

§ 180.254 Carbofuran; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate), its carbamate metabolite-2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate, and its phenolic metabolites 2,3-dihydro-2,2-dimethyl-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-3,-oxo-7-benzofuranol and 2,3-dihydro-2,2-dimethyl-3,7-benzofurandiol in or on the following raw agricultural commodities:

Commodity	Parts per million (ppm)
Alfalfa, forage (of which no more than 5 ppm are carbamates)	10
Alfalfa, hay (of which no more than 20 ppm are carbamates)	40
Banana	0.1
Barley, grain (of which not more than 0.1 ppm is carbamates)	0.2
Barley, straw (of which no more than 1.0 ppm is carbamates)	5.0
Beet, sugar, roots	0.1
Beet, sugar, tops (of which no more than 1 ppm is carbamates)	2
Coffee, bean, green	0.1
Corn, forage (of which no more than 5 ppm are carbamates)	25
Corn, grain (including popcorn) (of which no more than 0.1 ppm is carbamates)	0.2
Corn, stover (of which no more than 5 ppm are carbamates)	25
Corn, sweet, kernel plus cob with husks removed (of which no more than 0.2 ppm is carbamates)	1.0
Cotton, undelinted seed (of which no more than 0.2 ppm is carbamates)	1.0
Cranberry (of which no more than 0.3 ppm is carbamates)	0.5
Cucumber (of which not more than 0.2 ppm is carbamates)	0.4
Grape (of which no more than 0.2 ppm is carbamates)	0.4
Grape, raisin (of which no more than 1.0 ppm is carbamate	2.0
Grape, raisin, waste (of which no more than 3.0 ppm is carbamates	6.0
Melon (of which not more than 0.2 ppm is carbamates)	0.4
Milk (of which no more than 0.02 ppm is carbamates)	0.1

Commodity	Parts per million (ppm)
Oat, grain (of which not more than 0.1 ppm is carbamates)	0.2
Oat, straw (of which not more than 1.0 ppm is carbamates)	5.0
Pepper (of which no more than 0.2 ppm is carbamates)	1
Potato (of which no more than 1 ppm is carbamates)	2
Pumpkin (of which not more than 0.6 ppm is carbamates)	0.8
Rice, grain	0.2
Rice, straw (of which no more than 0.2 ppm is carbamates)	1
Sorghum, forage (of which no more than 0.5 ppm is carbamates)	3
Sorghum, grain, grain	0.1
Sorghum, grain, stover (of which no more than 0.5 ppm is carbamates)	3
Strawberry (of which no more than 0.2 ppm is carbamates)	0.5
Soybean (of which not more than 0.2 ppm is carbamates)	1.0
Soybean, forage (of which not more than 20.0 ppm are carbamates)	35.0
Soybean, hay (of which not more than 20.0 ppm are carbamates)	35.0
Squash (of which not more than 0.6 ppm is carbamates)	0.8
Sugarcane, cane	0.1
Sunflower, seed (of which not more than 0.5 ppm is carbamates)	1.0
Wheat, grain (of which not more than 0.1 ppm is carbamates)	0.2
Wheat, straw (of which not more than 1.0 ppm is carbamates)	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the insecticide carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate), its carbamate metabolite 2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate, and its phenolic metabolites 2,3-dihydro-2,2-dimethyl-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-3-oxo-7-benzofuranol, and 2,3-dihydro-2,2-dimethyl-3,7-benzofurandiol in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration/ Revocation date
Artichoke, globe (of which not more than 0.2 ppm is carbamates)	0.4	None
Canola, seed (of which no more than 0.2 ppm is carbamate)	1.0	2/22/98

(d) *Indirect or inadvertent residues.* [Reserved]

[39 FR 20597, June 12, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.254, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 74 FR 23094, May 15, 2009, § 180.254 was amended by revising the tables in paragraphs (a) and (c), effective Aug. 13, 2009. For the convenience of the user, the revised text is set forth as follows:

§ 180.254 Carbofuran; tolerances for residues.

(a) * * *

Commodity	Parts per million (ppm)	Expiration/ Revocation date
Alfalfa, forage (of which no more than 5 ppm are carbamates)	10	12/31/09
Alfalfa, hay (of which no more than 20 ppm are carbamates)	40	12/31/09
Banana	0.1	12/31/09
Barley, grain (of which not more than 0.1 ppm is carbamates)	0.2	12/31/09
Barley, straw (of which no more than 1.0 ppm is carbamates)	5.0	12/31/09
Beet, sugar, roots	0.1	12/31/09
Beet, sugar, tops (of which no more than 1 ppm is carbamates)	2	12/31/09
Coffee, bean, green	0.1	12/31/09
Corn, forage (of which no more than 5 ppm are carbamates)	25	12/31/09
Corn, grain (including popcorn) (of which no more than 0.1 ppm is carbamates)	0.2	12/31/09
Corn, stover (of which no more than 5 ppm are carbamates)	25	12/31/09
Corn, sweet, kernel plus cob with husks removed (of which no more than 0.2 ppm is carbamates)	1.0	12/31/09
Cotton, undelinted seed (of which no more than 0.2 ppm is carbamates)	1.0	12/31/09
Cranberry (of which no more than 0.3 ppm is carbamates)	0.5	12/31/09
Cucumber (of which not more than 0.2 ppm is carbamates)	0.4	12/31/09
Grape (of which no more than 0.2 ppm is carbamates)	0.4	12/31/09
Grape, raisin (of which no more than 1.0 ppm is carbamate	2.0	12/31/09
Grape, raisin, waste (of which no more than 3.0 ppm is carbamates	6.0	12/31/09
Melon (of which not more than 0.2 ppm is carbamates)	0.4	12/31/09
Milk (of which no more than 0.02 ppm is carbamates)	0.1	12/31/09
Oat, grain (of which not more than 0.1 ppm is carbamates)	0.2	12/31/09
Oat, straw (of which not more than 1.0 ppm is carbamates)	5.0	12/31/09
Pepper (of which no more than 0.2 ppm is carbamates)	1	12/31/09
Potato (of which no more than 1 ppm is carbamates)	2	12/31/09

Commodity	Parts per million (ppm)	Expiration/ Revocation date
Pumpkin (of which not more than 0.6 ppm is carbamates)	0.8	12/31/09
Rice, grain	0.2	12/31/09
Rice, straw (of which no more than 0.2 ppm is carbamates)	1	12/31/09
Sorghum, forage (of which no more than 0.5 ppm is carbamates)	3	12/31/09
Sorghum, grain, grain	0.1	12/31/09
Sorghum, grain, stover (of which no more than 0.5 ppm is carbamates)	3	12/31/09
Strawberry (of which no more than 0.2 ppm is carbamates)	0.5	12/31/09
Soybean (of which not more than 0.2 ppm is carbamates)	1.0	12/31/09
Soybean, forage (of which not more than 20.0 ppm are carbamates)	35.0	12/31/09
Soybean, hay (of which not more than 20.0 ppm are carbamates)	35.0	12/31/09
Squash (of which not more than 0.6 ppm is carbamates)	0.8	12/31/09
Sugarcane, cane	0.1	12/31/09
Sunflower, seed (of which not more than 0.5 ppm is carbamates)	1.0	12/31/09
Wheat, grain (of which not more than 0.1 ppm is carbamates)	0.2	12/31/09
Wheat, straw (of which not more than 1.0 ppm is carbamates)	5.0	12/31/09

* * * * *

(c) * * *

Commodity	Parts per million (ppm)	Expiration/ Revocation date
Artichoke, globe (of which not more than 0.2 ppm is carbamates)	0.4	12/31/09

* * * * *

§ 180.257 Chloroneb; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide chloroneb (1,4-dichloro-2,5-dimethoxybenzene) and its metabolite 2,5-dichloro-4-methoxyphenol (free and conjugated), calculated as chloroneb, in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, dry, seed	0.2
Bean, succulent	0.2
Beet, sugar, roots	0.2
Beet, sugar, tops	0.2
Cowpea, forage	2.0
Cowpea, hay	2.0
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Cotton, gin byproducts	1.0
Cotton, undelinted seed	0.2
Goat, fat	0.2
Goat, meat	0.2
Goat, meat byproducts	0.2
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	0.2
Horse, fat	0.2
Horse, meat	0.2
Horse, meat byproducts	0.2
Milk	0.05
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Soybean, forage	2.0
Soybean, hay	2.0
Soybean, seed	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39440, July 1, 2003, as amended at 72 FR 53460, Sept. 19, 2007]

§ 180.258 Ametryn; tolerances for residues.

(a) *General.* Tolerances are established for residues of the desiccant and herbicide (2-ethylamino)-4-(isopropylamino)-6-(methylthio)-*s*-triazine in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana	0.25
Corn, field, forage	0.1
Corn, field, grain	0.05
Corn, field, stover	0.05
Corn, pop, grain	0.05
Corn, pop, stover	0.05
Corn, sweet, forage	0.5
Corn, sweet, kernel plus cob with husks removed	0.25
Corn, sweet, stover	0.5
Pineapple	0.05
Sugarcane, cane	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 29121, July 6, 1978, as amended at 48 FR 13175, Mar. 30, 1983; 48 FR 21132, May 11, 1983; 52 FR 33237, Sept. 2, 1987; 63 FR 57075, Oct. 26, 1998; 73 FR 54961, Sept. 24, 2008]

§ 180.259 Propargite; tolerances for residues.

(a) *General.* Tolerances are established for residues of the pesticide propargite (2-(*p-tert*-butylphenoxy) cyclohexyl 2-propynyl sulfite) in or on the following food commodities.

Commodity	Parts per million
Almond	0.1
Almond, hulls	55.0
Bean, dry, seed	0.2
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Citrus, oil	30.0
Corn, field, forage	10.0
Corn, field, grain	0.1
Corn, field, stover	10.0
Corn, pop, grain	0.1
Corn, pop, stover	10.0
Corn, sweet, forage	10.0
Corn, sweet, stover	10.0
Cotton, undelinted seed	0.1
Egg	0.1
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.1
Grain, aspirated fractions	0.4
Grape	10.0
Grapefruit	5.0
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.1
Hop, dried cones	100.0
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.1
Lemon	5.0
Milk, fat (0.08 ppm in milk)	2.0
Nectarine	4.0
Orange	10.0
Peanut	0.1
Peppermint, tops	50.0
Poultry, fat	0.1
Potato	0.1
Sheep, fat	0.1
Sheep, meat	0.1
Sheep, meat byproducts	0.1
Sorghum, grain, forage	10.0
Sorghum, grain, grain	5.0
Sorghum, grain, stover	10.0
Spearmint, tops	50.0
Tea, dried	10.0
Walnut	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of propargite in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, sweet, kernel plus cob with husks removed	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33710, May 24, 2000, as amended at 72 FR 41930, Aug. 1, 2007; 73 FR 54961, Sept. 24, 2008]

§ 180.261 *N*-(Mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) and its oxygen analog; tolerances for residues.

(a) *General.* Tolerances are established for the sum of the residues for the insecticide *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) and its oxygen analog *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorothioate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa	40
Almond, hulls	10
Apple	10
Apricot	5
Blueberry	10
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Cherry	10
Cotton, undelinted seed	0.1
Cranberry	10
Fruit, citrus	5
Goat, fat	0.2
Goat, meat byproducts	0.2
Goat, meat	0.2
Grape	10
Hog, fat	0.2
Hog, meat byproducts	0.2
Hog, meat	0.2
Horse, fat	0.2
Horse, meat byproducts	0.2
Horse, meat	0.2
Kiwifruit	25
Nectarine	5
Nut	0.1(N)
Peach	10
Pear	10
Pea	0.5
Pea, field, hay	10
Pea, field, vines	10
Plum, prune, fresh	5
Potato	0.1
Sheep, fat	0.2
Sheep, meat byproducts	0.2
Sheep, meat	0.2
Sweet potato, roots	10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the sum of the residue for the insecticide *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) and its oxygen

analog *N*-(mercaptomethyl) phthalimide *S*-(*O*,*O*-dimethyl phosphorothioate) in or on the following raw agricultural commodity:

Commodity	Parts per million
Crabapple	20
Pistachio	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 46538, Oct. 10, 1978, as amended at 45 FR 8981, Feb. 11, 1980; 48 FR 37213, Aug. 17, 1983; 52 FR 48539, Dec. 23, 1987; 53 FR 657, Jan. 11, 1988; 53 FR 39090, Oct. 5, 1988; 63 FR 57075, Oct. 26, 1998; 67 FR 49616, July 31, 2002]

§ 180.262 Ethoprop; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nematocide and insecticide ethoprop (*O*-ethyl *S*,*S*-dipropyl phosphorodithioate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana	0.02
Bean, lima	0.02
Bean, snap, succulent	0.02
Cabbage	0.02
Corn, forage	0.02
Corn, grain	0.02
Corn, stover	0.02
Corn, sweet, kernel plus cob with husks removed	0.02
Cucumber	0.02
Hop, dried cones	0.02
Peppermint, tops	0.02
Pineapple	0.02
Potato	0.02
Spearmint, tops	0.02
Sugarcane, cane	0.02
Sweet potato, roots	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 53004, Nov. 24, 1982, as amended at 48 FR 51485, Nov. 9, 1983; 52 FR 33237, Sept. 2, 1987; 53 FR 30053, Aug. 10, 1988; 63 FR 57075, Oct. 26, 1998; 64 FR 39078, July 21, 1999; 66 FR 38955, July 26, 2001; 67 FR 49616, July 31, 2002; 73 FR 53731, Sept. 17, 2008; 73 FR 54961, Sept. 24, 2008]

§ 180.263 Phosalone; tolerances for residues.

Tolerances are established for residues of the insecticide phosalone (*S*-(6-chloro-3-(mercaptomethyl)-2-benzoxazolinone)*O*,*O*,-diethyl phosphorodithioate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond	0.1
Apple	10.0
Apricot	15.0
Cherry	15.0
Grape	10.0
Peach	15.0
Pear	10.0
Plum, prune, fresh	15.0

[47 FR 42740, Sept. 29, 1982, as amended at 63 FR 57066, Oct. 26, 1998; 64 FR 3428, Jan. 22, 1999; 67 FR 49616, July 31, 2002]

§ 180.269 Aldicarb; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the insecticide and nematocide aldicarb (2-methyl-2-(methylthio)propionaldehyde *O*-(methylcarbamoyl) oxime and its cholinesterase-inhibiting metabolites 2-methyl 2-(methylsulfinyl) propionaldehyde *O*-(methylcarbamoyl) oxime and 2-methyl-2-(methylsulfonyl) propionaldehyde *O*-(methylcarbamoyl) oxime in or on the following food commodities:

Commodity	Parts per million
Bean, dry, seed	0.1
Beet, sugar, roots	0.05
Beet, sugar, tops	1
Citrus, dried pulp	0.6
Coffee, bean, green	0.1
Cotton, undelinted seed	0.1
Cotton, hulls	0.3
Grapefruit	0.3
Lemon	0.3
Lime	0.3
Orange, sweet	0.3
Peanut	0.05
Pecan	0.5
Potato	1
Sorghum, grain, bran	0.5
Sorghum, grain, grain	0.2
Sorghum, grain, stover	0.5
Soybean	0.02
Sugarcane, cane	0.02
Sweet potato, roots	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33710, May 24, 2000, as amended at 69 FR 6567, Feb. 11, 2004; 73 FR 54961, Sept. 24, 2008]

§ 180.272 Tribuphos; tolerances for residues.

(a) *General.* Tolerances are established for residues of the defoliant tribuphos (*S,S,S*-tributyl phosphorotrithioate) in or on food commodities as follows:

Commodity	Parts per million
Cattle, fat	0.15
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Cotton, gin byproducts	40.0
Cotton, undelinted seed	4.0
Goat, fat	0.15
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, fat	0.15
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.15
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.01
Sheep, fat	0.15
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33698, May 24, 2000, as amended at 67 FR 49616, July 31, 2002; 72 FR 53460, Sept. 19, 2007]

§ 180.274 Propanil; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide propanil (3′, 4′-dichloropropionanilide) and its metabolites convertible to 3, 4-dichloroaniline (3, 4-DCA) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.05
Cattle, meat byproducts	1.0
Crayfish	0.05
Egg	0.30
Goat, fat	0.10
Goat, meat	0.05
Goat, meat byproducts	1.0
Hog, fat	0.10
Hog, meat	0.05
Hog, meat byproducts	1.0
Horse, fat	0.10
Horse, meat	0.05
Horse, meat byproducts	1.0
Milk	0.05
Poultry, fat	0.05
Poultry, meat	0.10
Poultry, meat byproducts	0.50
Rice, bran	40
Rice, grain	10
Rice, hulls	30
Rice, straw	75
Sheep, fat	0.10
Sheep, meat	0.05
Sheep, meat byproducts	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34827, June 26, 1998, as amended at 72 FR 28888, May 23, 2007]

§ 180.275 Chlorothalonil; tolerances for residues.

(a) *General.* (1) Tolerances are established for the fungicide chlorothalonil (tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on the following food commodities.

Commodity	Parts per million
Almond	0.05
Almond, hulls	1.0
Apricot	0.5
Asparagus	0.1
Banana (NMT 0.05 ppm in edible pulp)	0.5
Bean, dry, seed	0.1
Bean, snap, succulent	5
Blueberry	1.0
Brassica, head and stem, subgroup 5A	5.0
Carrot, roots	1
Celery	15
Cherry, sweet	0.5
Cherry, tart	0.5
Cocoa bean, dried bean	0.05
Coffee, bean, green	0.20
Corn, sweet, kernel plus cob with husks removed	1
Cranberry	5.0
Ginseng	4.0
Horseradish	4.0
Lentil	0.10
Lychee	15
Mango	1.0
Mushroom	1.0
Nectarine	0.5
Okra	6.0
Onion, bulb	0.5
Onion, green	5
Papaya	15

Commodity	Parts per million
Parsnip, roots	1
Passionfruit	3
Pea, edible podded	5
Peach	0.5
Peanut	0.3
Pistachio	0.2
Plum	0.2
Plum, prune	0.2
Potato	0.1
Rhubarb	4.0
Soybean	0.2
Starfruit	3.0
Tomato	5
Vegetable, cucurbit, group 9	5.0
Vegetable, fruiting, group 8, except tomato	6.0
Yam, true	0.10

(2) Tolerances are established for the metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on the following food commodities.

Commodity	Parts per million
Cattle, fat	0.1
Cattle, kidney	0.5
Cattle, meat byproducts, except kidney	0.05
Cattle, meat	0.03
Goat, fat	0.1
Goat, kidney	0.5
Goat, meat byproducts, except kidney	0.05
Goat, meat	0.03
Hog, fat	0.1
Hog, kidney	0.5
Hog, meat byproducts, except kidney	0.05
Hog, meat	0.03
Horse, fat	0.1
Horse, kidney	0.5
Horse, meat byproducts, except kidney	0.05
Horse, meat	0.03
Milk	0.1
Sheep, fat	0.1
Sheep, kidney	0.5
Sheep, meat byproducts, except kidney	0.05
Sheep, meat	0.03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of chlorothalonil and its metabolite in or on the following raw agricultural commodities:

Commodity	Parts per million
Hazelnut	0.1
Mint hay	2
Persimmon	1.5

(d) *Indirect or inadvertent residues.* [Reserved]

[42 FR 56114, Oct. 21, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.275, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.276 Formetanate hydrochloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide formetanate hydrochloride (m-[[dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride) in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple	0.50
Apple, wet pomace	1.5
Grapefruit	1.5
Lemon	0.60
Lime	0.03
Nectarine	0.40
Orange	1.5
Peach	0.40
Pear	0.50
Tangelo	0.03
Tangerine	0.03

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide formetanate hydrochloride (*m*-[[(dimethylamino) methylene]amino]phenyl methylcarbamate hydrochloride) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances in this paragraph will expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Onion, dry bulb	0.02	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34827, June 26, 1998, as amended at 69 FR 43924, July 23, 2004; 73 FR 9232, Feb. 20, 2008; 73 FR 52613, Sept. 10, 2008; 74 FR 636, Jan. 7, 2009]

§ 180.278 Phenmedipham; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide phenmedipham (3-methoxycarbonylaminophenyl-3′-

methylcarbanilate) in or on the following food commodities:

Commodity	Parts per million
Beet, garden, roots	0.2
Beet, garden, tops	0.2
Beet, sugar, dried pulp	0.5
Beet, sugar, molasses	0.2
Beet, sugar, roots	0.1
Beet, sugar, tops	0.1
Spinach	4.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 28888, May 23, 2007]

§ 180.284 Zinc phosphide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the phosphine resulting from the use of the rodenticide zinc phosphide in or on the raw agricultural commodities as follows:

Commodity	Parts per million
Alfalfa, forage	0.2
Alfalfa, hay	0.2
Barley, grain	0.05
Barley, hay	0.2
Barley, straw	0.2
Bean, dry, seed	0.05
Beet, sugar, roots	0.05
Beet, sugar, tops	0.2
Grape	0.01
Grass (rangeland)	0.1
Potato	0.05
Sugarcane, cane	0.01
Timothy, hay	0.5
Timothy, forage	0.5
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of phosphine resulting from the use of the rodenticide zinc phosphide in connection with use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	1.0	12/31/05
Alfalfa, hay	1.0	12/31/05
Clover, forage	0.1	12/31/05
Clover, hay	0.1	12/31/05
Timothy, seed	0.1	12/31/05

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on the following raw agricultural commodities as follows:

Commodity	Parts per million
Artichoke, globe	0.01
Beet, sugar, roots	0.04
Beet, sugar, tops	0.02

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 45182, Aug. 25, 1998, as amended at 63 FR 67799, Dec. 9, 1998; 64 FR 40772, July 28, 1999; 64 FR 61791, Nov. 15, 1999; 65 FR 8874, Feb. 23, 2000; 65 FR 49941, Aug. 16, 2000; 65 FR 62634, Oct. 19, 2000; 66 FR 64773, Dec. 14, 2001; 68 FR 2247, Jan. 16, 2003; 68 FR 56195, Sept. 30, 2003; 70 FR 7046, Feb. 10, 2005]

§ 180.287 Amitraz; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide amitraz (N′-[2,4-dimethylphenyl]-N-[[(2,4-dimethylphenyl)imino] methyl]]-N-methylmethanimidamide) and its metabolites containing the 2,4-dimethylaniline moiety (calculated as the parent) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.02
Cattle, meat byproducts	0.2
Cotton, undelinted seed[1]	1.0
Hog, fat	0.1
Hog, kidney	0.1
Hog, liver	0.1
Hog, meat	0.05
Hog, meat byproducts	0.3
Milk	0.03
Milk, fat	0.2
Pear	3.0

[1]There are no U.S. registrations on cottonseed as of May 3, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[44 FR 70145, Dec. 6, 1979, as amended at 51 FR 16846, May 7, 1986; 52 FR 5767, Feb. 26, 1987; 57 FR 53568, Nov. 12, 1992; 58 FR 14316, Mar. 17, 1993; 60 FR 12704, Mar. 8, 1995; 67 FR 49616, July 31, 2002; 72 FR 53454, Sept. 19, 2007]

§ 180.288 2-(Thiocyanomethylthio)benzothiazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide 2-(thiocyanomethylthio)benzothiazole in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.1(N)
Barley, straw	0.1(N)
Beet, sugar, roots	0.1(N)
Beet, sugar, tops	0.1(N)
Corn, field, forage	0.1(N)
Corn, grain	0.1(N)
Corn, stover	0.1(N)
Cotton, forage	0.1(N)
Cotton, undelinted seed	0.1(N)
Oat, forage	0.1(N)
Oat, grain	0.1(N)
Oat, hay	0.1(N)
Oat, straw	0.1(N)
Rice, grain	0.1(N)
Rice, straw	0.1(N)
Safflower, seed	0.1(N)
Sorghum, grain, forage	0.1(N)
Sorghum, grain, grain	0.1(N)
Sorghum, grain, stover	0.1(N)
Wheat, forage	0.1(N)
Wheat, grain	0.1(N)
Wheat, hay	0.1(N)
Wheat, straw	0.1(N)

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39440, July 1, 2003]

§ 180.289 Methanearsonic acid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide methanearsonic acid (calculated as As_2O_3) from application of the disodium and monosodium salts of methanearsonic acid in or on raw agricultural commodities as follows:

Commodity	Parts per million
Cotton, undelinted seed	0.7
Cotton, hulls	0.9
Fruit, citrus	0.35

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34828, June 26, 1998]

§ 180.291 Pentachloronitrobenzene; tolerance for residues.

(a) A tolerance of 0.1 part per million is established for negligible residues of the fungicide pentachloronitrobenzene in or on the raw agricultural commodity cotton, undelinted seed.

(b) Tolerances with regional registration (refer to § 180.1 (n)) are established for the combined residues of the fungicides pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and methyl pentachlorophenyl sulfide (MPCPS) in or on the following raw agricultural commodities:

Commodity	Parts per million
Collards	0.2
Kale	0.2
Mustard greens	0.2

[36 FR 22540, Nov. 25, 1971, as amended at 53 FR 9443, Mar. 23, 1988; 71 FR 74816, Dec. 13, 2006]

§ 180.292 Picloram; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the pesticide picloram (4-amino-3,5,6-trichloropicolinic acid) from its application in the acid form or in the form of its potassium, triethylamine, or triisopropanolamine salts expressed as picloram in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.5
Barley, straw	1.0
Cattle, fat	0.2
Cattle, kidney	5.0
Cattle, liver	0.5
Cattle, meat	0.2
Cattle, meat byproducts, except kidney and liver	0.2

Commodity	Parts per million
Egg	0.05
Goat, fat	0.2
Goat, kidney	5.0
Goat, liver	0.5
Goat, meat	0.2
Goat, meat byproducts, except kidney and liver	0.2
Grain, aspirated fractions	4.0
Grass, forage	80.0
Hog, fat	0.2
Hog, kidney	5.0
Hog, liver	0.5
Hog, meat	0.2
Hog, meat byproducts, except kidney and liver	0.2
Horse, fat	0.2
Horse, kidney	5.0
Horse, liver	0.5
Horse, meat	0.2
Horse, meat byproducts, except kidney and liver	0.2
Milk	0.05
Oat, forage	1.0
Oat, grain	0.5
Oat, straw	1.0
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.2
Sheep, kidney	5.0
Sheep, liver	0.5
Sheep, meat	0.2
Sheep, meat byproducts, except kidney and liver	0.2
Wheat, forage	1.0
Wheat, grain	0.5
Wheat, straw	1.0

(2) Tolerances are established for residues of picloram [4-amino-3,5,6-trichloropicolinic acid] resulting from the application of the pesticide to growing crops in the following:

Commodity	Parts per million
Barley, pearled barley	3.0
Oat, groats/rolled oats	3.0
Wheat, bran	3.0
Wheat, germ	3.0
Wheat, middlings	3.0
Wheat, shorts	3.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[41 FR 19221, May 11, 1976, as amended at 47 FR 53005, Nov. 24, 1982; 64 FR 425, Jan. 5, 1999; 64 FR 39082, July 21, 1999; 72 FR 41930, Aug. 1, 2007]

§ 180.293 Endothall; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of endothall, 7-oxabicyclo [2, 2, 1] heptane-2, 3-dicarboxylic acid and its monomethyl ester in or on the following food commodities:

Commodity	Parts per million
Cotton, undelinted seed	0.1
Fish	0.1
Hop, dried cones	0.1
Potato	0.1
Rice, grain	0.05
Rice, straw	0.05

(2) An interim tolerance of 0.2 parts per million is established for residues of the herbicide endothall (7 - oxabicyclo[2.2.1] heptane-2,3-dicarboxylic acid) in water, potable from use of its potassium, sodium, di-*N*, *N*-dimethylalkylamine, and mono-*N*-*N*,-dimethylalkylamine salts as algicides or herbicides to control aquatic plants in canals, lakes, ponds, and other potential sources of water, potable.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[41 FR 23717, June 11, 1976, as amended at 51 FR 4498, Feb. 5, 1986; 62 FR 49931, Sept. 24, 1997; 63 FR 42249, Aug. 7, 1998; 67 FR 35048, May 17, 2002; 71 FR 47106, Aug. 16, 2006; 71 FR 74816, Dec. 13, 2006; 72 FR 52018, Sept. 12, 2007]

§ 180.294 Benomyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide benomyl (methyl 1-(butylcarbamoyl)-2-benzimidazolecarbamate) and its metabolites containing the benzimidazole moiety (calculated as benomyl) in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Almond, hulls	1.0	1/1/07
Apple, postharvest	7.0	1/1/08
Apricot, postharvest	15.0	1/1/08
Banana, postharvest, not more than 0.2 ppm shall be present in the pulp after peel is removed and discarded	1.0	1/1/08
Barley, grain	0.2	1/1/08
Barley, straw	0.2	1/1/08
Bean	2.0	1/1/07
Beet, sugar, roots	0.2	1/1/07
Beet, sugar, tops	15.0	1/1/07

Commodity	Parts per million	Expiration/Revocation Date
Blackberry	7.0	1/1/08
Blueberry	7.0	1/1/08
Boysenberry	7.0	1/1/08
Broccoli	0.2	1/1/06
Brussels sprouts	15.0	1/1/06
Cabbage	0.2	1/1/06
Cabbage, chinese, bok choy	10.0	1/1/06
Cabbage, chinese, napa	10.0	1/1/06
Carrot, roots	0.2	1/1/07
Cattle, fat	0.1	1/1/08
Cattle, meat	0.1	1/1/08
Cattle, meat byproducts	0.1	1/1/08
Cauliflower	0.2	1/1/06
Celery	3.0	1/1/07
Cherry, postharvest	15.0	1/1/08
Citrus, dried pulp	50.0	1/1/08
Collards	0.2	1/1/06
Corn, sweet, forage	0.2	1/1/08
Corn, sweet, kernel plus cob with husks removed	0.2	1/1/08
Corn, sweet, stover	0.2	1/1/08
Cucumber	1.0	1/1/07
Currant	7.0	1/1/08
Dewberry	7.0	1/1/08
Egg	0.1	1/1/08
Eggplant	0.2	1/1/09
Fruit, citrus, postharvest	10.0	1/1/08
Garlic	0.2	1/1/06
Goat, fat	0.1	1/1/08
Goat, meat	0.1	1/1/08
Goat, meat byproducts	0.1	1/1/08
Grape	10.0	1/1/08
Grape, raisin	50.0	1/1/08
Hog, fat	0.1	1/1/08
Hog, meat	0.1	1/1/08
Hog, meat byproducts	0.1	1/1/08
Horse, fat	0.1	1/1/08
Horse, meat	0.1	1/1/08
Horse, meat byproducts	0.1	1/1/08
Kale	0.2	1/1/06
Kohlrabi	0.2	1/1/06
Loganberry	7.0	1/1/08
Mango	3.0	1/1/08
Melon	1.0	1/1/07
Milk	0.1	1/1/08
Mushroom, postharvest	10.0	1/1/08
Mustard greens	0.2	1/1/06
Nectarine, postharvest	15.0	1/1/08
Nut	0.2	1/1/07
Oat, grain	0.2	1/1/08
Oat, straw	0.2	1/1/08
Peach, postharvest	15.0	1/1/08
Peanut	0.2	1/1/08
Peanut, hay	15.0	1/1/08
Pear, postharvest	7.0	1/1/08
Pepper	0.2	1/1/09
Pineapple, postharvest	35.0	1/1/08
Pistachio	0.2	1/1/07
Plum, postharvest	15.0	1/1/08
Plum, prune, fresh, postharvest	15.0	1/1/08
Poultry, fat	0.1	1/1/08
Poultry, liver	0.2	1/1/08
Poultry, meat	0.1	1/1/08
Poultry, meat byproducts, except liver	0.1	1/1/08
Pumpkin	1.0	1/1/07
Raspberry	7.0	1/1/08
Rice, grain	5.0	1/1/08
Rice, hulls	20.0	1/1/08
Rice, straw	15.0	1/1/08
Rutabaga	0.2	1/1/07
Rye, grain	0.2	1/1/08
Rye, straw	0.2	1/1/08
Sheep, fat	0.1	1/1/08
Sheep, meat	0.1	1/1/08
Sheep, meat byproducts	0.1	1/1/08
Soybean	0.2	1/1/07
Spinach	0.2	1/1/07
Squash, summer	1.0	1/1/07
Squash, winter	1.0	1/1/07
Strawberry	5.0	1/1/08
Sweet potato, roots	0.2	1/1/07
Tomato	5.0	1/1/09
Tomato, concentrated products	50.0	1/1/09
Turnip, roots	0.2	1/1/07
Wheat, grain	0.2	1/1/08
Wheat, straw	15.0	1/1/08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the fungicide benomyl (methyl 1-[butylcarbamoyl]-2-benzimidazolecarbamate) and its metabolites containing the benzimidazole moiety (calculated as benomyl) in or on the raw agricultural commodities.

Commodity	Parts per million	Expiration/Revocation Date
Avocado	3.0	1/1/08
Dandelion, leaves	10.0	1/1/07
Papaya	3.0	1/1/08
Pistachio	0.2	1/1/07
Turnip, greens	6.0	1/1/07
Watercress	10.0	1/1/07

(d) *Indirect or inadvertent residues.* [Reserved]

[52 FR 58536, Dec. 23, 1987, as amended at 52 FR 58538, Dec. 23, 2987; 53 FR 9024, Mar. 18, 1988; 59 FR 46354, Sept. 8, 1994; 63 FR 2167, Jan. 14, 1998; 67 FR 46905, July 17, 2002]

§ 180.296 Dimethyl phosphate of 3-hydroxy-*N*-methyl-*cis*-crotonamide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide Dimethyl phosphate of 3-hydroxy-*N*-methyl-*cis*-crotonamide in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation date
Cotton, undelinted seed	0.1	12/31/00
Peanut	0.05	12/31/00
Potato	0.1	12/31/00
Sugarcane, cane	0.1	12/31/00

Commodity	Parts per million	Expiration/ Revocation date
Tomato	0.5	12/31/00
Tomato, concentrated products	2.0	12/31/00

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 19492, Apr. 21, 1999]

§ 180.297 *N*-1-Naphthyl phthalamic acid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide *N*-1-naphthyl phthalamic acid from application of its sodium salt in or on the following raw agricultural commodities:

Commodity	Parts per million
Cantaloupe	0.1(N)
Cucumber	0.1(N)
Muskmelon	0.1(N)
Watermelon	0.1(N)

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 32306, May 16, 1980, as amended at 63 FR 57075, Oct. 26, 1998]

§ 180.298 Methidathion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide methidathion (*O,O*-dimethyl phosphorodithioate, *S*-ester with 4-(mercaptomethyl-2-methoxy-1,3,4-thiadiazolin-5-one) in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	6.0
Artichoke, globe	0.05
Citrus, oil	420.0
Cotton, undelinted seed	0.2
Fruit, citrus, group 10, except tangerine	4.0
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.05
Mango	0.05
Nut, tree, group 14	0.05
Olive	0.05
Safflower, seed	0.5
Sorghum, forage, forage	2.0
Sorghum, grain, forage	2.0
Sorghum, grain, grain	0.2
Sorghum, grain, stover	2.0
Sunflower, seed	0.5
Tangerine	6.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the insecticide methidathion (O,O-dimethyl phosphorodithioate, S-ester with 4-(mercaptomethyl-2-methoxy-1,3,4-thiadiazolin-5-one), in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	5.0	3/31/08
Alfalfa, hay	5.0	3/31/08
Kiwifruit	0.1	None
Longan	0.1	None
Starfruit	0.1	None
Sugar apple	0.2	None
Timothy, forage	5.0	3/31/08
Timothy, hay	5.0	3/31/08

(d) *Indirect or inadvertent residues.* [Reserved]

[43 FR 44845, Sept. 29, 1978, as amended at 43 FR 45363, Oct. 2, 1978; 46 FR 18314, Mar. 24, 1981; 50 FR 1054, Jan. 9, 1985; 50 FR 5070, Feb. 6, 1985; 53 FR 23391, June 22, 1988; 54 FR 20125, May 10, 1989; 55 FR 2377, Jan. 24, 1990; 55 FR 24083, June 14, 1990; 55 FR 49389, Nov. 28, 1990; 57 FR 31325, July 15, 1992; 63 FR 57075, Oct. 26, 1998; 66 FR 50833, Oct. 5, 2001; 72 FR 53460, Sept. 19, 2007]

§ 180.299 Dicrotophos; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide dicrotophos, dimethyl phosphate of 3-hydroxy-*N,N*-dimethyl-cis-crotonamide, in or on the following food commodities:

Commodity	Parts per million
Cotton, gin byproducts	2.0
Cotton, undelinted seed	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 52613, Sept. 10, 2008]

§ 180.300 Ethephon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant regulator ethephon [(2-chloroethyl) phosphonic acid] in or on food commodities as follows:

Commodity	Parts per million
Apple	5.0
Apple, juice	10.0
Barley, bran	5.0
Barley, grain	2.0
Barley, straw	10.0
Blackberry	30.0
Blueberry	20.0
Cantaloupe	2.0
Cattle, fat	0.02
Cattle, kidney	1.0
Cattle, meat	0.02
Cattle, meat byproducts, except kidney	0.2
Cherry	10.0
Coffee, bean, green	0.5
Cotton, gin byproducts	180.0
Cotton, undelinted seed	6.0
Cucumber	0.1
Egg	0.002
Goat, fat	0.02
Goat, kidney	1.0
Goat, meat	0.02
Goat, meat byproducts, except kidney	0.2
Grape	2.0
Grape, raisin	12.0
Hazelnut	0.80
Hog, fat	0.02
Hog, kidney	1.0
Hog, meat	0.02
Hog, meat byproducts, except kidney	0.2
Horse, fat	0.02
Horse, kidney	1.0
Horse, meat	0.02
Horse, meat byproducts, except kidney	0.2
Milk	0.01
Nut, macadamia	0.5
Pepper	30.0
Pineapple	2.0
Poultry, fat	0.02
Poultry, liver	0.05
Poultry, meat	0.01
Poultry, meat byproducts, except liver	0.01
Sheep, fat	0.02
Sheep, kidney	1.0
Sheep, meat	0.02
Sheep, meat byproducts, except kidney	0.2
Sugarcane, molasses	1.5
Tomato	2.0
Walnut	0.5
Wheat, bran	5.0
Wheat, germ	5.0
Wheat, grain	2.0
Wheat, middlings	5.0
Wheat, shorts	5.0
Wheat, straw	10.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(n), of 0.1 part per million is established for residues of the plant regulator ethephon [(2-chloroethyl)phosphonic acid] in or on the food commodity sugarcane.

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33710, May 24, 2000, as amended at 72 FR 53455, Sept. 19, 2007]

§ 180.301 Carboxin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide carboxin (5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide) and its metabolites determined as aniline and expressed as parent compound, in or on food commodities as follows:

Commodity	Parts per million
Barley, grain	0.2
Barley, straw	0.2
Bean, dry, seed	0.2
Bean, succulent	0.2
Canola, seed	0.03
Cattle, fat	0.05
Cattle, meat byproducts	0.1
Cattle, meat	0.05
Corn, field, forage	0.2
Corn, field, grain	0.2
Corn, field, stover	0.2
Corn, pop, grain	0.2
Corn, pop, stover	0.2
Corn, sweet, forage	0.2
Corn, sweet, kernel plus cob with husks removed	0.2
Corn, sweet, stover	0.2
Cotton, undelinted seed	0.2
Egg	0.05
Goat, fat	0.05
Goat, meat byproducts	0.1
Goat, meat	0.05
Hog, fat	0.05
Hog, meat byproducts	0.1
Hog, meat	0.05
Horse, fat	0.05
Horse, meat byproducts	0.1
Horse, meat	0.05
Milk	0.05
Oat, forage	0.5
Oat, grain	0.2
Oat, straw	0.2
Onion, bulb	0.2
Peanut	0.2
Peanut, hay	0.2
Poultry, fat	0.1
Poultry, meat byproducts	0.1
Poultry, meat	0.1
Rice, grain	0.2
Rice, straw	0.2
Safflower, seed	0.2
Sheep, fat	0.05
Sheep, meat byproducts	0.1
Sheep, meat	0.05
Soybean, seed	0.2

Commodity	Parts per million
Wheat, forage	0.5
Wheat, grain	0.2
Wheat, straw	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 55222, Dec. 8, 1982, as amended at 50 FR 81, Jan. 2, 1985; 62 FR 4915, Feb. 3, 1997; 63 FR 4586, Jan. 30, 1998; 64 FR 11801, Mar. 10, 1999; 66 FR 9773, Feb. 12, 2001; 66 FR 64773, Dec. 14, 2001; 67 FR 40218, June 12, 2002; 67 FR 72853, Dec. 9, 2002; 71 FR 56383, Sept. 27, 2006]

§ 180.303 Oxamyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide oxamyl, methyl *N*,*N*-dimethyl-*N*-[(methylcarbamoyl)-oxy]-1-thiooxamimidate, and its oxime metabolite methyl *N*,*N*-dimethyl-*N*-hydroxy-1-thiooxamimidate calculated as oxamyl in or on the following food commodities:

Commodity	Parts per million
Apple	2
Banana	0.3
Cantaloupe	2.0
Carrot	0.1
Celery	10.0
Cotton, undelinted seed	0.2
Cucumber	2.0
Eggplant	2.0
Fruit, citrus, group 10	3
Garlic, bulb	0.2
Melon, honeydew	2.0
Onion, bulb	0.2
Peanut	0.05
Peanut, hay	2.0
Pear	2.0
Peppermint, tops	10.0
Pepper, bell	2.0
Pepper, nonbell	5.0
Pineapple	1
Pineapple, process residue	2.0
Pumpkin	2.0
Soybean, seed	0.1
Spearmint, tops	10.0
Squash, summer	2.0
Squash, winter	2.0
Tomato	2
Vegetable, tuberous and corm, subgroup 1C	0.1
Watermelon	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54961, Sept. 24, 2008]

§ 180.304 Oryzalin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide oryzalin, 3,5-dinitro-N_4,N_4-dipropylsulfanilamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.05
Avocado	0.05
Berry group 13	0.05
Cranberry	0.05
Fig	0.05
Fruit, citrus, group 10	0.05
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.05
Grape	0.05
Kiwifruit	0.05
Nut, tree, group 14	0.05
Olive	0.05
Pistachio	0.05
Pomegranate	0.05
Strawberry	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of oryzalin, 3,5-dinitro-N_4,N_4-dipropylsulfanilamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Guava	0.05
Papaya	0.05

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 54434, Sept. 15, 2006]

§ 180.309 α-Naphthaleneacetamide; tolerances for residues.

(a) *General.* Tolerances are established for combined negligible residues of the plant regulator α-naphthaleneacetamide and its metabolite α-naphthaleneacetic acid (calculated as α-naphthaleneacetic acid) in or on the following food commodities:

Commodity	Parts per million
Apple	0.1
Pear	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39440, July 1, 2003]

§ 180.311 Cacodylic acid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the defoliant cacodylic acid (dimethylarsinic acid), expressed as As2O3, in or on the following raw agricultural commodity as follows:

Commodity	Parts per million
Cotton, undelinted seed	2.8

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 6567, Feb. 11, 2004]

§ 180.312 4-Aminopyridine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the bird repellent 4-aminopyridine in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Corn, field, forage	0.1	1/15/06
Corn, field, grain	0.1	1/15/06
Corn, field, stover	0.1	1/15/06
Corn, pop, grain	0.1	1/15/06
Corn, pop, stover	0.1	1/15/06
Corn, sweet, forage	0.1	1/15/06
Corn, sweet, kernel plus cob with husks removed	0.1	1/15/06
Corn, sweet, stover	0.1	1/15/06
Sunflower, seed	0.1	1/15/06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39441, July 1, 2003, as amended at 70 FR 55268, Sept. 21, 2005]

§ 180.314 Triallate; tolerances for residues.

(a) *General.* Tolerances are established for residues of triallate, S-2,3,4-trichloroallyl diisopropylthiocarbamate and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCPSA) in or on the following food commodity:

Commodity	Parts per million
Bermudagrass, hay	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with a regional registration, as defined in 180.1(m),are established for residues of the herbicide (S-2, 3, 4-trichloroallyl diisopropylthiocarbamate) and its metabolite 2, 3, 3-trichloroprop-2-enesulfonic acid (TCPSA) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	1.0
Barley, straw	0.3
Beet, sugar, dried pulp	0.2
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Pea, dry	0.2
Pea, field, hay	1.0
Pea, field, vines	0.5
Pea, succulent	0.2
Wheat, forage	0.5
Wheat, grain	0.05
Wheat, hay	1.0
Wheat, straw	1.0

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 28888, May 23, 2007, as amended at 73 FR 5109, Jan. 29, 2008; 73 FR 53738, Sept. 17, 2008; 74 FR 29963, June 24, 2009]

§ 180.315 Methamidophos; tolerances for residues.

(a) Tolerances are established for residues of the insecticide methamidophos (*O,S*-dimethyl phosphoramidothioate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Broccoli	1.0
Brussels sprouts	1.0
Cabbage	1.0
Cauliflower	1.0

Commodity	Parts per million
Cotton, undelinted seed	0.1
Cucumber	1.0
Eggplant	1.0
Lettuce	1.0
Melon	0.5
Pepper	1.0
Potato	0.1
Tomato	1.0

(b) Tolerances with regional registration, as defined in § 180.1(n), are established for residues of methamidophos in or on the following raw agricultural commodities:

Commodity	Parts per million
Celery	1

[47 FR 13525, Mar. 31, 1982, as amended at 48 FR 44537, Sept. 29, 1983; 52 FR 33238, Sept. 2, 1987; 67 FR 49617, July 31, 2002]

§ 180.316 Pyrazon; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide pyrazon (5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone) and its metabolites (calculated as pyrazon) in or on the following food commodities:

Commodity	Parts per million
Beet, garden, roots	0.9
Beet, garden, tops	7.0
Beet, sugar, molasses	1.5
Beet, sugar, roots	0.2
Beet, sugar, tops	3.0
Cattle, fat	0.10
Cattle, liver	0.15
Cattle, meat	0.10
Cattle, meat byproducts, except liver	0.10
Goat, fat	0.10
Goat, liver	0.15
Goat, meat	0.10
Goat, meat byproducts, except liver	0.10
Horse, fat	0.10
Horse, liver	0.15
Horse, meat	0.10
Horse, meat byproducts, except liver	0.10
Milk	0.02
Sheep, fat	0.10
Sheep, liver	0.15
Sheep, meat	0.10
Sheep, meat byproducts, except liver	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for combined residues of the herbicide pyrazon, 5-amino-4-chloro-2-phenyl-3(2*H*)-pyridazinone, and its metabolites (calculated as pyrazon), in or on the following food commodities:

Commodity	Parts per million
Corn, field, forage	0.5
Corn, field, stover	0.5
Soybean, forage	0.5
Soybean, hay	0.5
Wheat, forage	0.3
Wheat, hay	0.2
Wheat, straw	0.1

[68 FR 39441, July 1, 2003, as amended at 73 FR 52614, Sept. 10, 2008]

§ 180.317 Propyzamide; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide) in or on the following food commodities:

Commodity	Parts per million
Alfalfa, seed	10.0
Animal feed, nongrass, group 18	10.0
Apple	0.1
Artichoke, globe	0.01
Blackberry	0.05
Blueberry	0.05
Boysenberry	0.05
Cattle, fat	0.2
Cattle, kidney	0.4
Cattle, liver	0.4
Cattle, meat	0.02
Cattle, meat byproducts, except kidney and liver	0.02
Egg	0.02
Endive	1.0
Fruit, stone, group 12	0.1
Goat, fat	0.2
Goat, kidney	0.4
Goat, liver	0.4
Goat, meat	0.02
Goat, meat byproducts, except kidney and liver	0.02
Grape	0.1
Hog, fat	0.2
Hog, kidney	0.4
Hog, liver	0.4
Hog, meat	0.02
Hog, meat byproducts, except kidney and liver	0.02
Horse, fat	0.2
Horse, kidney	0.4
Horse, liver	0.4
Horse, meat	0.02
Horse, meat byproducts, except kidney and liver	0.02
Lettuce, head	1.0
Milk	0.02
Pear	0.1
Poultry, fat	0.02
Poultry, liver	0.2
Poultry, meat	0.02
Poultry, meat byproducts, except liver	0.02

Commodity	Parts per million
Radicchio	2.0
Raspberry	0.05
Sheep, fat	0.2
Sheep, kidney	0.4
Sheep, liver	0.4
Sheep, meat	0.02
Sheep, meat byproducts, except kidney and liver	0.02

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide) in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cranberry	0.05	12/31/09

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m) are established for the combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide) in or on the following food commodities:

Commodity	Parts per million
Pea, field, seed	0.05
Rhubarb	0.1

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined indirect or inadvertent residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide) in or on the following food commodities:

Commodity	Parts per million
Grain, cereal, forage, group 16	0.6
Grain, cereal, hay, group 16	0.2
Grain, cereal, straw, group 16	0.3

[72 FR 52018, Sept. 12, 2007]

§ 180.318 4-(2-Methyl-4-chlorophenoxy) butyric acid; tolerance for residues.

(a) *General.* (1) A tolerance is established for the herbicide 4-(2-methyl-4-chlorophenoxy) butyric acid in or on the following food commodity:

Commodity	Parts per million
Pea	0.1(N)

(2) Tolerances are established for the combined residues, free and conjugated, of the herbicide MCPB, 4-(4-chloro-2-methylphenoxy)butanoic acid, and its metabolite MCPA, (4-chloro-2-methylphenoxy)acetic acid, in or on the following food commodities:

Commodity	Parts per million
Peppermint, tops	0.20
Spearmint, tops	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39441, July 1, 2003, as amended at 73 FR 66785, Nov. 12, 2008]

§ 180.319 Interim tolerances.

While petitions for tolerances for negligible residues are pending and until action is completed on these petitions, interim tolerances are established for residues of the listed pesticide chemicals in or on the following raw agricultural commodities:

Substances	Uses	Tolerance in parts per million	Raw agricultural commodity
Coordination product of zinc ion and maneb.	Fungicide	1.0 (Calculated as zinc ethylenebisdithiocarbamate)	Potato
Endothall (7-oxabicyclo-(2,2,1) heptane 2,3- dicarboxylic acid).	Herbicide	0.2	Beet, sugar

Substances	Uses	Tolerance in parts per million	Raw agricultural commodity
Isopropyl carbanilate (IPC)	Herbicide	5.0	Alfalfa, hay; clover, hay; and grass, hay
		2.0	Alfalfa, forage; clover, forage; and grass, forage
		0.1	Flax, seed; lentil; lettuce, head and lettuce, leaf; pea; safflower, seed; spinach; and beet, sugar, roots and beet, sugar, tops
		0.5	Egg; cattle, fat; cattle meat; cattle, meat byproducts; goat, fat; goat, meat; goat, meat byproducts; hog, fat; hog, meat; hog, meat byproducts; horse, fat; horse, meat; horse, meat byproducts; milk; sheep, fat; sheep meat; sheep, meat byproducts; poultry, fat; poultry, meat; poultry, meat byproducts
Parathion (O,O-diethyl-O-p-nitrophenythiophosphate) or its methyl homolog.	Herbicide	0.5	Rye
Pentachloronitrobenzene	Fungicide	1.0	Peanut
		0.1	Bean, broccoli, Brussels sprouts, cabbage, cauliflower, garlic, pepper, potato, and tomato

[71 FR 74816, Dec. 13, 2006, as amended at 72 FR 37654, July 11, 2007; 73 FR 52614, Sept. 10, 2008]

§ 180.324 Bromoxynil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage	0.1
Alfalfa, hay	0.5
Barley, grain	0.05
Barley, hay	9.0
Barley, straw	4.0
Corn, field, forage	0.3
Corn, field, grain	0.05
Corn, field, stover	0.2
Corn, pop, grain	0.05
Corn, pop, stover	0.2
Flax, seed	0.1
Garlic	0.1
Grain, aspirated fractions	0.3
Grass, forage	3.0
Grass, hay	3.0
Oat, forage	0.3
Oat, grain	0.05
Oat, hay	9.0
Oat, straw	4.0
Onion, bulb	0.1
Peppermint, hay	0.1
Rye, forage	1.0
Rye, grain	0.05
Rye, straw	2.0
Sorghum, grain, forage	0.5
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.2
Spearmint, hay	0.1
Wheat, forage	1.0
Wheat, grain	0.05
Wheat, hay	4.0
Wheat, straw	2.0

(2) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite 3,5-dibromo-4-hydroxybenzoic acid (DBHA) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

Commodity	Parts per million
Cattle, fat	1
Cattle, meat byproducts	3.5
Cattle, meat	0.5
Cotton, gin byproducts	7.0
Cotton, hulls	5.0
Cotton, undelinted seed	1.5
Egg	0.05
Goat, fat	1
Goat, meat byproducts	3.5
Goat, meat	0.5
Hog, fat	1
Hog, meat byproducts	3.5
Hog, meat	0.5
Horse, fat	1
Horse, meat byproducts	3.5
Horse, meat	0.5
Milk	0.1
Poultry, fat	0.05
Poultry, meat byproducts	0.3
Poultry, meat	0.05
Sheep, fat	1
Sheep, meat byproducts	3.5
Sheep, meat	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 33023, June 18, 1997, as amended at 63 FR 26480, May 13, 1998; 66 FR 47402, Sept. 12, 2001; 70 FR 7046, Feb. 10, 2005; 72 FR 35666, June 29, 2007; 72 FR 41930, Aug. 1, 2007]

§ 180.325 2-(m-Chlorophenoxy) propionic acid; tolerances for residues.

(a) *General.* A tolerance is established for negligible residues of the plant regulator 2-(m-chlorophenoxy) propionic acid from application of the acid or of 2-(m-chlorophenoxy)propionamide in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Pineapple	0.3	2/1/07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 43924, July 23, 2004]

§ 180.328 Napropamide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide napropamide, *N*,*N*-diethyl-2-(1-napthalenyloxy) propionamide, in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
Almond, hulls	0.1	None
Artichoke, globe	0.1	4/26/09
Asparagus	0.1	None
Avocado	0.1	4/26/09
Basil	0.1	None
Berry group 13	0.1	None
Coffee, green bean	0.1	None
Cranberry	0.1	None
Fig	0.1	4/26/09
Fruit, citrus	0.1	4/26/09
Fruit, pome	0.1	4/26/09
Fruit, stone	0.1	4/26/09
Grape	0.1	None
Kiwifruit	0.1	None
Marjoram	0.1	None
Nut, tree, group 14	0.1	None
Olive	0.1	4/26/09
Peppermint, tops	0.1	None
Persimmon	0.1	None
Pistachio	0.1	04/26/09
Rhubarb	0.1	None
Rosemary	0.1	None
Savory, summer	0.1	None
Savory, winter	0.1	None
Spearmint, tops	0.1	None
Strawberry	0.1	None
Sweet potato, roots	0.1	None
Vegetable, brassica, leafy, group 5	0.1	None
Vegetable, fruiting, group 8	0.1	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances are established for residues of the herbicide napropamide, *N*,*N*-diethyl-2-(1-napthalenyloxy) propionamide, in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
Pomegranate	0.1	4/26/09

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 52614, Sept. 10, 2008]

§ 180.330 S-(2-(Ethylsulfinyl)ethyl) O,O-dimethyl phosphorothioate; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the insecticide oxydemeton-methyl (S-(2-(ethylsulfinyl)ethyl) O,O-dimethyl phosphorothioate) and its metabolite oxydemeton-methyl sulfone in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	5.0
Alfalfa, hay	11.0
Bean, lima	0.2
Beet, sugar, roots	0.3
Beet, sugar, tops	0.5
Broccoli	1.0
Brussels sprouts	1.0
Cabbage	2.0
Cauliflower	1.0
Clover, forage	5.0
Clover, hay	10.0
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.5
Corn, sweet, stover	3.0
Cotton, undelinted seed	0.02
Cucumber	1.0
Eggplant	1.0
Grapefruit	1.0
Hazelnut	0.05
Lemon	1.0
Lettuce, head	2.0

Commodity	Parts per million
Melon	0.2
Onion, bulb	0.05
Orange	1.0
Pepper	0.75
Peppermint, tops	12.5
Pumpkin	0.2
Safflower, seed	1.0
Sorghum, forage, forage	2.0
Sorghum, grain, forage	2.0
Sorghum, grain, grain	0.75
Spearmint, tops	12.5
Squash, summer	1.0
Squash, winter	0.3
Strawberry	2.0
Walnut	0.05

(2) Tolerances are established for the combined residues of the insecticide oxydemeton-methyl (S-(2-(ethylsulfinyl)ethyl) O,O-dimethyl phosphorothioate) and its cholinesterase-inhibiting metabolites in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Egg	0.01
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(m), are established for the combined residues of the insecticide oxydemeton-methyl (S-(2-(ethylsulfinyl)-ethyl) O,O-dimethyl phosphorothioate) and its metabolite oxydemeton-methyl sulfone in or on the following food commodities:

Commodity	Parts per million
Broccoli raab	2.0

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 54578, Sept. 26, 2007]

§ 180.331 4-(2,4-Dichlorophenoxy) butyric acid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide 4-(2,4-dichlorophenoxy) butyric acid (2,4-DB), both free and conjugated, determined as the acid, in or on food commodities, as follows:

Commodity	Parts per million
Alfalfa, forage	0.7
Alfalfa, hay	2.0
Cattle, meat byproducts	0.05
Clover	0.2
Goat, meat byproducts	0.05
Hog, meat byproducts	0.05
Horse, meat byproducts	0.05
Peanut	0.2
Peppermint, tops	0.2
Sheep, meat byproducts	0.05
Soybean, forage	0.7
Soybean, hay	2.0
Soybean, seed	0.5
Spearmint, tops	0.2
Trefoil, forage	0.7
Trefoil, hay	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54961, Sept. 24, 2008]

§ 180.332 Metribuzin; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide metribuzin (4-amino-6-(1,1-dimethyl- ethyl)-3-(methylthio)-;1,2,4-triazin-5(4*H*)-one) and its triazinone metabolites in or on food commodities:

Commodity	Parts per million
Alfalfa, forage	2.0
Alfalfa, hay	7.0
Asparagus	0.1
Barley, grain	0.75
Barley, hay	7.0
Barley, pearled barley	3.0
Barley, straw	1.0
Carrot, roots	0.3
Cattle, fat	0.7
Cattle, meat	0.7
Cattle, meat byproducts	0.7
Corn, field, forage	0.1
Corn, field, grain	0.05
Corn, field, stover	0.1
Corn, pop, grain	0.05
Corn, sweet, forage	0.1
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.1
Egg	0.01

Commodity	Parts per million
Goat, fat	0.7
Goat, meat	0.7
Goat, meat byproducts	0.7
Grass, forage	2.0
Grass, hay	7.0
Hog, fat	0.7
Hog, meat	0.7
Hog, meat byproducts	0.7
Horse, fat	0.7
Horse, meat	0.7
Horse, meat byproducts	0.7
Lentil	0.05
Milk	0.05
Pea, dry, seed	0.05
Pea, field, hay	4.0
Pea, field, vines	0.5
Pea, succulent	0.1
Potato	0.6
Potato, chips	3.0
Potato, processed potato waste	3.0
Poultry, fat	0.7
Poultry, meat	0.7
Poultry, meat byproducts	0.7
Sainfoin, forage	2.0
Sainfoin, hay	7.0
Sheep, fat	0.7
Sheep, meat	0.7
Sheep, meat byproducts	0.7
Soybean, seed	0.3
Soybean, forage	4.0
Soybean, hay	4.0
Sugarcane, cane	0.1
Sugarcane, molasses	2.0
Tomato	0.1
Wheat, bran	3.0
Wheat, forage	2.0
Wheat, germ	3.0
Wheat, grain	0.75
Wheat, hay	7.0
Wheat, middlings	3.0
Wheat, shorts	3.0
Wheat, straw	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[42 FR 62913, Dec. 14, 1977, as amended at 43 FR 41396, Sept. 18, 1978; 44 FR 26744, May 7, 1979; 44 FR 45387, Aug. 2, 1979; 52 FR 23654, June 24, 1987; 55 FR 26440, June 28, 1990; 62 FR 66024, 66025, Dec. 17, 1997; 65 FR 33698, May 24, 2000; 66 FR 63198, Dec. 5, 2001; 67 FR 49617, July 31, 2002]

§ 180.337 Oxytetracycline; tolerance for residues.

Tolerances are established for residues of the pesticide oxytetracycline in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	0.35
Peach	0.35
Pear	0.35

[60 FR 34871, July 5, 1995, as amended at 72 FR 62794, Nov. 7, 2007]

§ 180.339 MCPA; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide MCPA ((4-chloro-2-methylphenoxy)acetic acid), both free and conjugated, resulting from the direct application of MCPA or its sodium or dimethylamine salts, or its 2-ethylhexyl ester in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	0.5
Alfalfa, hay	2.0
Barley, grain	1.0
Barley, hay	40
Barley, straw	25
Clover, forage	0.5
Clover, hay	2.0
Flax, seed	0.1
Grain, aspirated fractions	3.0
Grass, forage	300
Grass, hay	20
Lespedeza, forage	0.5
Lespedeza, hay	2.0
Oat, forage	20
Oat, grain	1.0
Oat, hay	115
Oat, straw	25
Pea, dry	0.1
Pea, field, hay	0.1
Pea, succulent	0.1
Pea, field, vines	0.1
Rye, forage	20
Rye, grain	1.0
Rye, straw	25
Trefoil, forage	0.5
Trefoil, hay	2.0
Vetch, forage	0.5
Vetch, hay	2.0
Wheat, forage	20
Wheat, grain	1.0
Wheat, hay	115
Wheat, straw	25

(2) Tolerances are established for residues of the herbicide MCPA ((4-chloro-2-methylphenoxy)acetic acid) resulting from the direct application of MCPA or its sodium or dimethylamine salts, or its 2-ethylhexyl ester in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.1

Commodity	Parts per million
Cattle, meat byproducts	0.1
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.1
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.1
Milk	0.1
Sheep, fat	0.1
Sheep meat	0.1
Sheep meat byproducts	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 28888, May 23, 2007, as amended at 73 FR 5109, Jan. 29, 2008]

§ 180.341 2,4-Dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate; tolerances for residues.

(a) *General.* Tolerances are established for combined negligible residues of a fungicide and insecticide that is a mixture of 2,4-dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple [1]	0.1
Grape [1]	0.1

[1] There are no U.S. registrations on apple and grape as of October 24, 2002.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[40 FR 29715, July 15, 1975, as amended at 63 FR 57076, Oct. 26, 1998; 69 FR 43924, July 23, 2004]

§ 180.342 Chlorpyrifos; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the pesticide chlorpyrifos *per se* (*O,O*-diethyl- *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate) in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	13
Almond	0.2
Almond, hulls	12
Apple	0.01
Apple, wet pomace	0.02
Banana	0.1
Beet, sugar, dried pulp	5.0
Beet, sugar, molasses	15
Beet, sugar, roots	1.0
Beet, sugar, tops	8.0
Cattle, fat	0.3
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cherry, sweet	1.0
Cherry, tart	1.0
Citrus, dried pulp	5.0
Citrus, oil	20
Corn, field, forage	8.0
Corn, field, grain	0.05
Corn, field, refined oil	0.25
Corn, field, stover	8.0
Corn, sweet, forage	8.0
Corn, sweet, kernel plus cob with husk removed	0.05
Corn, sweet, stover	8.0
Cotton, undelinted seed	0.2
Cranberry	1.0
Cucumber	0.05
Egg	0.01
Fig	0.01
Fruit, citrus, group 10	1.0
Goat, fat	0.2
Goat, meat	0.05
Goat, meat byproducts	0.05
Hazelnut	0.2
Hog, fat	0.2
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.25
Horse, meat	0.25
Horse, meat byproducts	0.25
Kiwifruit	2.0
Lettuce	1.0
Milk, fat (Reflecting 0.01 ppm in whole milk)	0.25
Nectarine	0.05
Onion, bulb	0.5
Peach	0.05
Peanut	0.2
Peanut, refined oil	0.2
Pear	0.05
Pecan	0.2
Pepper	1.0
Peppermint, tops	0.8
Peppermint, oil	8.0
Plum, prune, fresh	0.05
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Pumpkin	0.05
Radish	2.0
Rutabaga	0.5
Sheep, fat	0.2
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Spearmint, tops	0.8
Spearmint, oil	8.0
Sorghum, grain, forage	0.5
Sorghum, grain, grain	0.5
Sorghum, grain, stover	2.0
Soybean, seed	0.3
Strawberry	0.2
Sunflower, seed	0.1
Sweet potato, roots	0.05

Commodity	Parts per million
Turnip, roots	1.0
Turnip, tops	0.3
Vegetable, brassica, leafy, group 5	1.0
Vegetable, legume, group 6. except soybean	0.05
Walnut	0.2
Wheat, forage	3.0
Wheat, grain	0.5
Wheat, straw	6.0

(2) Chlorpyrifos [*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] may be safely used in accordance with the following prescribed conditions.

(i) Application shall be limited solely to spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared or served. Contamination of food or food contact surfaces shall be avoided. Food must be removed or covered during treatment.

(ii) Spray concentration for spot treatment shall be limited to a maximum of 0.5 percent of the active ingredient by weight. A course, low-pressure spray shall be used to avoid atomization or splashing of the spray.

(iii) Paint-on application for spot treatment shall be limited to a maximum of 2 percent of the active ingredient by weight.

(iv) Crack and crevice treatment shall be limited to a maximum of 2 percent of the active ingredient by weight. Equipment capable of delivering a pinstream of insecticide shall be used.

(v) Application via adhesive strips shall contain a maximum of 10% by weight of the controlled-release product in food-handling establishments where food and food products are held, processed, prepared, or served. A maximum of 36 strips (or 5.15 grams of chlorpyrifos) is to be used per 100 square feet of floor space. The strips are not to be placed in exposed areas where direct contact with food, utensils, and food-contact surfaces would be likely to occur.

(vi) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(3) A tolerance of 0.1 part per million is established for residues of chlorpyrifos, per se, in or on food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food service establishments where food and food products are prepared and served, as a result of the application of chlorpyrifos in microencapsulated form.

(i) Application of a microencapsulated product shall be limited solely to spot and/or crack and crevice treatment in food handling establishments where food and food products are prepared and served. All treatments shall be applied in such a manner as to avoid contamination of food or food contact surfaces.

(ii) Spray concentrations shall be limited to a maximum of 0.5 percent of the active ingredient by weight.

(iii) For crack and crevice treatment, equipment capable of delivering a pin stream of spray directly into cracks and crevices or capable of applying small amounts of insecticide into cracks and crevices shall be used.

(iv) For spot treatment, an individual spot shall not exceed 2 square feet.

(v) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in 180.1(m), are established for residues of the pesticide chlorpyrifos *per se* (*O,O*-diethyl- *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate) in or on the following food commodities:

Commodity	Parts per million
Asparagus	5.0
Grape	0.01

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33711, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 71 FR 74817, Dec. 13, 2006; 73 FR 53739, Sept. 17, 2008]

§ 180.345 Ethofumesate; tolerances for residues.

(a) *General.* Tolerances for the combined residues of the herbicide ethofumesate (2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl

methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate both calculated as parent compound in or on the following food commodities:

Commodity	Parts per million
Beet, garden, roots	0.5
Beet, garden, tops	5.0
Beet, sugar, molasses	0.5
Beet, sugar, refined sugar	0.2
Beet, sugar, roots	0.3
Beet, sugar, tops	4.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Garlic	0.25
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Grass, straw	1.0
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Onion, bulb	0.25
Shallot, bulb	0.25
Shallot, fresh leaves	0.25
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* Tolerances with regional registration as defined in 40 CFR 180.1(m) are established for the combined residues of ethofumesate,(2-ethoxy -2, 3-dihydro-3, 3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities:

Commodity	Parts per million
Carrot, roots	7.0

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34828, June 26, 1998, as amended at 71 FR 51516, Aug. 30, 2006; 72 FR 52019, Sept. 12, 2007]

§ 180.349 Fenamiphos; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the nematocide fenaminphos, (ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl)phosphoramidate, and its cholinesterase inhibiting metabolites ethyl 3-methyl-4-(methylsulfinyl)phenyl (1-methylethyl)phosphoramidate and ethyl 3-methyl-4-(methylsulfonyl)phenyl (1-methylethyl)phosporamidate in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Apple	0.25	12/31/09
Banana [1]	0.10	None
Brussels sprouts	0.05	12/31/09
Cabbage	0.10	12/31/09
Cherry, sweet	0.25	12/31/09
Cherry, tart	0.25	12/31/09
Citrus, dried pulp	2.5	None
Citrus, oil	25.0	None
Eggplant	0.05	12/31/09
Fruit, citrus, group 10 [1]	0.50	None
Garlic [1]	0.50	None
Grape [1]	0.10	None
Grape, raisin	0.30	None
Okra	0.30	12/31/09
Peach	0.25	12/31/09
Peanut	1.0	12/31/09
Pineapple [1]	0.30	None
Raspberry	0.10	12/31/09
Strawberry	0.60	12/31/09

[1] There are no U.S. registrations as of December 31, 2009.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of Fenamiphos (ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl) phosphoramidate) and its cholinesterase-inhibiting metabolites ethyl 3-methyl-4-(methylsulfinyl)phenyl (1-methylethyl) phosphoramidate and ethyl 3-methyl-4-(methylsulfonyl)phenyl (1-methylethyl) phosphoramidate in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Asparagus	0.02	12/31/09
Beet, garden roots	1.5	12/31/09
Beet, garden, tops	1.0	12/31/09
Cabbage, Chinese, bok choy	0.50	12/31/09
Kiwifruit	0.10	12/31/09
Pepper, nonbell	0.60	12/31/09

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33712, May 24, 2000, as amended at 73 FR 53739, Sept. 17, 2008]

§ 180.350 Nitrapyrin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the soil microbiocide nitrapyrin [2-chloro-6-(trichloromethyl) pyridine] and its metabolite, 6-chloropicolinic acid in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	1.0
Corn, field, grain	0.1
Corn, field, milled byproducts	0.2
Corn, field, stover	1.0
Corn, pop, grain	0.1
Corn, pop, stover	1.0
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	1.0
Sorghum, forage, forage	0.5
Sorghum, grain, forage	0.5
Sorghum, grain, grain	0.1
Sorghum, grain, stover	0.5
Wheat, bran	3.0
Wheat, forage	2.0
Wheat, grain	0.5
Wheat, milled byproducts, except flour	2.0
Wheat, straw	6.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[46 FR 58315, Dec. 1, 1981, as amended at 47 FR 22957, May 26, 1982; 52 FR 33238, Sept. 2, 1987; 58 FR 32304, June 9, 1993; 63 FR 57076, Oct. 26, 1998; 72 FR 53461, Sept. 19, 2007]

§ 180.352 Terbufos; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide terbufos (phosphorodithioic acid, *S*-(t-butylthio)methyl *O,O*-diethyl ester) and its phosphorylated (cholinesterase-inhibiting) metabolites (phosphorothioic acid, *S*-(t-butylthio)methyl *O,O*-diethyl ester; phosphorothioic acid, *S*-(t-butylsulfinyl)methyl *O,O*-diethyl ester; phosphorothioic acid, *S*-(t-butylsulfonyl)methyl *O,O*-diethyl ester; phosphorodithioic acid, *S*-(t-butylsulfinyl)methyl *O,O*-diethyl ester; and phosphorodithioic acid, *S*-(t-butylsulfonyl)methyl *O,O*-diethyl ester) in or on food commodities:

Commodity	Parts per million
Banana	0.025
Beet, sugar, roots	0.05
Beet, sugar, tops	0.1
Coffee, green bean [1]	0.05
Corn, field, forage	0.5
Corn, field, grain	0.5
Corn, field, stover	0.5
Corn, pop, grain	0.5
Corn, pop, stover	0.5
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, forage	0.5
Corn, sweet, stover	0.5
Sorghum, grain, forage	0.5
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.5

[1] There are no U. S. registrations as of August 2, 1995, for the use of terbufos on the growing crop, coffee.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 53740, Sept. 17, 2008]

§ 180.353 Desmedipham; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide desmedipham, (ethyl-*m*-hydroxycarbanilate carbanilate) in or on the following raw agricultural commodities in the table that follows:

Commodity	Parts per million
Beet, garden, roots	0.05
Beet, garden, tops	1.0
Beet, sugar, roots	0.1
Beet, sugar, tops	5.0
Spinach	6.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[40 FR 4658, Jan. 31, 1975, as amended at 62 FR 45747, Aug. 29, 1997; 63 FR 49472, Sept. 16, 1998; 64 FR 46292, Aug. 25, 1999; 65 FR 82293, Dec. 28, 2000; 66 FR 64773, Dec. 14, 2001; 68 FR 37764, June 25, 2003; 69 FR 71717, Dec. 10, 2004; 72 FR 53449, Sept. 19, 2007; 73 FR 53740, Sept. 17, 2008]

§ 180.355 Bentazon; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the following food commodities:

Commodity	Parts per million
Bean, dry, seed	0.05
Bean, succulent	0.5
Corn, field, forage	3.0
Corn, field, grain	0.05
Corn, field, stover	3.0
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cowpea, forage	10.0
Cowpea, hay	3.0
Flax, seed	1.0
Pea, dry, seed	1.0
Pea, field, hay	8.0
Pea, field, vines	3.0
Pea, succulent	3.0
Peanut	0.05
Peanut, hay	3.0
Pepper, nonbell	0.05
Peppermint, tops	1.0
Rice, grain	0.05
Rice, hulls	0.25
Rice, straw	3.0
Sorghum, forage	0.20
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.05
Soybean, forage	8.0
Soybean, hay	8.0
Soybean, seed	0.05
Spearmint, tops	1.0

(2) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its metabolite 2-amino-*N*-isopropyl benzamide (AIBA) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat byproducts	0.05
Cattle, meat	0.05
Egg	0.05
Goat, fat	0.05
Goat, meat byproducts	0.05
Goat, meat	0.05
Hog, fat	0.05
Hog, meat byproducts	0.05
Hog, meat	0.05
Milk	0.02
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, meat byproducts	0.05
Sheep, meat	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration as defined in § 180.1(n), are established for combined residues of the herbicide, bentazon (3-isopropyl-1H-2, 1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the following food commodities:

Commodity	Parts per million
Clover, forage	1.0
Clover, hay	2.0

(d) *Indirect or inadvertent residues.* [Reserved]

[42 FR 26979, May 26, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.355, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.356 Norflurazon; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide norflurazon (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) and its desmethyl metabolite 4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3(2*H*)-pyridazinone in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	5.0
Alfalfa, seed	0.1
Almond, hulls	1.0
Almond	0.1
Apple	0.1
Apricot	0.1
Asparagus	0.05
Avocado	0.20
Blackberry	0.1
Blueberry	0.2
Cattle, fat	0.1
Cattle, liver	0.50
Cattle, meat	0.1
Cattle, meat byproducts, except liver	0.1
Cherry	0.1
Citrus, dried pulp	0.4
Citrus, molasses	1.0
Cotton, undelinted seed	0.1
Cranberry	0.1
Fruit, citrus	0.2
Goat, fat	0.1
Goat, liver	0.50
Goat, meat	0.1

Commodity	Parts per million
Goat, meat byproducts, except liver	0.1
Grape	0.1
Hazelnut	0.1
Hog, fat	0.1
Hog, liver	0.50
Hog, meat	0.1
Hog, meat byproducts, except liver	0.1
Hop, dried cones	3.0
Hop, vines	1.0
Horse, fat	0.1
Horse, liver	0.50
Horse, meat	0.1
Horse, meat byproducts, except liver	0.1
Milk	0.1
Nectarine	0.1
Peach	0.1
Peanut	0.05
Peanut, hay	5.50
Peanut, hay	1.5
Pear	0.1
Pecan	0.1
Plum, prune, fresh	0.1
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Raspberry	0.2
Sheep, fat	0.1
Sheep, liver	0.50
Sheep, meat	0.1
Sheep, meat byproducts, except liver	0.1
Soybean	0.1
Soybean, forage	1.0
Soybean, hay	1.0
Walnut	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 14909, Apr. 7, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.356, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.360 Asulam; tolerance for residues.

(a) *General.* Tolerances are established for the combined residues of asulam (methyl sulfanilylcarbamate) and its sulfanilamide containing metabolites in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.2
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.2
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.2
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.2
Milk	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.2
Sugarcane, cane	1.0
Sugarcane, molasses	30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 39441, July 1, 2003, as amended at 72 FR 37654, July 11, 2007]

§ 180.361 Pendimethalin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide pendimethalin [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	4.0
Alfalfa, seed	0.10
Almond, hulls	0.4
Apple, wet pomace	0.20
Artichoke, globe	0.1
Asparagus	0.15
Beans	0.10
Beans, forage	0.10
Beans, hay	0.10
Brassica head and stem, subgroup 5-A	0.1
Carrot	0.5
Citrus, oil	0.5
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Corn, pop, grain	0.1
Corn, sweet, forage	0.1
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	0.1
Cotton, gin byproducts	3.0
Cotton, undelinted seed	0.1
Crayfish	0.05
Fruit, citrus, group 10	0.1
Fruit, pome, group 11	0.10
Fruit, stone, group 12	0.10
Garlic	0.1
Grape	0.1
Juneberry	0.10
Leek	0.20
Nut, tree, group 14	0.1

Commodity	Parts per million
Onion, bulb	0.1
Onion, green	0.20
Onion, welsh	0.20
Peanut	0.1
Peanut, hay	0.1
Peas (except field peas)	0.10
Peppermint, oil	1.0
Peppermint, tops	0.2
Pistachio	0.1
Pomegranate	0.10
Potato	0.1
Rice, grain	0.1
Rice, straw	0.1
Shallot	0.2
Sorghum, forage	0.1
Sorghum, grain, grain	0.1
Sorghum, grain, stover	0.1
Soybean, forage	0.1
Soybean, hay	0.1
Soybean, seed	0.1
Spearmint, oil	1.0
Spearmint, tops	0.2
Strawberry	0.10
Sugarcane, cane	0.1
Sunflower, seed	0.1
Vegetable, fruiting, group 8	0.10
Wheat, grain	0.10
Wheat, forage	3.0
Wheat, hay	0.60
Wheat, straw	0.30

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of the herbicide pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Bermuda grass, forage	25	12/31/09
Bermuda grass, hay	60	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[49 FR 15293, Apr. 18, 1984]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.361, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.362 Hexakis (2-methyl-2-phenylpropyl)distannoxane; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of hexakis (2-methyl-2-phenylpropyl)distannoxane in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	80.0
Apple	15.0
Apple, wet pomace	100.0
Cherry, sweet	6.0
Cherry, tart	6.0
Citrus, dried pulp	100.0
Citrus, oil	140.0
Cucumber	4.0
Eggplant	6.0
Fruit, citrus, group 10	20.0
Grape	5.0
Grape, raisin	20.0
Nut, tree, group 14	0.5
Papaya	2.0
Peach	10.0
Pear	15.0
Pistachio	0.5
Plum, prune, fresh	4.0
Plum, prune, dried	20.0
Strawberry	10.0

(2) Tolerances are established for the combined residues of hexakis (2-methyl-2-phenylpropyl)distannoxane and its organotin metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane, and 2-methyl-2phenylpropylstannoic acid in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.5
Cattle, meat	0.5
Cattle, meat byproducts	0.5
Egg	0.1
Goat, fat	0.5
Goat, meat	0.5
Goat, meat byproducts	0.5
Hog, fat	0.5
Hog, meat	0.5
Hog, meat byproducts	0.5
Horse, fat	0.5
Horse, meat	0.5
Horse, meat byproducts	0.5
Milk, fat	0.1
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
Sheep, fat	0.5
Sheep, meat	0.5
Sheep, meat byproducts	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of

the insecticide hexakis [2-methyl-2-phenylpropyl] distannoxane and its organotin metabolites calculated as hexakis [2-methyl-2-phenylpropyl] distannoxane in or on the food commodities:

Commodity	Parts per million
Raspberry	10.0

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33713, May 24, 2000, as amended at 72 FR 41930, Aug. 1, 2007; 73 FR 5109, Jan. 29, 2008]

§ 180.364 Glyphosate; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of glyphosate *N*-(phosphonomethyl)glycine resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on the following food commodities:

Commodity	Parts per million
Acerola	0.2
Alfalfa, seed	0.5
Almond, hulls	25
Aloe vera	0.5
Ambarella	0.2
Animal feed, nongrass, group 18	400
Artichoke, globe	0.2
Asparagus	0.5
Atemoya	0.2
Avocado	0.2
Bamboo, shoots	0.2
Banana	0.2
Barley, bran	30
Beet, sugar, dried pulp	25
Beet, sugar, roots	10
Beet, sugar, tops	10
Berry group 13	0.2
Betelnut	1.0
Biriba	0.2
Blimbe	0.2
Borage, seed	0.1
Breadfruit	0.2
Cacao bean, bean	0.2
Cactus, fruit	0.5
Cactus, pads	0.5
Canistel	0.2
Canola, seed	20
Chaya	1.0
Cherimoya	0.2
Citrus, dried pulp	1.5
Coconut	0.1
Coffee, bean, green	1.0
Corn, field, forage	6.0
Corn, field, grain	5.0
Corn, pop, grain	0.1
Corn, sweet, grain	0.1
Cotton, gin byproducts	210
Cotton, undelinted seed	40
Cranberry	0.2
Crambe, seed	0.1
Custard apple	0.2
Date, dried fruit	0.2
Dokudami	2.0
Durian	0.2
Epazote	1.3
Feijoa	0.2
Fig	0.2
Fish	0.25
Flax, meal	8.0
Flax, seed	4.0
Fruit, citrus, group 10	0.5
Fruit, pome, group 11	0.2
Fruit, stone, group 12	0.2
Galangal, roots	0.2
Ginger, white, flower	0.2
Gourd, buffalo, seed	0.1
Governor's plum	0.2
Gow kee, leaves	0.2
Grain, cereal, forage, fodder and straw, group 16, except field corn, forage	100
Grain, cereal, group 15 except field corn, popcorn, rice, sweet corn, and wild rice	30
Grape	0.2
Grass, forage, fodder and hay, group 17	300
Guava	0.2
Herbs subgroup 19A	0.2
Hop, dried cones	7.0
Ilama	0.2
Imbe	0.2
Imbu	0.2
Jaboticaba	0.2
Jackfruit	0.2
Jojoba, seed	0.1
Juneberry	0.2
Kava, roots	0.2
Kenaf, forage	200
Kiwifruit	0.2
Lesquerella, seed	0.1
Leucaena, forage	200
Lingonberry	0.2
Longan	0.2
Lychee	0.2
Mamey apple	0.2
Mango	0.2
Mangosteen	0.2
Marmaladebox	0.2
Meadowfoam, seed	0.1
Mioga, flower	0.2
Mustard, seed	0.1
Noni	0.20
Nut, pine	1.0
Nut, tree, group 14	1.0
Okra	0.5
Olive	0.2
Oregano, Mexican, leaves	2.0
Palm heart	0.2
Palm heart, leaves	0.2
Palm, oil	0.1
Papaya	0.2
Papaya, mountain	0.2
Passionfruit	0.2
Pawpaw	0.2
Pea, dry	8.0
Peanut	0.1
Peanut, hay	0.5
Pepper leaf, fresh leaves	0.2
Peppermint, tops	200
Perilla, tops	1.8

Commodity	Parts per million
Persimmon	0.2
Pineapple	0.1
Pistachio	1.0
Pomegranate	0.2
Pulasan	0.2
Quinoa, grain	5.0
Rambutan	0.2
Rapeseed, seed	20
Rice, grain	0.1
Rice, wild, grain	0.1
Rose apple	0.2
Safflower, seed	85
Salal	0.2
Sapodilla	0.2
Sapote, black	0.2
Sapote, mamey	0.2
Sapote, white	0.2
Sesame, seed	0.1
Shellfish	3.0
Soursop	0.2
Spanish lime	0.2
Spearmint, tops	200
Spice subgroup 19B	7.0
Star apple	0.2
Starfruit	0.2
Stevia, dried leaves	1.0
Strawberry	0.2
Sugar apple	0.2
Sugarcane, cane	2.0
Sugarcane, molasses	30
Sunflower, seed	85
Surinam cherry	0.2
Tamarind	0.2
Tea, dried	1.0
Tea, instant	7.0
Teff, grain	5.0
Ti, leaves	0.2
Ti, roots	0.2
Ugli fruit	0.5
Vegetable, bulb, group 3	0.2
Vegetable, cucurbit, group 9	0.5
Vegetable, foliage of legume, subgroup 7A, except soybean	0.2
Vegetable, fruiting, group 8	0.1
Vegetable, leafy, brassica, group 5	0.2
Vegetable, leafy, except brassica, group 4	0.2
Vegetable, leaves of root and tuber, group 2, except sugar beet tops	0.2
Vegetable, legume, group 6 except soybean and dry pea	5.0
Vegetable, root and tuber, group 1, except sugar beet	0.2
Wasabi, roots	0.2
Water spinach, tops	0.2
Watercress, upland	0.2
Wax jambu	0.2
Yacon, tuber	0.2

(2) Tolerances are established for combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities:

Commodity	Parts per Million
Cattle, meat byproducts	5.0
Egg	0.05
Goat, meat byproducts	5.0
Grain aspirated fractions	310.0
Hog, meat byproducts	5.0
Horse, meat byproducts	5.0
Poultry, meat	4.0
Poultry, meat byproducts	1.0
Sheep, meat byproducts	5.0
Soybean, forage	100.0
Soybean, hay	200.0
Soybean, hulls	120.0
Soybean, seed	20.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 64911, Oct. 1, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.364, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.367 *n*-Octyl bicycloheptenedicarboximide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide *n*-octyl bicycloheptene-dicarboximide, resulting from dermal application, in food commodities as follows:

Commodity	Parts per million
Cattle, fat	0.3
Goat, fat	0.3
Hog, fat	0.3
Horse, fat	0.3
Milk, fat	0.3
Sheep, fat	0.3

(2) *N*-octylbicycloheptene dicarboximide may be safely used in accordance with the following prescribed conditions:

(i) It is used in combination with piperonyl butoxide and pyrethrins for insect control in food-processing and food-storage areas, provided that the food is removed or covered prior to such use.

(ii) Residues in food resulting from the use described in paragraph (a)(2)(i) of this section shall not exceed 10 parts per million of *N*- octylbicycloheptene dicarboximide, 10 parts per million of

piperonyl butoxide, and 1 part per million of pyrethrins.

(iii) To assure safe use of the pesticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33713, May 24, 2000]

§ 180.368 Metolachlor; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues (free and bound) of the herbicide metolachlor, 2-chloro-*N*-(2- ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, and its metabolites, determined as the derivatives, 2- [(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2- hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.30
Animal feed, nongrass, group 18	1.0
Cattle, fat	0.04
Cattle, kidney	0.20
Cattle, liver	0.10
Cattle, meat	0.04
Cattle, meat byproducts, except kidney and liver	0.04
Corn, field, forage	6.0
Corn, field, grain	0.10
Corn, field, stover	6.0
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.10
Corn, sweet, stover	6.0
Cotton, gin byproducts	4.0
Cotton, undelinted seed	0.10
Dill	0.50
Egg	0.04
Goat, fat	0.04
Goat, kidney	0.20
Goat, liver	0.10
Goat, meat	0.04
Goat, meat byproducts, except kidney and liver	0.04
Grass, forage	10
Grass, hay	0.20
Horse, fat	0.04
Horse, kidney	0.20
Horse, liver	0.10
Horse, meat	0.04
Horse, meat byproducts, except kidney and liver	0.04
Milk	0.02
Nut, tree, group 14	0.10
Okra	0.50
Pea and bean, dried shelled, except soybean, subgroup 6C	0.10
Pea and bean, succulent shelled, subgroup 6B	0.30
Peanut	0.20
Peanut, hay	20
Peanut, meal	0.40
Potato	0.20
Poultry, fat	0.04
Poultry, meat	0.04
Poultry, meat byproducts	0.04
Safflower, seed	0.10
Sheep, fat	0.04
Sheep, kidney	0.20
Sheep, liver	0.10
Sheep, meat	0.04
Sheep, meat byproducts, except kidney and liver	0.04
Sorghum, grain, forage	1.0
Sorghum, grain, grain	0.30
Sorghum, grain, stover	4.0
Soybean, forage	5.0
Soybean, hay	8.0
Soybean, seed	0.20
Spinach	0.50
Tomato	0.10
Vegetable, foliage of legume, subgroup 7A, except soybean	15.0
Vegetable, legume, edible podded, subgroup 6A	0.50

(2) Tolerances are established for the combined residues (free and bound) of the herbicide *S*-metolachlor *S*-2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-[2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on the following raw agricultural commodities:

Commodity	Parts per million
Asparagus	0.10
Beet, sugar, molasses	2.0
Beet, sugar, roots	0.5
Beet, sugar, tops	15.0
Brassica, head and stem, subgroup 5A	0.60
Cattle, fat	0.04
Cattle, kidney	0.20
Cattle, liver	0.05
Cattle, meat	0.02
Cattle, meat byproducts, except kidney and liver	0.04
Corn, field, grain	0.10
Corn, field, forage	6.0
Corn, field, stover	6.0
Corn, pop, grain	0.10
Corn, pop, stover	6.0
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.10
Corn, sweet, stover	6.0
Cotton, gin byproducts	4.0
Cotton, undelinted seed	0.10
Egg	0.02
Garlic	0.10

Commodity	Parts per million
Goat, fat	0.04
Goat, kidney	0.20
Goat, liver	0.05
Goat, meat	0.02
Goat, meat byproducts, except kidney and liver	0.04
Grass, forage	10.0
Grass, hay	0.20
Horse, fat	0.04
Horse, kidney	0.20
Horse, liver	0.05
Horse, meat	0.02
Horse, meat byproducts, except kidney and liver	0.04
Milk	0.02
Onion, bulb	0.10
Onion, green	2.0
Peanut	0.20
Pea and bean, dried shelled, except soybean, subgroup 6C	0.10
Peanut, hay	20.0
Peanut, meal	0.40
Poultry, fat	0.04
Poultry, meat	0.02
Poultry, meat byproducts	0.04
Pumpkin	0.10
Safflower, seed	0.10
Shallot, bulb	0.10
Sheep, fat	0.04
Sheep, kidney	0.20
Sheep, liver	0.05
Sheep, meat	0.02
Sheep, meat byproducts, except kidney and liver	0.04
Sorghum, grain, forage	1.0
Sorghum, grain, grain	0.3
Sorghum, grain, stover	4.0
Soybean, forage	5.0
Soybean, hay	8.0
Soybean, seed	0.20
Spinach	0.50
Squash, winter	0.10
Sunflower, seed	0.50
Sunflower, meal	1.0
Tomato, paste	0.30
Vegetable, foliage of legume, except soybean, subgroup 7A	15.0
Vegetable, fruiting, except tabasco pepper, group 8	0.10
Vegetable, leaf petioles, subgroup 4B	0.10
Vegetable, legume, edible podded, subgroup 6A	0.50
Vegetable, root, except sugar beet, subgroup 1B	0.30
Vegetable, tuberous and corm, subgroup 1C	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* (1) Tolerances with regional registration as defined in 180.1(m) are established for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on the following raw agricultural commodities:

Commodity	Parts per million
Pepper, nonbell	0.50

(2) Tolerances with regional registration as defined in 180.1(m) are established for the combined residues (free and bound) of the herbicide *S*-metolachlor, *S*-2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1- propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3- morpholinone, each expressed as the parent compound, in or on the following raw agricultural commodities:

Commodity	Parts per million
Pepper, tabasco	0.50

(d) *Indirect or inadvertent residues.* (1) Tolerances are established for the indirect or inadvertent combined residues (free and bound) of the herbicide metolachlor, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2- hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in the following raw agricultural commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18	1.0
Barley, grain	0.10
Barley, straw	0.50
Buckwheat, grain	0.10
Millet, forage	0.50
Millet, grain	0.10
Millet, straw	0.50
Oat, forage	0.50
Oat, grain	0.10
Oat, straw	0.50
Rice, grain	0.10
Rice, straw	0.50
Rye, forage	0.50
Rye, grain	0.10
Rye, straw	0.50
Wheat, forage	0.50
Wheat, grain	0.10
Wheat, straw	0.50

(2) Tolerances are established for the indirect or inadvertent combined residues (free and bound) of the herbicide *S*-metolachlor, *S*-2- chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6- methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on the following food commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18	1.0
Barley, grain	0.10
Barley, hay	1.0
Barley, straw	0.50
Buckwheat, grain	0.10
Oat, forage	0.50
Oat, grain	0.10
Oat, hay	1.0
Oat, straw	0.50
Rice, grain	0.10
Rice, straw	0.50
Rye, forage	0.50
Rye, grain	0.10
Rye, straw	0.50
Wheat, forage	0.50
Wheat, grain	0.10
Wheat, hay	1.0
Wheat, straw	0.50

[73 FR 53740, Sept. 17, 2008]

§ 180.369 Difenzoquat; tolerances for residues.

(a) *General.* Tolerances are established for residues of difenzoquat (1,2-dimethyl-3,5-diphenyl-1*H*-pyrazolium ion), derived from application of the methyl sulfate salt and calculated as the cation, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, bran	0.25
Barley, grain	0.05
Barley, straw	5.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Wheat, bran	0.25
Wheat, grain	0.05
Wheat, shorts	0.25
Wheat, straw	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 56399, Sept. 27, 2006]

§ 180.370 5-Ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide 5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole and its monoacid metabolite 3-carboxy-5-ethoxy-1,2,4-thiadiazole in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	0.1
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Corn, sweet, forage	0.1
Corn, sweet, stover	0.1
Cotton, gin byproducts	0.1
Cotton, undelinted seed	0.1
Peanut	0.1
Peanut, hay	0.1
Safflower, seed	0.1
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.1
Tomato	0.15
Vegetable, foliage of legume, group 7	0.1
Vegetable, legume, group 6	0.1
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[47 FR 49845, Nov. 3, 1982, as amended at 48 FR 12088, Mar. 23, 1983; 63 FR 57076, Oct. 26, 1998; 72 FR 41931, Aug. 1, 2007; 73 FR 54961, Sept. 24, 2008]

§ 180.371 Thiophanate-methyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of thiophanate-methyl (dimethyl [(1,2-phenylene) bis (iminocarbonothioyl)] bis(carbamate)) and its metabolite methyl 2-benzimidazoyl carbamate (MBC), calculated as thiophanate-methyl in or on the following commodities:

Commodity	Parts per million
Almond	0.1
Almond, hulls	0.5
Apple	2.0
Apricot	15.0
Banana	2.0
Bean, dry, seed	0.2
Bean, snap, succulent	0.2
Beet, sugar, roots	0.2
Beet, sugar, tops	15.0
Cattle, fat	0.15
Cattle, meat	0.15
Cattle, meat byproducts	0.15
Cherry, sweet	20.0
Cherry, tart	20.0
Goat, fat	0.15
Goat, meat	0.15
Goat, meat byproducts	0.15
Grape	5.0
Horse, fat	0.15
Horse, meat	0.15
Horse, meat byproducts	0.15
Milk	0.15
Onion, bulb	0.5
Onion, green	3.0
Peach	3.0
Peanut	0.1
Peanut, hay	5.0
Pear	3.0
Pecan	0.1
Pistachio	0.1
Plum	0.5
Potato	0.1
Sheep, fat	0.15
Sheep, meat	0.15
Sheep, meat byproducts	0.15
Soybean, seed	0.2
Soybean, hulls	1.5
Strawberry	7.0
Sugarcane, cane	0.1
Vegetable, cucurbit, group 9	1.0
Wheat, grain	0.1
Wheat, hay	0.1
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* Tolerances are established for the combined residues of thiophanate-methyl (dimethyl [(1,2-phenylene) bis (iminocarbonothioyl)] bis(carbamate)) and its metabolite methyl 2-benzimidazoyl carbamate (MBC), calculated as thiophanate-methyl in or on the following commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Blueberry	1.5	6/30/09
Citrus	0.5	12/31/09
Cotton, gin byproducts	5.0	12/31/08
Cotton, undelinted seed	0.05	12/31/08
Mushroom	0.01	12/31/09
Vegetable, fruiting, group 8	0.5	12/31/09

(c) *Tolerances with regional registrations.* Tolerances with a regional registration, as defined in 180.1(m), are established for the combined residues of thiophanate-methyl(dimethyl[(1,2-phenylene)bis(iminocarbonothioyl)]bis(carbamate)) and its metabolite methyl 2-benzimidazoyl carbamate (MBC), calculated as thiophanate-methyl in or on the following commodities:

Commodity	Parts per million
Canola, seed	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33699, May 24, 2000, as amended at 67 FR 55150, Aug. 28, 2002; 67 FR 57753, Sept. 12, 2002; 72 FR 37654, July 11, 2007; 72 FR 71801, Dec. 19, 2007; 74 FR 636, Jan. 7, 2009]

§ 180.372 2,6-Dimethyl-4-tridecylmorpholine; tolerances for residues.

(a) *General.* A tolerance is established for residues of the fungicide 2,6-dimethyl-4-tridecylmorpholine in or on the following food commodity:

Commodity	Parts per million
Banana[1]	1.0

[1] There are no U.S. registrations.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54961, Sept. 24, 2008]

§ 180.373 [Reserved]

§ 180.377 Diflubenzuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide diflubenzuron (*N*-[[(4-

chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) in or on the following food commodities:

Commodity	Parts per million
Artichoke, globe	6.0
Cattle, fat	0.05
Cattle, meat	0.05
Cotton, undelinted seed	0.2
Egg	0.05
Goat, fat	0.05
Goat, meat	0.05
Grapefruit	0.5
Hog, fat	0.05
Hog, meat	0.05
Horse, fat	0.05
Horse, meat	0.05
Milk	0.05
Mushroom	0.2
Orange, sweet	0.5
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Soybean	0.05
Soybean, hulls	0.5
Tangerine	0.5

(2) Tolerances are established for combined residues of the insecticide diflubenzuron and its metabolites 4-chlorophenlyurea and 4-chloroaniline in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	6.0
Barley, grain	0.06
Barley, hay	3.0
Barley, straw	1.8
Brassica, leafy greens, subgroup 5B	9.0
Cattle, meat byproducts	0.15
Fruit, stone, group 12, except cherry	0.07
Goat, meat byproducts	0.15
Grain, aspirated fractions	11
Grass, forage, fodder, and hay, group 17	6.0
Hog, meat byproducts	0.15
Horse, meat byproducts	0.15
Nut, tree, group 14	0.06
Oat, forage	7.0
Oat, grain	0.06
Oat, hay	6.0
Oat, straw	3.5
Peanut	0.10
Peanut, hay	55
Peanut, refined oil	0.20
Pear	0.50
Pepper	1.0
Pistachio	0.06
Pummelo	0.50
Rice, grain	0.02
Rice, straw	0.8
Sheep, meat byproducts	0.15
Turnip greens	9.0
Wheat, forage	7.0
Wheat, grain	0.06
Wheat, hay	6.0
Wheat, straw	3.5

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for of the insecticide diflubenzuron, (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/revocation date
Alfalfa, forage	6.0	12/31/11
Alfalfa, hay	6.0	12/31/11
Lemon	0.8	12/31/10
Wheat, aspirated grain fractions	30	12/31/08
Wheat, milled byproducts	0.10	12/31/08

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33699, May 24, 2000, as amended at 65 FR 47882, Aug. 4, 2000; 66 FR 16144, Mar. 23, 2001; 67 FR 7092, Feb. 15, 2002; 67 FR 35048, May 17, 2002; 67 FR 59017, Sept. 19, 2002; 67 FR 59181, Sept. 20, 2002; 68 FR 51484, Aug. 27, 2003; 69 FR 29459, May 24, 2004; 70 FR 75739, Dec. 21, 2005; 71 FR 69033, Nov. 29, 2006; 72 FR 40758, July 25, 2007; 73 FR 72357, Nov. 28, 2008]

§ 180.378 Permethrin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide cis- and trans-permethrin isomers [cis-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] and [trans-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] in/on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	20
Alfalfa, hay	45
Almond	0.05
Almond, hulls	20
Artichoke, globe	5.0
Asparagus	2.0
Avocado	1.0
Broccoli	2.0
Brussels sprouts	1.0
Cabbage	6.0
Cattle, fat	1.5
Cattle, meat	0.10
Cattle, meat byproducts	0.10

Commodity	Parts per million
Cauliflower	0.5
Cherry, sweet	4.0
Cherry, tart	4.0
Corn, field, forage	50
Corn, field, grain	0.05
Corn, field, stover	30
Corn, pop, grain	0.05
Corn, pop, stover	30
Corn, sweet, forage	50
Corn, sweet, kernel plus cob with husks removed	0.10
Corn, sweet, stover	30
Egg	0.10
Eggplant	0.50
Fruit, pome, group 11	0.05
Garlic, bulb	0.10
Grain, aspirated fractions	0.50
Goat, fat	1.5
Goat, meat	0.10
Goat, meat byproducts	0.10
Hazelnut	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	1.5
Horse, meat	0.10
Horse, meat byproducts	0.10
Horseradish	0.50
Kiwifruit	2.0
Leaf petioles subgroup 4B	5.0
Leafy greens subgroup 4A	20
Lettuce, head	20
Milk, fat (reflecting 0.88 ppm in whole milk)	3.0
Mushroom	5.0
Onion, bulb	0.10
Peach	1.0
Pepper, bell	0.50
Pistachio	0.10
Potato	0.05
Poultry, fat	0.15
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	1.5
Sheep, meat	0.10
Sheep, meat byproducts	0.10
Soybean, seed	0.05
Spinach	20
Tomato	2.0
Vegetable, cucurbit, group 9	1.5
Walnut	0.05
Watercress	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m) are established for the combined residues of the insecticide cis- and trans-permethrin isomers [cis-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] and [trans-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] in/on the following food commodities:

Commodity	Parts per million
Collards	15
Grass, forage	15
Grass, hay	15
Papaya	1.0
Turnip, tops	10
Turnip, roots	0.20

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 52019, Sept. 12, 2007]

§ 180.379 Cyano(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl) benzeneacetate; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide Cyano(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl)benzeneacetate in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	15.0
Almond	0.2
Apple	2.0
Artichoke, globe	0.2
Bean, dry, seed	0.25
Bean, snap, succulent	2.0
Broccoli	2.0
Blueberry	3.0
Cabbage	10.0
Caneberry subgroup 13A	3.0
Cantaloupe	1.0
Carrot, roots	0.5
Cattle, fat	1.5
Cattle, meat byproducts	1.5
Cattle, meat	1.5
Cauliflower	0.5
Collards	10.0
Corn, grain	0.02
Corn, forage	50.0
Corn, stover	50.0
Corn, sweet, kernel plus cob with husks removed	0.1
Cotton, undelinted seed	0.2
Cucumber	0.5
Currant	3.0
Eggplant	1.0
Elderberry	3.0
Fruit, stone	10.0
Goat, fat	1.5
Goat, meat byproducts	1.5
Goat, meat	1.5
Gooseberry	3.0
Hazelnut	0.2
Hog, fat	1.5
Hog, meat byproducts	1.5
Hog, meat	1.5
Horse, fat	1.5
Horse, meat byproducts	1.5
Horse, meat	1.5
Huckleberry	3.0
Melon, honeydew	1.0
Milk	0.3
Milk, fat	7.0

Commodity	Parts per million
Muskmelon	1.0
Peanut	0.02
Pear	2.0
Pea	1.0
Pea, dry, seed	0.25
Pecan	0.2
Pepper	1.0
Potato	0.02
Pumpkin	1.0
Radish, roots	0.3
Radish, tops	8.0
Sheep, fat	1.5
Sheep, meat byproducts	1.5
Sheep, meat	1.5
Soybean	0.05
Squash, summer	0.5
Squash, winter	1.0
Sugarcane, cane	2.0
Sunflower, seed	1.0
Tomato	1.0
Turnip, greens	20.0
Turnip, roots	0.5
Walnut	0.2
Watermelon	1.0

(2) A food additive tolerance of 0.05 parts per million is established for residues of the insecticide cyano(37phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate and an isomer, (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate, as follows:

(i) In or on food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed, or prepared.

(ii) Application of cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate shall be limited to space treatment with a maximum of 0.5 fluid ounce of a 0.05-percent active ingredient solution per 1,000 cubic feet of space, or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 0.2-percent active ingredient solution per 1,000 square feet of surface. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food. Food-contact surfaces and equipment should be thoroughly cleaned with an effective cleaning compound and rinsed with potable water before using.

(iii) Application of (S)-cyano(3-phenoxyphenyl) methyl-(S)-4-chloro-alpha-(1-methylethyl)benzeneacetate shall be limited to space treatment with a maximum of 1.0 fluid ounce of a 0.25-percent active ingredient solution per 1,000 cubic feet of space, or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 0.05-percent active ingredient solution per 1,000 square feet of surface, or as a pressurized spot/crack and crevice spray of a 0.25-percent solution. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food. Food-contact surfaces and equipment should be thoroughly cleaned with an effective cleaning compound and rinsed with potable water before using.

(iv) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(3) A regulation is established permitting residues of the insecticide 4-cyano(3-phenoxyphenyl)methyl 4-chloro-alpha-(1-methylethyl)benzeneacetate in or on the following commodities:

Commodity	Parts per million
Soybean, hulls	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of the insecticide cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate in or on the following raw agricultural commodities:

Commodity	Parts per million
Okra	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[44 FR 6099, Jan. 31, 1979. Redesignated and amended at 44 FR 37919, June 29, 1979; further amended at 55 FR 26440, June 28, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.379, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and on GPO Access.

§ 180.380 Vinclozolin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety in or on the food commodities in the table below. There are no U.S. registrations for grape (wine) as of July 30, 1997.

Commodity	Parts per million	Expiration/ Revocation Date
Bean, succulent	2.0	11/30/05
Canola, seed	1.0	11/30/08
Cattle, fat	0.05	11/30/08
Cattle, meat	0.05	11/30/08
Cattle, meat byproducts	0.05	11/30/08
Egg	0.05	11/30/08
Goat, fat	0.05	11/30/08
Goat, meat	0.05	11/30/08
Goat, meat byproducts	0.05	11/30/08
Grape, wine	6. 0	None
Hog, fat	0.05	11/30/08
Hog, meat	0.05	11/30/08
Hog, meat byproducts	0.05	11/30/08
Horse, fat	0.05	11/30/08
Horse, meat	0.05	11/30/08
Horse, meat byproducts	0.05	11/30/08
Lettuce, head	10.0	11/30/05
Lettuce, leaf	10.0	11/30/05
Milk	0.05	11/30/08
Poultry, fat	0.1	11/30/08
Poultry, meat	0.1	11/30/08
Poultry, meat byproducts	0.1	11/30/08
Sheep, fat	0.05	11/30/08
Sheep, meat	0.05	11/30/08
Sheep, meat byproducts	0.05	11/30/08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

(e) *Revoked tolerances subject to the channel of trade provisions.* The following table lists commodities with residues of vinclozolin resulting from lawful use are subject to the channels of trade provisions of section 408(l)(5) of the FFDCA:

Commodity	Parts per million
Cucumber	1.0
Fruit, stone, except plum, prune, fresh	25.0
Pepper, bell	3.0
Strawberry	10.0

[62 FR 38474, July 18, 1997, as amended at 63 FR 7308, Feb. 13, 1998; 65 FR 44468, July 18, 2000; 67 FR 40189, June 12, 2002; 68 FR 56189, Sept. 30, 2003; 68 FR 69323, Dec. 12, 2003; 70 FR 55268, Sept. 21, 2005]

§ 180.381 Oxyfluorfen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	0.1
Artichoke, globe	0.05
Avocado	0.05
Banana	0.05
Broccoli	0.05
Cabbage	0.05
Cacao bean, dried bean	0.05
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Cauliflower	0.05
Coffee, bean, green	0.05
Corn, field, grain	0.05
Cotton, undelinted seed	0.05
Date, dried fruit	0.05
Egg	0.03
Feijoa	0.05
Fig	0.05
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.05
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Grape	0.05
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Horseradish	0.05
Kiwifruit	0.05
Milk	0.01
Nut, tree, group 14	0.05
Olive	0.05
Onion, bulb	0.05
Peppermint, tops	0.05
Persimmon	0.05
Pistachio	0.05
Pomegranate	0.05
Poultry, fat	0.2
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Soybean	0.05
Spearmint, tops	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of

the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following food commodities:

Commodity	Parts per million
Blackberry	0.05
Chickpea, seed	0.05
Grass, forage	0.05
Grass, hay	0.05
Grass, seed screenings	0.05
Guava	0.05
Papaya	0.05
Raspberry	0.05
Taro, corm	0.05
Taro, leaves	0.05

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 85022, Dec. 24, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.381, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.383 Sodium salt of acifluorfen; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide sodium salt of acifluorfen, sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, and its metabolites (the corresponding acid, methyl ester, and amino analogues) in or on the following raw agricultural commodities:

Commodity	Parts per million
Peanut	0.1
Rice, grain	0.1
Rice, straw	0.2
Soybean, seed	0.1
Strawberry	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 24877, Apr. 11, 1980, as amended at 46 FR 61272, Dec. 16, 1981; 47 FR 39490, Sept. 8, 1982; 61 FR 30165, June 14, 1996; 62 FR 39974, July 25, 1997; 67 FR 35048, May 17, 2002; 69 FR 6567, Feb. 11, 2004; 71 FR 54434, Sept. 15, 2006]

§ 180.384 Mepiquat (N,N-dimethylpiperidinium); tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the plant growth regulator mepiquat (N,N-dimethylpiperidinium) in or on the following commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.1
Cotton, gin byproducts	6.0
Cotton, undelinted seed	2.0
Goat, meat byproducts	0.1
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Sheep, meat byproducts	0.1

(2) Tolerances are established for residues of the plant growth regulator mepiquat chloride (N,N-dimethylpiperidinium chloride) in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.1
Goat, fat	0.1
Goat, meat	0.1
Grape	1.0
Grape, raisin	5.0
Hog, fat	0.1
Hog, meat	0.1
Horse, fat	0.1
Horse, meat	0.1
Sheep, fat	0.1
Sheep, meat	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 3118, Jan. 23, 2002]

§ 180.385 Diclofop-methyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide diclofop-methyl (methyl 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoate) and its metabolites, 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoic acid and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy]propanoic acid, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, straw	0.1
Wheat, grain	0.1
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 23425, Apr. 7, 1980, as amended at 50 FR 20211, May 15, 1985; 51 FR 3599, Jan. 29, 1986; 51 FR 19176, May 28, 1986; 63 FR 57077, Oct. 26, 1998; 72 FR 41931, Aug. 1, 2007]

§§ 180.388–180.389 [Reserved]

§ 180.390 Tebuthiuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide tebuthiuron (N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea) and its metabolites N-(5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea, N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methylurea, and N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage	10.0
Grass, hay	10.0

(2) Tolerances are established for the combined residues of the herbicide tebuthiuron (N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea) and its metabolites N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methylurea, N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea, 2-dimethylethyl-5-amino-1,3,4-thiadiazole, and N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, meat	1.0
Cattle, meat byproducts	5.0
Goat, fat	1.0
Goat, meat	1.0
Goat, meat byproducts	5.0
Horse, fat	1.0
Horse, meat	1.0
Horse, meat byproducts	5.0
Sheep, fat	1.0
Sheep, meat	1.0
Sheep, meat byproducts	5.0

(3) A tolerance is established for the combined residues of the herbicide tebuthiuron (N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea) and its metabolites N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methylurea, N-(5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methylurea, N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea, N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea, and N-(5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea in or on the following raw agricultural commodities:

Commodity	Parts per million
Milk	0.8

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 53461, Sept. 19, 2007]

§ 180.395 Hydramethylnon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide tetrahydro-5,5-dimethyl-2(1*H*)-pyrimidinone(3-(4-(trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene)hydrazone in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage	2.0
Grass, hay	2.0
Pineapple	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 55198, Aug. 19, 1980, as amended at 63 FR 10543, Mar. 4, 1998; 63 FR 65073, Nov. 25, 1998; 66 FR 28672, May 24, 2001; 68 FR 37764, June 25, 2003; 68 FR 48312, Aug. 13, 2003; 72 FR 41931, Aug. 1, 2007]

§ 180.396 Hexazinone; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) and its plant metabolites; A [3-(4-hydroxycyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], B [3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], C [3-(4-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], D [3-cyclohexyl)-1-methyl-1,3,5-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione], and E [3-(4-hydroxycyclohexyl)-1-methyl-1,3,5-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione] (calculated as hexazinone) in the following commodities:

Commodity	Parts per million
Alfalfa, forage	2.0
Alfalfa, hay	8.0
Alfalfa, seed	2.0
Blueberry	0.6
Grass, forage	10.0
Pineapple	0.6

(2) Tolerances are established for the combined residues of hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) and its animal tissue metabolites; B [3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], and F (3-cyclohexyl-6-amino-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) (calculated as hexazinone) in the following food commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.1
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.1
Sheep, fat	0.1
Sheep, meat	0.1
Sheep, meat byproducts	0.1

(3) Tolerances are established for the combined residues of hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) and its metabolites; B [3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], C [3-(4-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], C-2 [3-(3-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione] and F (3-cyclohexyl-6-amino-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) (calculated as hexazinone) in milk:

Commodity	Parts per million
Milk	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) and which excludes use of hexazinone on sugarcane in Florida, are established for the combined residues of hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione and its plant metabolites; A [3-(4-hydroxycyclohexyl)-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1*H*,3*H*)-dione], B [3-cyclohexyl-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], C [3-(4-hydroxycyclohexyl)-6-(methylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione], D [(3-cyclohexyl)-1-methyl-1,3,5-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione], and E [3-(4-hydroxycyclohexyl)-1-methyl-1,3,5-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione] (calculated as hexazinone) in the following commodities:

Commodity	Parts per milliom
Sugarcane, cane	0.6
Sugarcane, molasses	4.0

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33713, May 24, 2000, as amended at 71 FR 56399, Sept. 27, 2006]

§ 180.399 Iprodione; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	2.0
Almond	0.3
Apricot	20.0
Bean, dry, seed	2.0
Bean, forage	90.0
Bean, succulent	2.0
Blueberry	15.0
Boysenberry	15.0
Broccoli	25.0
Caneberry subgroup 13A	25.0
Carrot, roots	5.0
Cherry, sweet, postharvest	20.0
Cherry, tart	20.0
Cotton, undelinted seed	0.10
Cowpea, hay	90.0
Currant	15.0
Garlic	0.1
Ginseng	2.0
Ginseng, dried root	4.0
Grape	60.0
Grape, raisin	300
Kiwifruit	10.0
Lettuce	25.0
Nectarine, postharvest	20.0
Onion, bulb	0.5
Peach, postharvest	20.0
Peanut	0.5
Peanut, hay	150.0
Plum, postharvest	20.0
Plum, prune	20.0
Potato	0.5
Raspberry	15.0
Rice, bran	30.0
Rice, grain	10.0
Rice, hulls	50.0
Rice, straw	20.0
Strawberry	15.0

(2) Tolerances are established for the combined residues of iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolites [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide] and [*N*-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide], all expressed as iprodione equivalents in or on the following food commodities of animal origin:

Commodity	Parts per million
Cattle, fat	0.5
Cattle, kidney	3.0
Cattle, liver	3.0
Cattle, meat	0.5
Cattle, meat byproducts, except kidney and liver	0.5
Egg	1.5
Goat, fat	0.5
Goat, kidney	3.0
Goat, liver	3.0
Goat, meat	0.5
Goat, meat byproducts, except kidney and liver	0.5
Hog, fat	0.5
Hog, kidney	3.0
Hog, liver	3.0
Hog, meat	0.5
Hog, meat byproducts, except kidney and liver	0.5
Horse, fat	0.5
Horse, kidney	3.0
Horse, liver	3.0
Horse, meat	0.5
Horse, meat byproducts, except kidney and liver	0.5
Milk	0.5
Poultry, fat	3.5
Poultry, liver	5.0
Poultry, meat	1.0
Poultry, meat byproducts, except liver	1.0
Sheep, fat	0.5
Sheep, kidney	3.0
Sheep, liver	3.0
Sheep, meat	0.5
Sheep, meat byproducts, except kidney and liver	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in or on the following food commodity:

Commodity	Parts per million
Mustard greens	15.0

(d) *Indirect or inadvertent residues.* [Reserved]

[48 FR 40385, Sept. 7, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.399, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.401 Thiobencarb; tolerances for residues.

(a) Tolerances are established for the combined residues of the herbicide thiobencarb (*S*-[(4-chlorophenyl)methyl]diethyl-carbamothioate) and its chlorobenzyl and chlorophenyl moiety-containing metabolites in or on the following raw agricultural commodities:

Commodity	Part per million
Cattle, fat	0.2
Cattle, meat byproducts	0.2
Cattle, meat	0.2
Egg	0.2
Goat, fat	0.2
Goat, meat byproducts	0.2
Goat, meat	0.2
Hog, fat	0.2
Hog, meat byproducts	0.2
Hog, meat	0.2
Horse, fat	0.2
Horse, meat byproducts	0.2
Horse, meat	0.2
Milk	0.05
Poultry, fat	0.2
Poultry, meat byproducts	0.2
Poultry, meat	0.2
Rice, grain	0.2
Rice, straw	1.0
Sheep, fat	0.2
Sheep, meat byproducts	0.2
Sheep, meat	0.2

(b) Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the herbicide thiobencarb (S-[(4-chlorophenyl)methyl]diethylcarbamothioate) and its chlorobenzyl and chlorophenyl moiety-containing metabolites in or on the following raw agricultural commodities:

Commodity	Parts per million
Celery	0.2
Endive	0.2
Lettuce	0.2

[47 FR 6833, Feb. 17, 1982, as amended at 56 FR 2440, Jan. 23, 1991]

§ 180.403 Thidiazuron; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the defoliant thidiazuron (N-phenyl-N-1,2,3-thiadiazol-5-ylurea) and its aniline containing metabolites in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.4
Cattle, meat	0.4
Cattle, meat byproducts	0.4
Cotton, gin byproducts	24.0
Cotton, undelinted seed	0.3
Goat, fat	0.4
Goat, meat	0.4
Goat, meat byproducts	0.4
Hog, fat	0.4
Hog, meat	0.4
Hog, meat byproducts	0.4
Horse, fat	0.4
Horse, meat	0.4
Horse, meat byproducts	0.4
Milk	0.05
Sheep, fat	0.4
Sheep, meat	0.4
Sheep, meat byproducts	0.4

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33700, May 24, 2000, as amended at 72 FR 53462, Sept. 19, 2007]

§ 180.404 Profenofos; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide profenofos (O-(4-bromo-2-chlorophenyl)-O-ethyl-S-propyl phosphorothioate) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cotton, gin byproducts	55.0
Cotton, undelinted seed	2.0
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33700, May 24, 2000, as amended at 66 FR 50833, Oct. 5, 2001; 67 FR 49617, July 31, 2002; 72 FR 54579, Sept. 26, 2007]

§ 180.405 Chlorsulfuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of chlorsulfuron (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) and its metabolite, 2-chloro-5-hydroxy-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl] benzenesulfonamide in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, straw	0.5
Oat, forage	20.0
Oat, grain	0.1
Oat, straw	0.5
Wheat, forage	20.0
Wheat, grain	0.1
Wheat, straw	0.5

(2) Tolerances are established for residues of chlorsulfuron (2-chloro-*N*-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl] benzenesulfonamide) in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.3
Cattle, meat	0.3
Cattle, meat byproducts	0.3
Goat, fat	0.3
Goat, meat	0.3
Goat, meat byproducts	0.3
Grass, forage	11.0
Grass, hay	19.0
Hog, fat	0.3
Hog, meat	0.3
Hog, meat byproducts	0.3
Horse, fat	0.3
Horse, meat	0.3
Horse, meat byproducts	0.3
Milk	0.1
Sheep, fat	0.3
Sheep, meat	0.3
Sheep, meat byproducts	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 52873, Aug. 14, 2002]

§ 180.406 Dimethipin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the harvest growth regulant dimethipin (2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetraoxide; CAS Reg. No. 55290–64–7) in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, meat	0.01	5/31/10
Cattle, meat byproducts	0.01	5/31/10
Cotton, undelinted seed	0.50	5/31/10
Goat, meat	0.01	5/31/10
Goat, meat byproducts	0.01	5/31/10
Hog, meat	0.01	5/31/10
Hog, meat byproducts	0.01	5/31/10
Horse, meat	0.01	5/31/10
Horse, meat byproducts	0.01	5/31/10
Sheep, meat	0.01	5/31/10
Sheep, meat byproducts	0.01	5/31/10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33700, May 24, 2000, as amended at 72 FR 52019, Sept. 12, 2007; 73 FR 54962, Sept. 24, 2008]

§ 180.407 Thiodicarb; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide thiodicarb (dimethyl *N,N′*-[thiobis[[(methylimino)carbonyloxy]] bis[ethanimidothioate]) and its metabolite methomyl (*S*-methyl *N*-[(methylcarbamoyl) oxy]thioacetimidate) in or on the following food commodities or groups. The time-limited tolerances expire and are revoked on the dates listed in the following table:

Commodity	Parts per million	Expiration/ revocation date
Broccoli	7.0	None
Cabbage	7.0	None
Cauliflower	7.0	None
Corn, sweet, kernel plus cob with husks removed	2.0	None
Cotton, undelinted seed	0.4	None
Cotton, hulls	0.8	None
Soybean, hulls	0.8	None
Soybean	0.2	None
Vegetable, leafy, except brassica, group 4	35	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 44595, Aug. 22, 1997]

§ 180.408 Metalaxyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide metalaxyl [*N*-(2,6-dmethylphyenyl)-*N*-(methoxyacetyl) alanine methylester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following food commodities:

Commodity	Parts per million
Alfalfa, forage	6.0
Alfalfa, hay	20.0
Almond	0.5
Almond, hulls	10.0
Apple	0.2
Apple, wet pomace	0.4
Apricot, dried	4.0
Asparagus	7.0
Avocado	4.0
Beet, garden, roots	0.1
Beet, garden, tops	0.1
Beet, sugar	0.1
Beet, sugar, molasses	1.0
Beet, sugar, roots	0.5
Beet, sugar, tops	10.0
Blueberry	2.0
Broccoli	2.0
Brussels sprouts	2.0
Cabbage	1.0
Cattle, fat	0.4
Cattle, kidney	0.4
Cattle, liver	0.4
Cattle, meat	0.05
Cattle, meat byproducts, except kidney and liver	0.05
Cauliflower	1.0
Citrus, oil	7.0
Citrus, dried pulp	7.0
Clover, forage	1.0
Clover, hay	2.5
Cotton, undelinted seed	0.1
Cranberry	4.0
Egg	0.05
Fruit, citrus	1.0
Fruit, stone, group 12	1.0
Ginseng	3.0
Goat, fat	0.4
Goat, kidney	0.4
Goat, liver	0.4
Goat, meat	0.05
Goat, meat byproducts, except kidney and liver	0.05
Grain, cereal, group 15, except barley, oat and wheat	0.1
Grain, crop	0.1
Grape	2.0
Grape, raisin	6.0
Grass, forage	10.0
Grass, hay	25.0
Hog, fat	0.4
Hog, kidney	0.4
Hog, liver	0.4
Hog, meat	0.05
Hog, meat byproducts, except kidney and liver	0.05
Hop, dried cones	20
Hop, vines	2.0
Horse, fat	0.4
Horse, kidney	0.4
Horse, liver	0.4
Horse, meat	0.05
Horse, meat byproducts, except kidney and liver	0.05
Lettuce, head	5.0
Milk	0.02
Mustard greens	5.0
Onion, bulb	3.0
Onion, green	10.0
Peanut	0.2
Peanut, hay	20.0
Peanut, meal	1.0
Peanut, hulls	2.0
Pineapple	0.1
Pineapple, fodder	0.1
Pineapple, forage	0.1
Plum, prune, dried	4.0
Potato, processed (including potato, chips)	4.0
Potato, processed potato waste	4.0
Poultry, fat	0.4
Poultry, kidney	0.4
Poultry, liver	0.4
Poultry, meat	0.05
Poultry, meat byproducts, except kidney and liver	0.05
Potato	0.5
Raspberry	0.5
Sheep, fat	0.4
Sheep, kidney	0.4
Sheep, liver	0.4
Sheep, meat	0.05
Sheep, meat byproducts, except kidney and liver	0.05
Soybean, hulls	2.0
Soybean, meal	2.0
Soybean, seed	1.0
Spinach	10.0
Strawberry	10.0
Sunflower, seed	0.1
Sunflower, forage	0.1
Tomato, processed	3.0
Vegetable, brassica, leafy, group 5, except broccoli, cabbage, cauliflower, brussels sprouts, and mustard greens	0.1
Vegetable, cucurbit, group 9	1.0
Vegetable, foilage of legume, group 7	8.0
Vegetable, fruiting, group 8	1.0
Vegetable, leafy, except brassica, group 4, except spinach	5.0
Vegetable, leaves of root and tuber, group 2	15.0
Vegetable, legume, cannery waste	5.0
Vegetable, legume, group 6	0.2
Vegetable, root and tuber, group 1	0.5
Walnut	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration (refer to § 180.1(n)) are established for the combined residues of the

fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl, in or on the following raw agricultural commodity:

Commodity	Parts per million
Papaya	0.1

(d) *Indirect or inadvertent tolerances.* Tolerances are established for indirect or inadvertent residues of metalaxyl in or on the food commodities when present therein as a result of the application of metalaxyl to growing crops listed in paragraph (a) of this section and other non-food crops to read as follows:

Commodity	Part per million
Barley, grain	0.2
Barley, milling fractions	1.0
Barley, straw	2.0
Grain, cereal, forage, fodder and straw, group 16, except barley, oat, and wheat; forage	1.0
Grain, cereal, forage, fodder and straw, group 16, except barley, oat, and wheat; stover	1.0
Grain, cereal, forage, fodder and straw, group 16, except barley, oat, and wheat; straw	1.0
Oat, forage	2.0
Oat, grain	0.2
Oat milling fractions	1.0
Oat, straw	2.0
Wheat, forage	2.0
Wheat, grain	0.2
Wheat, milling fractions	1.0
Wheat, straw	2.0

[65 FR 33700, May 24, 2000, as amended at 72 FR 35666, June 29, 2007]

§ 180.409 Pirimiphos-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide pirimiphos-methyl (O-(2-diethylamino-6-methyl-4-pyrimidinyl) O,O-dimethyl phosphorothioate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat byproducts	0.02
Corn, field, grain	8.0
Corn, pop, grain	8.0
Goat, fat	0.02
Goat, meat byproducts	0.02
Grain, aspirated fractions	20.0
Hog, fat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, meat byproducts	0.02
Poultry, fat	0.02
Sheep, fat	0.02
Sheep, meat byproducts	0.02
Sorghum, grain, grain	8.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33714, May 24, 2000, as amended at 67 FR 41807, June 19, 2002; 67 FR 49617, July 31, 2002; 70 FR 44492, Aug. 3, 2005; 72 FR 53462, Sept. 19, 2007]

§ 180.410 Triadimefon; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide triadimefon, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone, and triadimenol, β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, expressed as triadimefon, in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Apple	1.0	7/25/10
Apple, wet pomace	4.0	7/25/10
Grape	1.0	7/25/10
Pear	1.0	7/25/10
Pineapple	2.0	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(m), are established for the combined residues of the fungicide triadimefon, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone, and triadimenol, β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, expressed as triadimefon, in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Raspberry	2.0	7/25/10

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54962, Sept. 24, 2008]

§ 180.411 Fluazifop-P-butyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the following commodities:

Commodity	Parts per million
Beans, dry, seed	50
Carrot, roots	2.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cotton, oil	0.2
Cotton, undelinted seed	0.1
Egg	0.05
Endive	6.0
Fruit, stone	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.05
Nut, macadamia	0.1
Onion, bulb	0.5
Peanut	1.5
Peanut, meal	2.2
Pecans	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, seed	2.5
Spinach	6.0
Sweet potato, roots	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide, fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the following commodities:

Commodity	Parts per million
Asparagus	3.0
Coffee, bean	0.1
Pepper, tabasco	1.0
Rhubarb	0.5

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33714, May 24, 2000, as amended at 74 FR 9372, Mar. 4, 2009]

§ 180.412 Sethoxydim; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051–80–2) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage	40
Alfalfa, hay	40
Almond, hulls	2.0
Apricot	0.2
Apple, wet pomace	0.8
Asparagus	4.0
Bean, succulent	15
Beet, sugar, molasses	10
Beet, sugar, tops	3.0
Blueberry	4.0
Borage, meal	10
Borage, seed	6.0
Buckwheat, flour	25
Buckwheat, grain	19
Caneberry subgroup 13 A	5.0
Canola, meal	40
Canola, seed	35
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	1.0
Cherry, sweet	0.2
Cherry, tart	0.2
Citrus, dried pulp	1.5
Clover, forage	35
Clover, hay	55
Coriander, leaves	4.0
Corn, field, forage	2.0
Corn, field, grain	0.5
Corn, field, stover	2.5
Corn, sweet, forage	3.0
Corn, sweet, kernel plus cob with husk removed	0.4
Corn, sweet, stover	3.5
Cotton, undelinted seed	5.0
Cowpea, forage	15
Cowpea, hay	50
Crambe, meal	40.0
Crambe, seed	35.0
Cranberry	2.5
Cuphea, seed	35.0
Dillweed, fresh leaves	10

Commodity	Parts per million
Echium, seed	35.0
Egg	2.0
Flax, seed	5.0
Fruit, citrus, group 10	0.5
Fruit, pome, group 11	0.2
Goat, fat	0.2
Goat, meat	0.2
Goat, meat byproducts	1.0
Gold of pleasure, meal	40.0
Gold of pleasure, seed	35.0
Grape	1.0
Grape, raisin	2.0
Hare's ear mustard, seed	35.0
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	1.0
Horse, fat	0.2
Horse, meat	0.2
Horse, meat byproducts	1.0
Juneberry	5.0
Lesquerella, seed	35.0
Lingonberry	5.0
Lunaria, seed	35.0
Meadowfoam, seed	35.0
Milk	0.5
Milkweed, seed	35.0
Mustard, seed	35.0
Nectarine	0.2
Nut, tree, group 14	0.2
Oil radish, seed	35.0
Okra	2.5
Pea and bean, dried shelled, except soybean, subgroup 6C	25
Pea, field, hay	40
Pea, field, vines	20
Pea, succulent	10
Peach	0.2
Peanut	25
Peppermint, tops	30
Pistachio	0.2
Poppy, seed	35.0
Potato granules/flakes	8.0
Potato waste, processed	8.0
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	2.0
Radish, tops	4.5
Rapeseed, meal	40
Rapeseed, seed	35
Safflower, seed	15
Salal	5.0
Sesame, seed	35.0
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	1.0
Soybean, hay	10
Soybean, seed	16
Spearmint, tops	30
Strawberry	10
Sunflower, meal	20
Sunflower, seed	7.0
Sweet rocket, seed	35.0
Turnip, tops	5.0
Vegetable, brassica, leafy, group 5	5.0
Vegetable, bulb, group 3	1.0
Vegetable, cucurbit, group 9	4.0
Vegetable, fruiting, group 8	4.0
Vegetable, leafy, except brassica, group 4	4.0
Vegetable, root and tuber, group 1	4.0

(b) *Section 18 emergency exemptions.*

(c) *Tolerances with regional registration.* Tolerances with regional registration, as defined in § 180.1(m), are established for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Artichoke, globe	5.0	None
Rhubarb	0.3	None

(d) *Indirect and inadvertent residues.* [Reserved]

[62 FR 17740, Apr. 11, 1997]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.412, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.413 Imazalil; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the fungicide imazalil, 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1*H*-imidazole, and its metabolite, 1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol, in or on the following food commodities:

Commodity	Parts per million
Banana	3.0
Barley, grain	0.1
Barley, hay	0.5
Barley, straw	0.5
Citrus, dried pulp	25.0
Citrus, oil	200.0
Fruit, citrus, postharvest	10.0
Wheat, forage	0.5
Wheat, grain	0.1
Wheat, hay	0.5
Wheat, straw	0.5

(2) Tolerances are established for the combined residues of the fungicide imazalil, 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1*H*-imidazole, and its metabolites, 3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]-2,4-imidazolidinedione (FK772) and 3-[2-(2,4-dichlorophenyl)-2-(hydroxy)]-2,4-imidazolidinedione (FK284), in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.2
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.2
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.2
Milk	0.02
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33715, May 24, 2000, as amended at 67 FR 46893, July 17, 2002; 71 FR 54434, Sept. 15, 2006]

§ 180.414 Cyromazine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, dry, except cowpea	3.0
Bean, lima	1.0
Broccoli	1.0
Cabbage, abyssinian	10.0
Cabbage, seakale	10.0
Cattle, fat	0.05
Cattle, kidney	0.2
Cattle, meat	0.05
Cattle, meat byproducts, except kidney	0.05
Egg	0.25
Garlic	0.2
Garlic, great-headed, bulb	0.2
Goat, fat	0.05
Goat, kidney	0.2
Goat, meat	0.05
Goat, meat byproducts, except kidney	0.05
Hanover salad, leaves	10.0
Hog, fat	0.05
Hog, kidney	0.2
Hog, meat	0.05
Hog, meat byproducts, except kidney	0.05
Horse, fat	0.05
Horse, kidney	0.2
Horse, meat	0.05
Horse, meat byproducts, except kidney	0.05
Leek	3.0
Mango [1]	0.3
Milk	0.05
Mushroom	1.0
Onion, bulb	0.2
Onion, green	3.0
Onion, potato	3.0
Onion, tree	3.0
Onion, welsh	3.0
Pepper	1.0
Potato	0.8
Poultry, fat (from chicken layer hens and chicken breeder hens only)	0.05
Poultry, meat (from chicken layer hens and chicken breeder hens only)	0.05
Poultry, meat byproducts (from chicken layer hens and chicken breeder hens only)	0.05
Rakkyo, bulb	0.2
Shallot, bulb	0.2
Shallot, fresh leaves	3.0
Sheep, fat	0.05
Sheep, kidney	0.2
Sheep, meat	0.05
Sheep, meat byproducts, except kidney	0.05
Tomato	0.5
Turnip, greens	10.0
Vegetable, brassica, leafy, group 5, except broccoli	10.0
Vegetable, leafy, except brassica, group 4	7.0
Vegetable, cucurbit, group 9	1.0

[1] There are no U.S. registrations on mango as of May 4, 2000.

(2) The additive cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) may be safely used in accordance with the following prescribed conditions:

(i) It is used as a feed additive only in feed for chicken layer hens and chicken breeder hens at the rate of not more than 0.01 pound of cyromazine per ton of poultry feed.

(ii) It is used for control of flies in manure of treated chicken layer hens and chicken breeder hens.

(iii) Feeding of cyromazine-treated feed must stop at least 3 days (72 hours) before slaughter. If the feed is formulated by any person other than the end user, the formulator must inform the end user, in writing, of the 3–day (72 hours) preslaughter interval.

(iv) To ensure safe use of the additive, the labeling of the pesticide formulation containing the feed additive shall conform to the labeling which is registered by the U.S. Environmental Protection Agency, and the additive shall be used in accordance with this registered labeling.

(v) Residues of cyromazine are not to exceed 5.0 parts per million (ppm) in poultry feed.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of

cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine), in or on the raw agricultural commodities when present therein as a result of the application of cyromazine to growing crops listed in paragraph (a)(1) of this section.

Commodity	Parts per million
Cotton, undelinted seed	0.1
Corn, sweet, kernel plus cob with husks removed	0.5
Corn, sweet, forage	0.5
Corn, sweet, stover	0.5
Radish, roots	0.5
Radish, tops	0.5

[65 FR 25860, May 4, 2000, as amended at 67 FR 72593, Dec. 6, 2002; 68 FR 55269, Sept. 24, 2003]

§ 180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate) in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Avocado	25	None
Banana	3.0	None
Blueberry	40	12/31/00
Bushberry subgroup 13B	40	None
Caneberry subgroup 13A	0.1	None
Cranberry	0.5	None
Fruit, citrus, group 10	5.0	None
Fruit, pome	10	None
Ginseng	0.1	None
Hop, dried cones	45	None
Juneberry	40	None
Lingonberry	40	None
Nut, macadamia	0.20	None
Onion, green	10.0	None
Pea, succulent	0.3	None
Pineapple	0.1	None
Pineapple, fodder	0.1	None
Pineapple, forage	0.1	None
Onion, bulb	0.5	None
Salal	40	None
Strawberry	75	None
Tomato	3	None
Turnip, greens	40	None
Turnip, roots	15	None
Vegetable, brassica, leafy, group 5	60	None
Vegetable, cucurbit, group 9	15	None
Vegetable, leafy, except brassica, group 4	100	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the fungicide aluminum tris (*O*-ethylphosphonate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Asparagus	0.1
Grape	10

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 36801, July 8, 1999, as amended at 64 FR 37875, July 14, 1999; 65 FR 50438, Aug. 18, 2000; 67 FR 55346, Aug. 29, 2002; 68 FR 11335, Mar. 10, 2003; 70 FR 7047, Feb. 10, 2005]

§ 180.416 Ethalfluralin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide ethalfluralin [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine] in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, dry, seed	0.05
Dill, dried leaves	0.05
Dill, fresh leaves	0.05
Mustard, seed	0.05
Peanut	0.05
Pea, dry, seed	0.05
Potato	0.05
Rapeseed, seed	0.05
Safflower, seed	0.05
Soybean	0.05
Sunflower, seed	0.05
Vegetable, cucurbit, group 9	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[49 FR 391, Jan. 4, 1984, as amended at 50 FR 4976, Feb. 5, 1985; 52 FR 11262, Apr. 8, 1987; 62 FR 66014, Dec. 17, 1997; 64 FR 5191, Feb. 3, 1999; 64 FR 54782, Oct. 8, 1999; 66 FR 37598, July 19, 2001; 66 FR 41454, Aug. 8, 2001; 67 FR 2342, Jan. 17, 2002; 67 FR 49617, July 31, 2002; 72 FR 68534, Dec. 5, 2007]

§ 180.417 Triclopyr; tolerances for residues.

(a) *General.* (1) Tolerances for residues of the herbicide triclopyr per se, as a result of the application/use of butoxyethyl ester of triclopyr and triethyylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Egg	0.05
Fish	3.0
Grass, forage	700.0
Grass, hay	200.0
Milk	0.01
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts, except kidney	0.1
Rice, grain	0.3
Rice, straw	10.0
Shellfish	3.5

(2) Tolerances for the combined residues of the herbicide triclopyr ((3,5,6-trichloro-2-pyridinyl)oxy) acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), as a result of the application/use of butoxyethyl ester of triclopyr or the triethylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.5
Cattle, liver	0.5
Cattle, meat	0.05
Cattle, meat byproducts, except kidney and liver	0.05
Goat, fat	0.05
Goat, kidney	0.5
Goat, liver	0.5
Goat, meat	0.05
Goat, meat byproducts, except kidney and liver	0.05
Hog, fat	0.05
Hog, kidney	0.5
Hog, liver	0.5
Hog, meat	0.05
Hog, meat byproducts, except kidney and liver	0.05
Horse, fat	0.05
Horse, kidney	0.5
Horse, liver	0.5
Horse, meat	0.05
Horse, meat byproducts, except kidney and liver	0.05
Sheep, fat	0.05
Sheep, kidney	0.5
Sheep, liver	0.5
Sheep, meat	0.05
Sheep, meat byproducts, except kidney and liver	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[50 FR 18486, May 1, 1985, as amended at 55 FR 26440, June 28, 1990; 60 FR 4095, Jan. 20, 1995; 62 FR 46894, Sept. 5, 1997; 63 FR 45406, Aug. 26, 1998; 67 FR 35048, May 17, 2002; 67 FR 58725, Sept. 18, 2002; 72 FR 41931, Aug. 1, 2007]

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cypermethrin (±)alpha cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	14.0
Cattle, fat	1.0
Cattle, meat	0.2
Cattle, meat byproducts	0.05
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.5
Egg	0.05
Goat, fat	1.0
Goat, meat	0.2
Goat, meat byproducts	0.05
Hog, fat	0.1
Hog, meat	0.05
Horse, fat	1.0
Horse, meat	0.2
Horse, meat byproducts	0.05
Lettuce, head	4.0
Milk, fat (reflecting 0.10 in whole milk)	2.5
Onion, bulb	0.1
Onion, green	6.0
Pecan	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Sheep, fat	1.0
Sheep, meat	0.2
Sheep, meat byproducts	0.05

(2) Tolerances are established for residues of the insecticide Z-cypermethrin (S-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate and its inactive R-isomers in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, hay	15.00
Alfalfa, forage	5.00
Alfalfa, seed	0.50
Almond, hulls	6
Animal feed, nongrass, group 18, forage	8
Animal feed, nongrass, group 18, hay	40
Beet, sugar, roots	0.05
Beet, sugar, tops	0.20
Berry group 13	0.8
Borage, seed	0.2
Brassica, head and stem, subgroup 5A	2.00
Brassica, leafy greens, subgroup 5B	14.00
Cabbage	2.00
Castor oil plant, refined oil	0.4
Castor oil plant, seed	0.2
Cattle, fat	1.00
Cattle, meat	0.2
Cattle, meat byproducts	0.05
Chinese tallowtree, refined oil	0.4

Commodity	Parts per million
Chinese tallowtree, seed	0.2
Cilantro, leaves	10
Citrus, dried pulp	1.8
Citrus, oil	4.0
Corn, field, forage	0.20
Corn, field, grain	0.05
Corn, field, stover	3.00
Corn, pop, grain	0.05
Corn, pop, stover	3.00
Corn, sweet, forage	15.00
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	15.00
Cotton, undelinted seed	0.5
Crambe, seed	0.2
Cuphea, seed	0.2
Echium, seed	0.2
Egg	0.05
Euphorbia, refined oil	0.4
Euphorbia, seed	0.2
Evening primrose, refined oil	0.4
Evening primrose, seed	0.2
Flax, seed	0.2
Food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments	0.05
Fruit, citrus, group 10	0.35
Fruit, pome, group 11	2
Fruit, stone, group 12	1
Goat, fat	1.00
Goat, meat	0.2
Goat, meat byproducts	0.05
Gold of pleasure, seed	0.2
Grain, aspirated fractions	10.0
Grape	2
Grass, forage, fodder, and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	35
Hare's-ear mustard, seed	0.2
Hog, fat	0.1
Hog, meat	0.05
Horse, fat	1.00
Horse, meat	0.2
Horse, meat byproducts	0.05
Jojoba, refined oil	0.4
Jojoba, seed	0.2
Lesquerella, seed	0.2
Lunaria, seed	0.2
Meadowfoam, seed	0.2
Milk, fat (reflecting 0.10 in whole milk)	2.50
Milkweed, seed	0.2
Mustard, seed	0.2
Niger seed, refined oil	0.4
Niger seed, seed	0.2
Nut, tree, group 14	0.05
Oil radish, seed	0.2
Okra	0.2
Onion, bulb	0.10
Onion, green	3.00
Pea and bean, dried shelled, except soybean, subgroup 6C	0.05
Pea and bean, succulent shelled, subgroup 6B	0.1
Peanut	0.05
Pecan	0.05
Poppy, seed	0.2
Poultry, fat	0.05
Poultry, meat	0.05
Rapeseed	0.2
Rice, grain	1.50
Rice, hulls	6.00
Rice, straw	2.00
Rice, wild, grain	1.5
Rose hip, refined oil	0.4
Rose hip, seed	0.2
Safflower, seed	0.2
Sesame, seed	0.2
Sheep, fat	1.00
Sheep, meat	0.2
Sheep, meat byproducts	0.05
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.5
Sorghum, grain, stover	5.0
Soybean, seed	0.05
Stokes aster, refined oil	0.4
Stokes aster, seed	0.2
Sugarcane, cane	0.60
Sunflower, refined oil	0.5
Sunflower, seed	0.2
Sweet rocket, seed	0.2
Tallowwood, refined oil	0.4
Tallowwood, seed	0.2
Tea oil plant, refined oil	0.4
Tea oil plant, seed	0.2
Turnip, greens	14
Vegetable, cucurbit, group 9	0.2
Vegetable, fruiting, group 8	0.2
Vegetable, leafy, except brassica, group 4	10.00
Vegetable, legume, edible podded, subgroup 6A	0.5
Vegetable, root and tuber, group 1, except sugar beet	0.1
Vernonia, refined oil	0.4
Vernonia, seed	0.2
Wheat, forage	3.0
Wheat, grain	0.2
Wheat, hay	6.0
Wheat, straw	7.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 63235, 63243, Nov. 26, 1997, as amended at 63 FR 48586, Sept. 11, 1998; 66 FR 47993, Sept. 17, 2001; 67 FR 6430, Feb. 12, 2002; 67 FR 56495, Sept. 4, 2002; 69 FR 71717, Dec. 10, 2004; 71 FR 78382, Dec. 29, 2006; 72 FR 53462, Sept. 19, 2007; 72 FR 71801, Dec. 19, 2007; 73 FR 1525, Jan. 9, 2008]

§ 180.419 Chlorpyrifos-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the insecticide chlorpyrifos-methyl [*O,-O,*-dimethyl *O*-(3,5,6-trichloro-2-pyridyl)] phosphorothioate and its metabolite (3,5,6-trichloro-2-pyridinol) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	6.0
Cattle, fat	0.5
Cattle, meat	0.5
Cattle, meat byproducts	0.5
Egg	0.1

Commodity	Parts per million
Goat, fat	0.5
Goat, meat	0.5
Goat, meat byproducts	0.5
Hog, fat	0.5
Hog, meat	0.5
Hog, meat byproducts	0.5
Horse, fat	0.5
Horse, meat	0.5
Horse, meat byproducts	0.5
Milk, fat (0.05 ppm (N) in whole milk	1.25
Oat, grain	6.0
Poultry, fat	0.5
Poultry, meat	.5
Poultry, meat byproducts	.5
Rice, grain	6.0
Sheep, fat	0.5
Sheep, meat	0.5
Sheep, meat byproducts	0.5
Sorghum, grain	6.0
Wheat, grain	6.0

(2) Tolerances are established for the combined residues of the insecticide chlorpyrifos-methyl (*O*,-*O*- dimethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate and its metabolite (3,5,6-trichloro-2-pyridinol) in or on the following food commodities when present therein as a result of application to stored grains:

Food	Parts per million
Barley milling fractions (except flour)	90
Oat, groats/rolled oats	130
Rice milling fractions (except flour)	30
Sorghum, grain, bran	90
Wheat milling fractions (except flour)	30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33715, May 24, 2000]

§ 180.420 Fluridone; tolerances for residues.

(a) Tolerances are established for the combined residues (free and bound) of the herbicide fluridone (1-methyl-3-phenyl-5-[3-trifluoromethyl)phenyl]-4(1*H*)-5-[3-(trifluoromethyl)phenyl]-4(1*H*)-pyridinone) in fish and crayfish at 0.5 part per million.

(b) Tolerances are established for residues of the herbicide fluridone in the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	.1
Cattle, liver	.1
Cattle, meat	.05
Cattle, meat byproducts	.05
Egg	.05
Goat, fat	.05
Goat, kidney	.1
Goat, liver	.1
Goat, meat	.05
Goat, meat byproducts	.05
Hog, fat	.05
Hog, kidney	.1
Hog, liver	.1
Hog, meat	.05
Hog, meat byproducts	.05
Horse, fat	.05
Horse, kidney	.1
Horse, liver	.1
Horse, meat	.05
Horse, meat byproducts	.05
Milk	.05
Poultry, fat	.05
Poultry, kidney	.01
Poultry, liver	.01
Poultry, meat	.05
Poultry, meat byproducts	.05
Sheep, fat	.05
Sheep, kidney	.1
Sheep, liver	.1
Sheep, meat	.05
Sheep, meat byproducts	.05

(c) Tolerances are established in the following irrigated crops and crop groupings for residues of the herbicide fluridone resulting from use of irrigation water containing residues of 0.15 ppm following applications on or around aquatic sites. Where tolerances are established at higher levels from other uses of fluridone on the following crops, the higher tolerance also applies to residues in the irrigated commodity. The tolerances follow:

Commodity	Parts per million
Avocado	0.1
Citrus	.1
Cotton, undelinted seed	.1
Cucurbits	.1
Fruit, pome	.1
Fruit, small	.1
Fruit, stone	.1
Grain, crop	.1
Grass, forage	.15
Hop, dried cones	.1
Legume, forage	.15
Nut	.1
Vegetable, fruiting	.1
Vegetable, leafy	.1
Vegetable, root crop	.1
Vegetable, seed and pod	.1

[51 FR 12146, Apr. 9, 1986, as amended at 55 FR 29829, July 20, 1990]

§ 180.421 Fenarimol; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	0.1
Apple, wet pomace	0.3
Banana	0.25
Cattle, fat	0.01
Cattle, kidney	0.01
Cattle, meat	0.01
Cattle, meat byproducts, except kidney	0.05
Cherry, sweet	1.0
Cherry, tart	1.0
Goat, fat	0.01
Goat, kidney	0.01
Goat, meat	0.01
Goat, meat byproducts, except kidney	0.05
Grape	0.1.
Hazelnut	0.02
Horse, fat	0.01
Horse, kidney	0.01
Horse, meat	0.01
Horse, meat byproducts, except kidney	0.05
Pear	0.1
Pecan	0.02
Sheep, fat	0.01
Sheep, kidney	0.01
Sheep, meat	0.01
Sheep, meat byproducts, except kidney	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[51 FR 39662, Oct. 30, 1986, as amended at 53 FR 27349, July 20, 1988; 53 FR 44403, Nov. 3, 1988; 54 FR 45734, Oct. 31, 1989; 60 FR 33354, June 28, 1995; 62 FR 49937, Sept. 24, 1997; 62 FR 61447, Nov. 18, 1997; 67 FR 35048, May 17, 2002; 67 FR 41807, June 19, 2002; 69 FR 6567, Feb. 11, 2004; 71 FR 32846, June 7, 2006; 71 FR 54434, Sept. 15, 2006]

§ 180.422 Tralomethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pesticide chemical tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate calculated as the parent in or on the following food commodities:

Commodity	Parts per million
Broccoli	0.5
Cotton, undelinted seed	0.02
Cotton, oil	0.20
Lettuce, head	1.00
Lettuce, leaf	3.00
Soybean	0.05
Sunflower, seed	0.05

(2) A tolerance of 0.02 part per million is established for the combined residues of the insecticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(RS)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate) and its metabolites *cis*-deltamethrin [(*S*-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-[2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and trans-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] as follows:

(i) In or on food commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food-handling establishments.

(ii) The insecticide may be present as a residue from application of tralomethrin in food-handling establishments, including food service, manufacturing, and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries in accordance with the following prescribed conditions:

(A) Application shall be limited to a general surface and spot and/or crack and crevice treatment in food-handling establishments where food and food products are held, processed, prepared, and served. General surface application may be used only when the facility is not in operation provided exposed food has been covered or removed from the area being treated. All food-contact surfaces and equipment must be thoroughly cleaned after general surface applications. Spot and/or crack and crevice application may be used while

the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of food and food-contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labelling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labelling.

(3) A tolerance of 0.02 part per million is established for the combined residues of the insecticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate) and its metabolites *cis*-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *trans*-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate as follows:

(i) In or on all feed items (other than those covered by a higher tolerance as a result of use on growing crops) in feed-handling establishments.

(ii) The insecticide may be present as a residue from application of tralomethrin in feed-handling establishments, including feed manufacturing and processing establishments in accordance with the following prescribed conditions:

(A) Application shall be limited to a general surface and spot and/or crack and crevice treatment in feed-handling establishments where feed and feed products are held or processed. General surface application may be used only when the facility is not in operation provided exposed feed has been covered or removed from the area being treated. All feed-contact surfaces and equipment must be thoroughly cleaned after general surface applications. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed feed is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of feed and feed- contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labelling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labelling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 63001, Nov. 26, 1997, as amended at 62 FR 66025, Dec. 17, 1997; 65 FR 33701, May 24, 2000; 71 FR 74817, Dec. 13, 2006]

§ 180.425 Clomazone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide clomazone, 2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone, in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, snap, succulent	0.05
Cabbage	0.1
Cotton, undelinted seed	0.05
Cucumber	0.1
Pea, succulent	0.05
Pepper	0.05
Peppermint, tops	0.05
Pumpkin	0.1
Rice, grain	0.02
Rice, straw	0.02
Soybean	0.05
Spearmint, tops	0.05
Squash, summer	0.1
Squash, winter	0.1
Sugarcane, cane	0.05
Sweet potato, roots	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, tuberous and corm, except potato, subgroup 1D	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[51 FR 9446, Mar. 19, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.425, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.426 2-[4,5-Dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-3-quinoline carboxylic acid; tolerance for residues.

A tolerance is established for residues of the herbicide 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-3-quinoline carboxylic acid, in or on the raw agricultural commodity soybean at 0.05 part per million.

[51 FR 13309, Apr. 2, 1986]

§ 180.427 Tau-Fluvalinate; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide tau-fluvalinate, cyano-(3-phenoxyphenyl)methyl *N*-[2-chloro-4-(trifluoromethyl)phenyl]-*D*-valinate, in or on the following food commodities:

Commodity	Parts per million
Honey	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertent residues.* [Reserved]

[65 FR 33701, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 73 FR 52616, Sept. 10, 2008]

§ 180.428 Metsulfuron methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide metsulfuron methyl (methyl 2-[[[[(4-methoxy-6-methyl-1,3,5- triazin-2-yl)amino]carbonyl]amino] sulfonyl] benzoate) and its metabolite methyl 2-[[[[(4-methoxy-6-methyl-1-,3,5- triazin-2-yl)amino]carbonyl]amino] sulfonyl]-4-hydroxybenzoate in or on the following raw material agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	20.0
Barley, straw	0.3
Grass, forage	15.0
Grass, hay	15.0
Grass, straw	15.0
Sorghum, grain, forage	0.2
Sorghum, grain, grain	0.1
Sorghum, grain, stover	0.2
Sugarcane, cane	0.05
Wheat, forage	5.0
Wheat, grain	0.1
Wheat, hay	20.0
Wheat, straw	0.3

(2) Tolerances are established for residues of metsulfuron methyl (methyl-2[[[[(4-methoxy- 6-methyl-1,3,5-triazin-2- yl)amino]carbonyl]amino] sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, kidney	0.5
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Goat, fat	0.1
Goat, kidney	0.5
Goat, meat	0.1
Goat, meat byproducts	0.1
Hog, fat	0.1
Hog, kidney	0.5
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1
Horse, kidney	0.5
Horse, meat	0.1
Horse, meat byproducts	0.1
Milk	0.05
Sheep, fat	0.1
Sheep, kidney	0.5
Sheep, meat	0.1
Sheep, meat byproducts	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 70191, Dec. 16, 1999, as amended at 66 FR 64773, Dec. 14, 2001; 67 FR 51097, Aug. 7, 2002]

§ 180.429 Chlorimuron ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide chlorimuron ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on the following raw agricultural commodities:

Commodity	Parts per million
Berry, low growing, except strawberry, subgroup 13–07H	0.02
Peanut	0.02
Soybean	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[74 FR 10494, Mar. 11, 2009]

§ 180.430 Fenoxaprop-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide fenoxaprop-ethyl [(±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate] and its metabolites [2-[4-](6-chloro-2-benzoxazoly)oxy]phenoxy]propanoic acid and 6-chloro- 2,3-dihydrobenzoxazol-2-one], each expressed as fenoxaprop-ethyl, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.1
Cattle, fat	0.05
Cattle, meat byproducts	0.05
Cattle, meat	0.05
Cotton, undelinted seed	0.05
Goat, fat	0.05
Goat, meat byproducts	0.05
Goat, meat	0.05
Hog, fat	0.05
Hog, meat byproducts	0.05
Hog, meat	0.05
Horse, fat	0.05
Horse, meat byproducts	0.05
Horse, meat	0.05
Milk	0.02
Peanut	0.05
Peanut, hulls	0.05
Rice, grain	0.05
Sheep, fat	0.05
Sheep, meat byproducts	0.05
Sheep, meat	0.05
Soybean	0.05
Wheat, grain	0.05
Wheat, straw	0.50

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide fenoxaprop-ethyl, [(±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid], and its metabolites (2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one), each expressed as fenoxaprop-ethyl, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA, in or on the food commodities in the following table. The tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Grass, forage	0.05	12/31/10
Grass, hay	0.05	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 1377, Jan. 9, 1998, as amended at 63 FR 19837, Apr. 22, 1998; 73 FR 33718, June 13, 2008]

§ 180.431 Clopyralid; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on the following commodities:

Commodity	Parts per million
Asparagus	1.0
Barley, grain	3.0
Barley, hay	9.0
Barley, milled fractions (except flour)	12
Barley, straw	9.0
Beet, garden, tops	3.0
Beet, garden, roots	4.0
Beet, sugar, molasses	10
Beet, sugar, roots	2.0
Beet, sugar, tops	3.0
Brassica, head and stem, subgroup 5A	2.0
Canola, meal	6.0
Canola, seed	3.0
Cattle, fat	1.0
Cattle, liver	3.0
Cattle, meat	1.0
Cattle, meat byproducts, except liver	36.0
Corn, field, forage	3.0
Corn, field, stover	10.0
Corn, field, grain	1.0
Corn, field, milled byproducts	1.5
Corn, pop, grain	1.0
Corn, pop, stover	10.0
Corn, sweet, forage	7.0
Corn, sweet, kernel plus cob with husks removed	1.0
Corn, sweet, stover	10.0
Crambe, seed	3.0
Cranberry	4.0
Egg	0.1
Flax, meal	6.0
Flax, seed	3.0
Fruit, stone, group 12	0.5
Goat, fat	1.0
Goat, liver	3.0
Goat, meat	1.0
Goat, meat byproducts, except liver	36.0
Grass, forage and hay	500.0
Hog, fat	0.2
Hog, meat	0.2

Commodity	Parts per million
Hog, meat byproducts	0.2
Hop, dried cones	5.0
Horse, fat	1.0
Horse, liver	3.0
Horse, meat	1.0
Horse, meat byproducts, except liver	36.0
Milk	0.2
Mint, hay	3.0
Mustard greens	5.0
Mustard, seed	3.0
Oat, forage	9.0
Oat, grain	3.0
Oat, groats/rolled oats	12
Oat, straw	9.0
Plum, prune, dried	1.5
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	0.2
Rapeseed, seed	3.0
Rapeseed, forage	3.0
Sheep, fat	1.0
Sheep, liver	3.0
Sheep, meat	1.0
Sheep, meat byproducts, except liver	36.0
Spinach	5.0
Strawberry	1.0
Turnip, greens	4.0
Turnip, roots	1.0
Wheat, forage	9.0
Wheat, grain	3.0
Wheat, milled fractions (except flour)	12
Wheat, straw	9.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[52 FR 10566, Apr. 2, 1987]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.431, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.432 Lactofen; tolerances for residues.

(a) Tolerances are established for residues of the herbicide lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Beans, snap, succulent, except lima bean	0.01
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.01
Peanut	0.01
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in 180.1(n) are established for residues of the herbicide, lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the following food commodities:

Commodity	Parts per million
Okra	0.02
Vegetables, fruiting, group 08	0.02

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 57216, Sept. 24, 2004, as amended at 72 FR 33906, June 20, 2007]

§ 180.433 Fomesafen; tolerances for residues.

(a) *General.* Tolerances are established for the residues of fomesafen 5-[2-chloro-4-(trifluoromethyl)phenoxy]-*N*-(methylsulfonyl)-2-nitrobenzamide from the application of its sodium salt in or on the following commodities:

Commodity	Parts per million
Bean, dry	0.05
Bean, snap, succulent	0.05
Cotton, gin byproducts	0.025
Cotton, undelinted seed	0.025
Soybean	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 25951, May 3, 2006, as amended at 72 FR 52020, Sept. 12, 2007]

§ 180.434 Propiconazole; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following commodities:

Commodity	Parts per million
Almond, hulls	7.0
Banana	0.2
Barley, bran	0.6

Commodity	Parts per million
Barley, grain	0.3
Barley, hay	1.4
Barley, straw	10
Beet, garden, roots	0.30
Beet, garden, tops	5.5
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	1.5
Beet, sugar, roots	0.3
Beet, sugar, tops	10
Berry group 13	1.0
Carrot, roots	0.25
Cattle, fat	0.05
Cattle, kidney	2.0
Cattle, liver	2.0
Cattle, meat	0.05
Cattle, meat byproducts, except liver and kidney	0.05
Cilantro, leaves	13
Corn, field, forage	12
Corn, field, grain	0.2
Corn, field, stover	30
Corn, pop, grain	0.2
Corn, pop, stover	30
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	30
Fruit, stone, group 12	1.0
Goat, fat	0.05
Goat, kidney	2.0
Goat, liver	2.0
Goat, meat	0.05
Goat, meat byproducts, except liver and kidney	0.05
Grain, aspirated fractions	30
Grass, forage	0.5
Grass, hay	0.5
Grass, straw	40
Hog, kidney	0.2
Hog, liver	0.2
Horse, fat	0.05
Horse, kidney	2.0
Horse, liver	2.0
Horse, meat	0.05
Horse, meat byproducts, except liver and kidney	0.05
Leaf petioles subgroup 4B	5.0
Milk	0.05
Mushroom	0.1
Nut, tree, group 14	0.1
Oat, forage	1.7
Oat, grain	0.3
Oat, hay	1.4
Oat, straw	10
Onion, bulb	0.2
Onion, green	9.0
Parsley, fresh leaves	13
Parsley, dried leaves	35
Peanut	0.2
Peanut, hay	20
Peppermint, tops	3.5
Pineapple	4.5
Pineapple, process residue	7.0
Pistachio	0.1
Rice, bran	15
Rice, grain	7.0
Rice, hulls	20
Rice, straw	18
Rye, bran	0.6
Rye, forage	1.7
Rye, grain	0.3
Rye, straw	10
Sheep, fat	0.05
Sheep, kidney	2.0
Sheep, liver	2.0
Sheep, meat	0.05
Sheep, meat byproducts, except liver and kidney	0.05
Sorghum, grain, forage	12
Sorghum, grain, grain	3.5
Sorghum, grain, stover	15
Soybean, forage	11
Soybean, hay	30
Soybean, seed	2.0
Spearmint, tops	3.5
Strawberry	1.3
Wheat, bran	0.6
Wheat, forage	1.7
Wheat, grain	0.3
Wheat, hay	1.4
Wheat, straw	10

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Nectarine	2.0	12/31/10
Peach	2.0	12/31/10

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in §180.1(m), is established for residues of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
Cranberry	1.0
Rice, wild, grain	0.5

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following commodities when present therein as a result of application of propiconazole

to growing crops in paragraphs (a) and (c) of this section:

Commodity	Parts per million
Alfalfa, forage	0.1
Alfalfa, hay	0.1

[71 FR 55306, Sept. 22, 2006, as amended at 72 FR 20439, Apr. 25, 2007; 74 FR 12613, Mar. 25, 2009]

§ 180.435 Deltamethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pesticide chemical deltamethrin [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (*S*)-*alpha*-cyano-3-phenoxybenzyl ester and its major metabolites, *trans* deltamethrin [(*S*)-*alpha*-cyano-*m*-phenoxybenzyl(1R,3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *alpha*-*R*-deltamethrin [(*R*)-*alpha*-cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on the following agricultural commodities:

Commodity	Parts per million
Almond, hulls	2.5
Apple, wet pomace	1.0
Artichoke, globe	0.5
Barley, bran	5.0
Cattle, fat	0.05
Cattle, meat	0.02
Cattle, meat byproducts	0.05
Corn, field, forage	0.7
Corn, field, refined oil	2.5
Corn, field, stover	5.0
Corn, pop, stover	5.0
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husks removed	0.03
Corn, sweet, stover	15
Cotton, refined oil	0.2
Cotton, undelinted seed	0.04
Egg	0.02
Fruit, pome, Group 11	0.2
Goat, fat	0.05
Goat, meat	0.02
Goat, meat byproducts	0.05
Grain, aspirated fractions	65
Grain, cereal, Group 15, except sweet corn	1.0
Hog, fat	0.05
Horse, fat	0.05
Horse, meat	0.02
Horse, meat byproducts	0.05
Lychee*	0.2
Milk, fat (reflecting 0.02 ppm in whole milk)	0.1
Nut, tree, Group 14	0.1
Onion, bulb	0.1
Onion, green	1.5
Poultry, fat	0.05
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Radish, tops	4.0
Rapeseed	0.2
Rice, hulls	2.5
Rye, bran	5.0
Sheep, fat	0.05
Sheep, meat	0.02
Sheep, meat byproducts	0.05
Sorghum, grain, forage	0.5
Sorghum, grain, stover	1.0
Soybean, seed	0.1
Soybean, hulls	0.2
Starfruit*	0.2
Sunflower, seed	0.1
Tomato	0.2
Tomato, concentrated products	1.0
Vegetable, cucurbit, Group 9	0.2
Vegetable, fruiting, Group 8	0.3
Vegetable, root, except sugar beet, Subgroup IB	0.2
Vegetable, tuberous and corm, Subgroup IC	0.04
Wheat, bran	5.0

*There are no U.S. registrations for use of deltamethrin on starfruit and lychee.

(2) A tolerance of 0.05 ppm is established for residues of the insecticide deltamethrin (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (*S*)-alpha-cyano-3-phenoxybenzyl ester and its major metabolites, trans deltamethrin (*S*)-alpha-cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and alpha-*R*-deltamethrin[(*R*)-alpha-cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] as follows:

(i) In or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments.

(ii) The insecticide may be present as a residue from application of deltamethrin in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries, feed handling establishments including feed manufacturing and processing establishments, in accordance with the following prescribed conditions:

(A) Application shall be limited to general surface and spot and/or crack

and crevice treatment in food/feed handling establishments where food/feed and food/feed products are held, processed, prepared and served. General surface application may be used only when the facility is not in operation provided exposed food/feed has been covered or removed from the area being treated. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed food/feed is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of food/feed or food/feed contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 63001, Nov. 26, 1997, as amended at 63 FR 45414, Aug. 26, 1998; 69 FR 62614, Oct. 27, 2004]

§ 180.436 Cyfluthrin and the isomer beta-cyfluthrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethyl-cyclopropane-carboxylate; CAS No. 68359–37–5) in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa	5.0
Alfalfa, forage	5.0
Alfalfa, hay	13
Almond, hulls	0.5
Barley, bran	0.5
Barley, grain	0.15
Beet, sugar, dried pulp	1.0
Beet, sugar, roots	0.10
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy greens, subgroup 5B	7.0
Buckwheat, grain	0.15
Carrot, roots	0.20
Cattle, fat	2.0
Cattle, meat	0.10
Cattle, meat byproducts	0.10
Citrus, dried pulp	0.3
Citrus, oil	0.3
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, hulls	2.0
Cotton, refined oil	2.0
Cotton, undelinted seed	1.0
Egg	0.01
Fruit, citrus, group 10	0.2
Fruit, pome, group 11	0.5
Fruit, stone, group 12	0.3
Goat, fat	2.0
Goat, meat	0.05
Goat, meat byproducts	0.05
Grain, aspirated fractions	150
Grain, cereal, forage, fodder and hay, group 16, forage, except rice	25
Grain, cereal, forage, fodder and hay, group 16, hay, except rice	6.0
Grain, cereal, forage, fodder and hay, group 16, stover, except rice	30
Grain, cereal, forage, fodder and hay, group 16, straw, except rice	7.0
Grape	1.0
Grape, raisin	3.5
Grass, forage, fodder and hay, group 17, forage	12
Grass, forage, fodder and hay, group 17, hay	50
Hog, fat	0.5
Hog, meat	0.01
Hog, meat byproducts	0.01
Hop, dried cones	20.0
Hop, vines	4.0
Horse, fat	2.0
Horse, meat	0.05
Horse, meat byproducts	0.05
Lettuce, head	2.0
Lettuce, leaf	3.0
Milk	0.2
Milk, fat	5.0
Millet, grain	0.15
Mustard greens	7.0
Nut, tree, group 14	0.01
Oat, bran	0.5
Oat, grain	0.15
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Pea, dry, seed	0.15
Pea, southern, succulent	0.25
Peanut	0.01
Peanut, hay	6.0
Pepper	0.50
Pistachio	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Radish, roots	1.0
Rye, bran	0.5
Rye, grain	0.15
Sheep, fat	2.0
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain	3.5
Soybean, forage	8.0
Soybean, hay	4.0
Soybean, seed	0.03
Sugarcane, cane	0.05
Sugarcane, molasses	0.20
Sunflower, forage	5.0
Sunflower, seed	0.02
Teosinte, grain	0.05
Tomato	0.20

Commodity	Parts per million
Tomato, paste	0.5
Tomato, pomace	5.0
Triticale, grain	0.15
Turnip, greens	7.0
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8	0.5
Vegetable, leafy, except brassica, group 4	6.0
Vegetable, tuberous and corm, subgroup 1C	0.01
Wheat, bran	0.5
Wheat, grain	0.15
Wheat, shorts	0.5

(2) A tolerance of 0.05 ppm is established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 69359–37–5) in food commodities exposed to the insecticide during treatment of food-handling establishments where food and food products are held, processed, prepared, or served. Treatments may be made by general surface, spot, and/or crack and crevice applications.

(i) General surface treatments shall be limited to a maximum of 3.8 grams of active ingredient per 1,000 square feet, applying to walls, floors, and ceilings with a low-pressure system. Cover or remove all food processing and/or handling equipment during application. Do not apply directly to food products. Reapplications may be made at 10-day intervals.

(ii) Crack and crevice or spot treatments shall be limited to a maximum of 0.1 percent of the active ingredient weight, applied with a low-pressure system with a pinpoint or variable-pattern nozzle. Dust formulation shall be limited to a maximum of 0.1 percent of the active ingredient by weight, applied using a hand duster, power duster, or other equipment capable of applying dust insecticide directly into voids and cracks and crevices. Dust applications should be made in a manner to avoid deposits on exposed surfaces or introducing the material into the air. Cover exposed food or remove food from premises. Do not apply directly to food. Reapplications may be made at 10-day intervals.

(iii) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(3) A tolerance of 0.05 part per million is established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 68359–37–5) in feed commodities exposed to the insecticide during treatment of feed-handling establishments where feed and feed products are held, processed, prepared, or served. Treatments may be made by general surface, spot, and/or crack and crevice applications.

(i) General surface tratments shall be limited to a maximum of 3.8 grams of active ingredient per 1,000 square feet, applying to walls, floors, and ceilings with a low-pressure system. Cover or remove all feed processing and/or handling equipment during application. Do not apply directly to feed products. Reapplications may be made at 10-day intervals.

(ii) Crack and crevice or spot treatments shall be limited to a maximum of 0.1 percent of the active ingredient by weight, applied with a low-pressure system with a pinpoint or variable-pattern nozzle. Dust formulation shall be limited to a maximum of 0.1 percent of the active ingredient by weight, applied using a hand duster, power duster, or other equipment capable of applying dust insecticide directly into voids and cracks and crevices. Dust applications should be made in a manner to avoid deposits on exposed surfaces or introducing the material into the air. Cover exposed feed or remove feed from premises. Do not apply directly to feed. Reapplications may be made at 10-day intervals.

(iii) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by EPA, and it shall be used in accordance with such label and labeling.

(4) Tolerances are established for residues of the isomer, beta-cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate [mixture comprising the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-

dimethylcyclopropanecarboxylate and (S)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate with the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate], in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa	5.0
Alfalfa, forage	5.0
Alfalfa, hay	13
Almond, hulls	0.5
Barley, bran	0.5
Barley, grain	0.15
Beet, sugar, dried pulp	1.0
Beet, sugar, roots	0.10
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy greens, subgroup 5B	7.0
Buckwheat, grain	0.15
Carrot, roots	0.20
Cattle, fat	2.0
Cattle, meat	0.10
Cattle, meat byproducts	0.10
Citrus, dried pulp	0.3
Citrus, oil	0.3
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, hulls	2.0
Cotton, refined oil	2.0
Cotton, undelinted seed	1.0
Egg	0.01
Fruit, citrus, group 10	0.2
Fruit, pome, group 11	0.5
Fruit, stone, group 12	0.3
Goat, fat	2.0
Goat, meat	0.05
Goat, meat byproducts	0.05
Grain, aspirated fractions	150
Grain, cereal, forage, fodder and hay, group 16, forage, except rice	25
Grain, cereal, forage, fodder and hay, group 16, hay, except rice	6.0
Grain, cereal, forage, fodder and hay, group 16, stover, except rice	30
Grain, cereal, forage, fodder and hay, group 16, straw, except rice	7.0
Grape	1.0
Grape, raisin	3.5
Grass, forage, fodder and hay, group 17, forage	12
Grass, forage, fodder and hay, group 17, hay	50
Hog, fat	0.5
Hog, meat	0.01
Hog, meat byproducts	0.01
Hop, dried cones	20.0
Hop, vines	4.0
Horse, fat	2.0
Horse, meat	0.05
Horse, meat byproducts	0.05
Lettuce, head	2.0
Lettuce, leaf	3.0
Milk	0.2
Milk, fat	5.0
Millet, grain	0.15
Mustard greens	7.0
Nut, tree, group 14	0.01
Oat, bran	0.5
Oat, grain	0.15
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Pea, dry, seed	0.15
Pea, southern, succulent	0.25
Peanut	0.01
Peanut, hay	6.0
Pepper	0.50
Pistachio	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Radish, roots	1.0
Rye, bran	0.5
Rye, grain	0.15
Sheep, fat	2.0
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain	3.5
Soybean, forage	8.0
Soybean, hay	4.0
Soybean, seed	0.03
Sugarcane, cane	0.05
Sugarcane, molasses	0.20
Sunflower, forage	5.0
Sunflower, seed	0.02
Teosinte, grain	0.05
Tomato	0.20
Tomato, paste	0.5
Tomato, pomace	5.0
Triticale, grain	0.15
Turnip, greens	7.0
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8	0.5
Vegetable, leafy greens, except Brassica, group 4	6.0
Vegetable, tuberous and corm, subgroup 1C	0.01
Wheat, bran	0.5
Wheat, grain	0.15
Wheat, shorts	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[53 FR 1924, Jan. 25, 1988]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.436, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.437 Methyl 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*p*-toluate and methyl 6-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*m*-toluate; tolerances for residues.

Tolerances are established for the combined residues of the herbicide methyl 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*p*-toluate and methyl

6-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-*m*-toluate in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.10
Barley, straw	2.00
Sunflower, seed	0.10
Wheat, grain	0.10
Wheat, straw	2.00

[53 FR 24069, June 27, 1988]

§ 180.438 Lambda-cyhalothrin and an isomer gamma-cyhalothrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, on plants and livestocks, as indicated in the following table.

Commodity	Parts per million
Alfalfa, forage	5.0
Alfalfa, hay	6.0
Almond, hulls	1.5
Apple, wet pomace	2.50
Avocado, imported	0.20
Barley, bran	0.2
Barley, grain	0.05
Barley, hay	2.0
Barley, straw	2.0
Brassica, head and stem, subgroup 5A	0.4
Buckwheat, grain	0.05
Canola, refined oil	2.0
Canola, seed	1.0
Cattle, fat	3.0
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Corn, field, flour	0.15
Corn, field, forage	6.0
Corn, field, grain	0.05
Corn, field, stover	1.0
Corn, pop, grain	0.05
Corn, pop, grain, flour	0.05
Corn, pop, stover	1.0
Corn, sweet, forage	6.0
Corn, sweet, stover	1.0
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, undelinted seed	0.05
Egg	0.01
Fruit, pome, group 11	0.30
Fruit, stone, group 12	0.50
Garlic	0.1
Goat, fat	3.0
Goat, meat	0.2
Goat, meat byproducts	0.2
Grain, aspirated fractions	2.0
Grass, forage, fodder and hay, group 17	7.0
Hog, fat	0.2
Hog, meat	0.01
Hog, meat byproducts	0.02
Hop, dried cones	10.0
Horse, fat	3.0
Horse, meat	0.2
Horse, meat byproducts	0.2
Lettuce, head	2.0
Lettuce, leaf	2.0
Milk, fat (reflecting 0.4 ppm in whole milk)	10.0
Nut, tree, group 14	0.05
Oat, grain	0.05
Oat, forage	2.0
Oat, hay	2.0
Oat, straw	2.0
Onion, bulb	0.1
Pea and bean, dried shelled, except soybean, subgroup 6C	0.10
Pea and bean, succulent shelled, subgroup 6B	0.01
Peanut	0.05
Peanut, hay	3.0
Pistachio	0.05
Poultry, fat	0.03
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rice, grain	1.0
Rice, hulls	5.0
Rice, straw	1.8
Rice, wild, grain	1.0
Rye, bran	0.2
Rye, grain	0.05
Rye, forage	2.0
Rye, straw	2.0
Sheep, fat	3.0
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Soybean	0.01
Sorghum, grain, grain	0.2
Sorghum, grain, forage	0.30
Sorghum, grain, stover	0.50
Sugarcane, cane	0.05
Sunflower, forage	0.2
Sunflower, seed, hulls	0.50
Sunflower, refined oil	0.30
Sunflower, seed	0.2
Tomato	0.1
Tomato, dry pomace	6.0
Tomato, wet pomace	6.0
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.20
Vegetable, legume, edible podded, subgroup 6A	0.20
Vegetable, tuberous and corm, subgroup 1C	0.02
Wheat, grain	0.05
Wheat, forage	2.0
Wheat, hay	2.0
Wheat, straw	2.0
Wheat, bran	0.2

(2) Tolerances[1] are established for the combined residues of the pyrethroid [gamma-cyhalothrin (the isolated active isomer of lambda-cyhalothrin) (*S*)-′-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate)) and its epimer (*R*)-′-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in/on the following commodities:

Commodity	Parts per million
Alfalfa, forage	5
Alfalfa, hay	6
Almond, hulls	1.5
Apple, pomace, wet	2.50
Avocado, imported	0.20
Brassica, head and stem, subgroup 5A	0.4
Canola, seed	0.15
Cattle, fat	3
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Corn, field, flour	0.15
Corn, field, forage	6.0
Corn, field, grain	0.05
Corn, field, stover	1.0
Corn, pop, grain	0.05
Corn, pop, stover	1.0
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	1.0
Cotton, undelinted seed	0.05
Egg	0.01
Fruit, pome, group 11	0.30
Fruit, stone, group 12	0.50
Garlic	0.10
Goat, fat	3.0
Goat, meat	0.2
Goat, meat byproducts	0.2
Grain, aspirated fractions	2.0
Hog, fat	3.0
Hog, meat	0.2
Hog, meat byproducts	0.2
Horse, fat	3.0
Horse, meat	0.2
Horse, meat byproducts	0.2
Lettuce, head	2.0
Lettuce, leaf	2.0
Milk, fat (reflecting 0.20 ppm in whole milk)	5.0
Nut, tree, group 14	0.05
Okra	0.20
Onion, bulb	0.1
Pea and bean, dried shelled, except soybean, subgroup 6C	0.10
Pea and bean, succulent shelled, subgroup 6B	0.01
Peanut	0.05
Peanut, hay	3.0
Pistachio	0.05
Poultry, fat	0.03
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rice, grain	1.0
Rice, hulls	5.0
Rice, straw	1.8
Sheep, fat	3.0
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Sorghum, grain, forage	0.30
Sorghum, grain, grain	0.20
Sorghum, grain, stover	0.50
Soybean	0.01
Sugarcane	0.05
Sunflower, forage	0.20
Sunflower, refined oil	0.30
Sunflower, seed	0.20
Sunflower, seed, hulls	0.50
Tomato	0.10
Tomato, dry pomace	6.0
Tomato, wet pomace	6.0
Vegetables, fruiting, group 8	0.20
Vegetable, legume, edible podded, subgroup 6A	0.20
Wheat, bran	2.0
Wheat, forage	2.0
Wheat, grain	0.05
Wheat, hay	2.0
Wheat, straw	2.0

[1] The analytical enforcement methods for lambda-cyhalothrin are applicable for determination of gamma-cyhalothrin residues in plant and animal commodities.

(3) A tolerance of 0.01 part per million is established for residues of the insecticide lamba-cyhalothrin and an isomer gamma-cyhalothrin in or on all food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed, or prepared.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the insecticide lambda-cyhalothrin (a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl -(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Barley, bran	0.2	12/31/08

Commodity	Parts per million	Expiration/ revocation date
Barley, grain	0.05	12/31/08
Barley, hay	2.0	12/31/08
Barley, straw	2.0	12/31/08
Clover, forage	5.0	12/31/08
Clover, hay	6.0	12/31/08
Grass, forage	5.0	12/31/08
Grass, hay	6.0	12/31/08
Rice, wild, grain	1.0	12/31/08

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74817, Dec. 13, 2006, as amended at 72 FR 45663, Aug. 15, 2007; 73 FR 39264, July 9, 2008]

§ 180.439 Thifensulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide thifensulfuron methyl (methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino] carbonyl] amino] sulfonyl]-2-thiophene carboxylate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.8
Barley, straw	0.10
Canola, seed	0.02
Corn, field, forage	0.10
Corn, field, grain	0.05
Corn, field, stover	0.10
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Flax, seed	0.02
Oat, forage	0.2
Oat, grain	0.05
Oat, hay	0.05
Oat, straw	0.10
Rice, grain	0.05
Rice, straw	0.05
Sorghum, grain, forage.	0.05
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.05
Soybean	0.10
Wheat, forage	2.5
Wheat, grain	0.05
Wheat, hay	0.7
Wheat, straw	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 55982, Sept. 17, 2004, as amended at 69 FR 63957, Nov. 3, 2004; 72 FR 13184, Mar. 21, 2007; 73 FR 47075, Aug. 13, 2008]

§ 180.440 Tefluthrin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide tefluthrin (2,3,5,6 tetrafluroro-4-methylphenyl)methyl-(1 alpha, 3 alpha)-(*Z*)-(±)-3(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-diemthylcyclopropanecarboxylate) and its metabolite (*Z*)-3-(2-chloro-3,3,3-trifluroro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid in or on the following commodities:

Commodity	Parts per million
Corn, field, fodder and forage, pop and sweet	0.06
Corn, field, grain and pop	0.06
Corn, sweet, kernel plus cob with husks removed	0.06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 62961, Nov. 26, 1997]

§ 180.441 Quizalofop ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide quizalofop (2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate), all expressed as quizalofop ethyl, in or on the following agricultural commodities:

Commodity	Parts per million
Bean, dry	0.4
Bean, succulent	0.25
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Cowpea, forage	3.0
Cowpea, hay	3.0
Pea, dry	0.25
Pea, field, hay	3.0
Pea, field, vines	3.0≤
Pea, succulent	0.3
Soybean, flour	0.5
Soybean, hulls	0.02
Soybean, meal	0.5
Soybean, soapstock	1.0
Soybean	0.05

(2) Tolerances are established for the combined residues of the herbicide quizalofop (2-[4-(6-chloroquinoxalin-2-yl

oxy)phenoxy]propanoic acid), quizalop-ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate), and quizalofop-methyl (methyl 2-[4-(6-chloroquinoxalin-2-yl-oxy)phenoxy]propanoate, all expressed as quizalofop ethyl, as follows:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.02
Cattle, meat byproducts	0.05
Egg	0.02
Goat, fat	0.05
Goat, meat	0.02
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.02
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.02
Horse, meat byproducts	0.05
Milk	0.01
Milk, fat	0.25
Poultry, fat	0.05
Poultry, meat	0.02
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.02
Sheep, meat byproducts	0.05

(3) Tolerances are established for the combined residues of the herbicide quizalofop-p ethyl ester [ethyl (*R*)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate], and its acid metabolite quizalofop-p [*R*-(2-(4-((6-quinoxalin-2-yl)oxy)phenoxy)propanoic acid], and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester, in or on the following raw agricultural commodities;

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Beet, sugar, molasses	0.2
Canola, meal	1.5
Canola, seed	1.0
Cotton, undelinted seed	0.1
Flax, seed	0.05
Lentil, seed	0.05
Peppermint, tops	2.0
Spearmint, tops	2.0
Sunflower, seed	1.9
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(4) Time limited tolerances to expire on June 14, 1999 are established for the combined residues of the herbicide quizalofop-p ethyl ester (ethyl (*R*)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and it acid metabolite quizalofop-p [*R*-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid), and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester in or on the following raw agricultural commodities:

Commodities	Parts per million
Beet, sugar, molasses	0.2
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Vegetable, foliage of legume, except soybean, subgroup 7A	3.0
Vegetable, legume, group 6	0.25

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the herbicide quizalofop-*p* ethyl ester [ethyl (*R*)-2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate], its acid metabolite quizalofop-*p* [*R*-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy]) propanoic acid], and the *S* enantiomers of both the ester and the acid, all expressed as quizalofop-*p* ethyl ester, in or the raw agricultural commodities, as follows:

Commodity	Parts per million
Pineapple	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 32759, June 16, 1998, as amended at 70 FR 7870, Feb. 16, 2005; 71 FR 56378, Sept. 27, 2006]

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	2.0
Artichoke, globe	1.0
Banana[1]	0.1
Beet, garden, roots	0.45

Commodity	Parts per million
Beet, garden, tops	15
Brassica, head and stem, subgroup 5A, except cabbage	0.6
Brassica, leafy greens, subgroup 5B	3.5
Bushberry subgroup 13-07B	1.8
Cabbage	4.0
Caneberry subgroup 13A	1.0
Cattle, fat	1.0
Cattle, meat byproducts	0.10
Cattle, meat	0.5
Coriander, dried leaves	25
Coriander, leaves	6.0
Coriander, seed	5.0
Corn, forage	3.0
Corn, grain (field, seed, and pop)	0.05
Corn, stover	5.0
Corn, sweet, kernel plus cob with husk removed	0.05
Cotton, undelinted seed	0.5
Eggplant	0.05
Egg	0.05
Fruit, citrus, group 10	0.05
Goat, fat	1.0
Goat, meat byproducts	0.10
Goat, meat	0.5
Grain, aspirated fractions	70
Grape	0.2
Groundcherry	0.5
Herb subgroup 19A	0.05
Hog, fat	1.0
Hog, meat byproducts	0.10
Hog, meat	0.5
Hop, dried cones	10.0
Horse, fat	1.0
Horse, meat byproducts	0.10
Horse, meat	0.5
Leafy petioles subgroup 4B	3.0
Lettuce, head	3.0
Mayhaw	1.4
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0
Nut, tree, group 14	0.05
Okra	0.50
Pea and bean, dried shelled, expect soybean, subgroup 6C	0.15
Pea and bean, succulent shelled, subgroup 6B	0.05
Peanut	0.05
Pear	0.5
Pepino	0.5
Pepper, bell	0.5
Pepper, nonbell	0.5
Pistachio	0.05
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Radish, tops	4.5
Rapeseed, seed	0.05
Sheep, fat	1.0
Sheep, meat byproducts	0.1
Sheep, meat	0.5
Soybean, hulls	0.50
Soybean, refined oil	0.30
Soybean, seed	0.2
Spinach	0.2
Strawberry	3.0
Tomato	0.15
Turnip, greens	3.5
Vegetable, cucurbit, group 9	0.4
Vegetable, legume, edible podded, subgroup 6A	0.6
Vegetable, root, subgroup 1B except sugar beet and garden beet	0.10
Vegetable, tuberous and corm, subgroup 1C	0.05

[1] There are no U.S. registrations as of April 30, 2003.

(2) A tolerance of 0.05 ppm is established for residues of the insecticide bifenthrin, (2-methyl[1,1′-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate, as follows:

(i) In or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments.

(ii) The insecticide may be present as a residue from application of bifenthrin in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries, feed handling establishments including feed manufacturing and processing establishments, in accordance with the following prescribed conditions:

(A) Application shall be limited to general surface and spot and/or crack and crevice treatment in food/feed handling establishments where food/feed and food/feed products are held, processed, prepared and served. General surface application may be used only when the facility is not in operation provided exposed food/feed has been covered or removed from the area being treated. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed food/feed is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of food/feed or food/feed contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residues of the insecticide bifenthrin ((2-methyl [1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in connection with use of the pesticide

under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Orchardgrass, forage	2.5	12/31/09
Orchardgrass, hay	4.5	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 31002, June 6, 1997]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.442, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.443 Myclobutanil; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and its alcohol metabolite (alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on the following food commodities:

Commodity	Parts per million
Almond	0.1
Almond, hulls	2.0
Apple	0.5
Apple, dry pomace	5.0
Apple, wet pomace	5.0
Artichoke, globe	0.90
Asparagus	0.02
Banana, postharvest	4.0
Bean, snap, succulent	1.0
Caneberry subgroup 13A	2.0
Canistel	3.0
Cattle, fat	0.05
Cattle, liver	1.0
Cattle, meat	0.1
Cattle, meat byproducts, except liver	0.2
Cherry, sweet	5.0
Cherry, tart	5.0
Cilantro, leaves	9.0
Cotton, undelinted seed	0.02
Currant	3.0
Egg	0.02
Fruit, stone, except cherry	2.0
Goat, fat	0.05
Goat, liver	1.0
Goat, meat	0.1
Goat, meat byproducts, except liver	0.2
Gooseberry	2.0
Grain, aspirated fractions	35
Grape pomace (wet and dry)	10.0
Grape	1.0
Grape, raisin	10.0
Grape, raisin, waste	25.0
Hog, fat	0.05
Hog, liver	1.0
Hog, meat	0.1
Hog, meat byproducts, except liver	0.2
Hop, dried cones	10
Horse, fat	0.05
Horse, liver	1.0
Horse, meat	0.1
Horse, meat byproducts, except liver	0.2
Leafy greens, subgroup 4A, except spinach	9.0
Mango	3.0
Mayhaw	0.70
Milk	0.2
Okra	4.0
Papaya	3.0
Peppermint, tops	3.0
Plum, prune, dried	8.0
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Sapodilla	3.0
Sapote, black	3.0
Sapote, mamey	3.0
Sheep, fat	0.05
Sheep, liver	1.0
Sheep, meat	0.1
Sheep, meat byproducts, except liver	0.2
Soybean, forage	3.5
Soybean, hay	15
Soybean, refined oil	0.40
Soybean, seed	0.25
Spearmint, tops	3.0
Star apple	3.0
Strawberry	0.50
Tomato	0.30
Tomato, puree	0.50
Tomato, paste	1.0
Vegetable, cucurbit, group 9	0.20
Vegetable, fruiting, group 8, except tomato	4.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide myclobutanil in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Vegetable, foliage of legume, group 07	1.0	12/31/09
Vegetable, legume, group 06	1.0	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile in or on the following food commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18	0.03
Grain, cereal, forage, fodder and straw, group 16	0.03
Grain, cereal, group 15	0.03
Vegetable, brassica, leafy, group 5	0.03
Vegetable, foliage of legume, group 7	0.03
Vegetable, fruiting, group 8	0.03
Vegetable, leafy, except brassica, group 4	0.03
Vegetable, leaves of root and tuber, group 2	0.03
Vegetable, legume, group 6	0.03
Vegetable, root and tuber, group 1	0.03

[54 FR 6131, Feb. 8, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.443, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.444 Sulfur dioxide; tolerances for residues.

A tolerance is established as follows for sulfite residues of the fungicide sulfur dioxide (determined as (SO_2)) in or on the following raw agricultural commodity(ies):

Commodity	Parts per million
Grape, postharvest	10.0

[54 FR 20126, May 10, 1989]

§ 180.445 Bensulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide bensulfuron methyl (methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Crayfish	0.05
Rice, grain	0.02
Rice, straw	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 9435, Feb. 25, 1998]

§ 180.446 Clofentezine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide clofentezine (3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine) in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	5.0
Almond	0.5
Apple, pomace	3.0
Apple	0.5
Apricot	1.0
Cherry	1.0
Grape	1.0
Nectarine	1.0
Peach	1.0
Pear	0.5
Persimmon	0.05
Walnut	0.02

(2) Tolerances are established for the combined residues of clofentezine and the 3-(2-chloro-4-hydroxyphenyl)-6-(2-chlorophenyl)-1,2,4,5-tetrazine metabolite in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, liver	0.4
Cattle, meat	0.05
Cattle, meat byproducts, except liver	0.05
Goat, fat	0.05
Goat, liver	0.4
Goat, meat	0.05
Goat, meat byproducts, except liver	0.05
Hog, fat	0.05
Hog, liver	0.4
Hog, meat	0.05
Hog, meat byproducts, except liver	0.05
Horse, fat	0.05
Horse, liver	0.4
Horse, meat	0.05
Horse, meat byproducts, except liver	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, liver	0.4
Sheep, meat	0.05
Sheep, meat byproducts, except liver	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[56 FR 15503, Apr. 17, 1991, as amended at 56 FR 22335, May 15, 1991; 59 FR 26947, May 25, 1994; 60 FR 12709, Mar. 8, 1995; 64 FR 19050, Apr. 19, 1999; 70 FR 11572, Mar. 9, 2005]

§ 180.447 Imazethapyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, applied as its acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Canola, seed [1]	0.10
Soybean	0.1
Vegetable, legume, group 6	0.1

1 There are no U.S. registrations for canola as of March 21, 2003.

(2) Tolerances are established for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid; its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid; and its metabolite CL 182704, 5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Alfalfa, seed	0.15
Alfalfa, seed screenings	0.15
Animal feed, nongrass, group 18, forage	3.0
Animal feed, nongrass, group 18, hay	5.5
Peanut	0.1
Rice, bran	1.2
Rice, grain	0.3
Rice, straw	0.4

(3) A tolerance is established for the sum of residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, and its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxy-ethyl)-3-pyridine carboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.10
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Crayfish	0.15
Goat, meat byproducts	0.10
Hog, meat byproducts	0.10
Horse, meat byproducts	0.10
Sheep, meat byproducts	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) of this chapter, are established for the sum of residues of the herbicide imazethapyr, 2- [4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl- 3-pyridine carboxylic acid, as its ammonium salt, and its metabolite, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1- hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, applied as its acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive	0.1
Lettuce, head	0.1
Lettuce, leaf	0.1

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 55331, Aug. 29, 2002, as amended at 68 FR 13849, Mar. 21, 2003; 71 FR 6359, Feb. 8, 2006]

§ 180.448 Hexythiazox; tolerance for residues.

(a) *General.* Tolerances are established for the combined residues of the miticide hexythiazox, trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million of the parent compound) in or on the following commodities:

Commodity	Parts per million
Almond, hulls	10
Apple, wet pomace	0.40
Caneberry subgroup 13A	1.0
Cattle, fat	0.02
Cattle, meat byproducts	0.02
Citrus, dried pulp	0.60
Citrus, oil	24

Commodity	Parts per million
Date, dried fruit	1.0
Fruit, pome, group 11	0.25
Fruit, stone, group 12, except plum	1.0
Goat, fat	0.02
Goat, meat byproducts	0.02
Grape	0.75
Hog, fat	0.02
Hog, meat byproducts	0.02
Hop, dried cones	2.0
Horse, fat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Nut, tree, group 14	0.30
Peppermint, tops	2.0
Pistachio	0.30
Plum	0.10
Plum, prune, dried	0.40
Plum, prune, fresh	0.10
Sheep, fat	0.02
Sheep, meat byproducts	0.02
Spearmint, tops	2.0
Strawberry	3.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Corn, field, forage	2.0	12/31/10
Corn, field, grain	0.05	12/31/10
Corn, field, stover	2.0	12/31/10

(c) *Tolerances with regional registrations.* Tolerances with regional registrations as defined 40 CFR 180.1(n), are established for the combined residues of the ovicide/miticide hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent) in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	6.0
Corn, field, grain	0.02
Corn, field, stover	2.5
Cotton, gin byproducts, CA only	3.0
Cotton, undelinted seed, CA only	0.20
Fruit, citrus group 10 (CA, AZ, TX only)	0.35

(d) *Indirect or inadvertent residues.* [Reserved]

[54 FR 17948, Apr. 26, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.448, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide avermectin B_1 (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)) and its delta-8,9-isomer in or on the following commodities:

Commodity	Parts per million
Almond	0.005
Almond, hulls	0.10
Apple	0.020
Apple, wet pomace	0.10
Avocado	0.020
Cattle, fat	0.015
Cattle, meat byproducts	0.02
Cattle, meat	0.02
Celeriac, roots	0.05
Celeriac, tops	0.05
Citrus, dried pulp	0.10
Citrus, oil	0.10
Citrus	0.02
Cotton, gin byproducts	0.15
Cotton, undelinted seed	0.005
Food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts)	0.01
Goat, meat	0.02
Goat, meat byproducts	0.02
Grape	0.02
Herb subgroup 19A, except chive	0.030
Hog, meat	0.02
Hog, meat byproducts	0.02
Hop, dried cones	0.20
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.005
Mint	0.010
Pear	0.02
Plum	0.010
Plum, prune, dried	0.025
Potato	0.005
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Sheep, meat	0.02

Commodity	Parts per million
Sheep, meat byproducts	0.02
Strawberry	0.02
Vegetable, cucurbit, group 9	0.005
Vegetable, fruiting, group 8	0.020
Vegetable, leafy, except brassica, group 4	0.10
Walnut	0.005

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of avermectin B_1 and it delta-8,9-isomer, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances will expire on the dates specified in the table.

Commodity	Parts per million	Expiration/revocation date
Bean, lima, seed	0.005	12/31/10
Onion, bulb	0.005	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 44095, Aug. 19, 1997]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.449, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.450 Beta-(4-Chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol (triadimenol) and its butanediol metabolite, 4-(4-chlorophenoxy)-2,2-dimethyl-4-(1*H*-1,2,4-triazol-l-yl)-1,3-butanediol, calculated as triadimenol, in or on the following commodities:

Commodity	Parts per million
Banana [1]	0.2
Barley, grain	0.05
Barley, straw	0.2
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Corn, pop, grain	0.05
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.05
Cotton, undelinted seed	0.02
Oat, forage	2.5
Oat, grain	0.05
Oat, straw	0.2
Rye, forage	2.5
Rye, grain	0.05
Rye, straw	0.1
Sorghum, forage	0.05
Sorghum, grain, grain	0.01
Sorghum, grain, stover	0.01
Wheat, forage	2.5
Wheat, grain	0.05
Wheat, straw	0.2

[1] There are no U.S. registrations for banana (whole) as of September 22, 1993.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54962, Sept. 24, 2008]

§ 180.451 Tribenuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.4
Barley, straw	0.10
Canola, seed	0.02
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Flax, seed	0.02
Oat, forage	0.05
Oat, grain	0.05
Oat, hay	0.05
Oat, straw	0.10
Rice, grain	0.05
Rice, straw	0.05
Sorghum, grain, forage	0.05
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.05
Soybean, seed	0.05
Sunflower, seed	0.05
Wheat, forage	0.3
Wheat, grain	0.05
Wheat, hay	0.5
Wheat, straw	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage, fodder and hay, group 17, except bermudagrass; forage	0.10
Grass, forage, fodder and hay, group 17, except bermudagrass; hay	0.10

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 56718, Sept. 22, 2004, as amended at 72 FR 11789, Mar. 14, 2007; 73 FR 47065, Aug. 13, 2008]

§ 180.452 Primisulfuron-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of primisulfuron-methyl (3-[4,6-bis-(difluoromethoxy)-pyrimidin-2-yl]-1-(2-methoxycarbonylphenylsulfonyl) urea) in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.10
Corn, forage	0.10
Corn, grain	0.02
Corn, stover	0.10
Corn, sweet, kernel plus cob with husks removed	0.10
Egg	0.10
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.10
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.10
Horse, fat	0.10
Horse, meat	0.10
Horse, meat byproducts	0.10
Milk	0.02
Poultry, fat	0.10
Poultry, meat	0.10
Poultry, meat byproducts	0.10
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[55 FR 21548, May 25, 1990, as amended at 62 FR 66020, Dec. 17, 1997; 63 FR 66458, Dec. 2, 1998; 67 FR 35049, May 17, 2002]

§ 180.454 Nicosulfuron, [3-pyridinecarboxamide, 2-((((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl))-N,N-dimethyl]; tolerances for residues.

Tolerances are established for the residues of the herbicide nicosulfuron [3-pyridinecarboxamide, 2-((((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl))-N,N-dimethyl] in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.1
Corn, forage	0.1
Corn, grain	0.1
Corn, stover	0.1
Corn, sweet, forage	0.1
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	0.1

[55 FR 28621, July 12, 1990, as amended at 61 FR 7734, Feb. 29, 1996]

§ 180.455 Procymidone; tolerances for residues.

A tolerance is established for the residues of the fungicide procymidone, *N*-(3,5-dichlorophenyl)-1,2-dimethylcyclopropane-1,2 dicarboximide, in or on the following raw agricultural commodity:

Commodity	Parts per million
Grape, wine	5.0

[59 FR 42514, Aug. 18, 1994]

§ 180.456 Oxadixyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide oxadixyl [2-methoxy-N-(2-oxo-1,3-oxazolidin-3-yl)-acet-2′,6′-xylidide] and its desmethyl (M-3) metabolite (2-hydroxy-N-(2-oxo-1,3-oxazolidin-3-yl)-acet-2′,6′-xylidide), calculated as oxadixyl in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Animal feed, nongrass, group, 18	0.1	9/27/03
Cotton, undelinted seed	0.1	9/27/03
Grain, cereal, group 15, except wheat	0.1	9/27/03
Grass, forage, fodder and hay, group 17	0.1	9/27/03
Pea	0.1	9/27/03
Soybean	0.1	9/27/03
Sunflower, seed	0.1	9/27/03
Vegetable, brassica, leafy, group 5	0.1	9/27/03
Vegetable, cucurbit, group 9	0.1	9/27/03
Vegetable, fruiting, group 8	0.1	9/27/03
Vegetable, leafy, except brassica, group 4	0.1	9/27/03
Vegetable, root and tuber, group 1	0.1	9/27/03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 45642, July 10, 2002]

§ 180.457 Beta-([1,1′-biphenyl]-4-yloxy)-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol; tolerances for residues.

A tolerance is established for the residues of the fungicide beta-([1,1′-biphenyl]-4-yloxy)-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol in or on the following raw agricultural commodity:

Commodity	Parts per million
Banana	0.2

There are no U.S. registrations as of April 1, 1992.

[57 FR 29032, June 30, 1992]

§ 180.458 Clethodim; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Cotton, undelinted seed	1.0
Egg	0.2
Goat, fat	0.2
Goat, meat	0.2
Goat, meat byproducts	0.2
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	0.2
Horse, fat	0.2
Horse, meat	0.2
Horse, meat byproducts	0.2
Milk	0.05
Potato	0.5
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	0.2
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Soybean	10.0

(2) Time limited tolerances are established for the combined residues of clethodim, ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Tomato, paste	3	4/30/03
Tomato, puree	2	4/30/03

(3) Tolerances are established for the combined residues of the herbicide clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim tolerance residues for the following commodities.

Commodity	Parts per million
Alfalfa, forage	6.0
Alfalfa, hay	10
Asparagus	1.7
Bean, dry, seed	2.5
Beet, sugar, molasses	1.0
Beet, sugar, roots	0.20
Beet, sugar, tops	1.0

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	3.0
Canola, meal	1.0
Canola, seed	0.50
Corn, field, forage	0.2
Corn, field, grain	0.2
Corn, field, stover	0.2
Cranberry	0.50
Clover, forage	10.0
Clover, hay	20.0
Flax, meal	1.0
Flax, seed	0.50
Flax seed	0.6
Herb subgroup 19A	12.0
Hop, dried cones	0.5
Leaf petioles subgroup 4B	0.60
Leafy greens subgroup 4A	2.0
Lettuce, leaf	2.0
Melon subgroup 9A	2.0
Mustard, seed	0.50
Onion, bulb	0.20
Onion, green	2.0
Peanut	3.0
Peanut, hay	3.0
Peanut, meal	5.0
Peppermint, tops	5.0
Potato, granules/flakes	2.0
Radish, tops	0.70
Safflower, meal	10.0
Safflower, seed	5.0
Sesame, seed	0.35
Spearmint, tops	5.0
Spinach	2.0
Squash/cucumber subgroup 9B	0.50
Strawberry	3.0
Sunflower, meal	10.0
Sunflower, seed	5.0
Turnip, greens	3.0
Vegetable, fruiting, group 8	1.0
Vegetable, legume group 6, except soybean	3.5
Vegetable, root, except sugar beet, subgroup 1B	1.0
Vegetable, tuberous and corm, subgroup 1C	1.0

(4) Tolerances are established for residues of the herbicide clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the following feeds.

Feed	Parts per million
Cotton, meal	2.0
Soybean, soapstock	15.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[59 FR 4835, Feb. 2, 1994, as amended at 60 FR 33360, June 28, 1995; 60 FR 40505, Aug. 9, 1995; 63 FR 17108, Apr. 8, 1998; 66 FR 14837, Mar. 14, 2001; 66 FR 30080, June 5, 2001; 66 FR 30333, June 6, 2001; 66 FR 47979, Sept. 17, 2001; 66 FR 67493, Dec. 31, 2001; 67 FR 46900, July 17, 2002; 70 FR 7047, Feb. 10, 2005; 72 FR 26316, May 9, 2007; 72 FR 71082, Dec. 14, 2007]

§ 180.459 Triasulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.02
Barley, straw	2.0
Cattle, fat	0.1
Cattle, kidney	0.5
Cattle, meat byproducts, except kidney	0.1
Cattle, meat	0.1
Goat, fat	0.1
Goat, kidney	0.5
Goat, meat byproducts, except kidney	0.1
Goat, meat	0.1
Grass, forage	7.0
Grass, hay	2.0
Hog, fat	0.1
Hog, kidney	0.5
Hog, meat byproducts	0.1
Hog, meat	0.1
Horse, fat	0.1
Horse, kidney	0.5
Horse, meat byproducts, except kidney	0.1
Horse, meat	0.1
Milk	0.02
Sheep, fat	0.1
Sheep, kidney	0.5
Sheep, meat byproducts, except kidney	0.1
Sheep, meat	0.1
Wheat, forage	5.0
Wheat, grain	0.02
Wheat, straw	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[60 FR 36731, July 18, 1995, as amended at 63 FR 44152, Aug. 18, 1998; 63 FR 66449, Dec. 2, 1998]

§ 180.460 Benoxacor; tolerances for residues.

(a) *General.* Tolerances are established for residues of the inert ingredient (safener) benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1, 4-benzoxazine) at 0.01 parts per million (ppm) when used in pesticide formulations containing metolachlor or S-metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor or S-metolachlor.

(b) *Section 18 energency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 7305, Feb. 13, 1998, as amended at 70 FR 21631, Apr. 27, 2005]

§ 180.461 Cadusafos; tolerances for residues.

A tolerance is established for the residues of the nematicide/insecticide cadusafos, *O*-ethyl *S,S*-di-*sec*-butyl phosphorodithioate, in or on the following raw agricultural commodity:

Commodity	Parts per million
Banana	0.01

There are no U.S. registrations as of May 10, 1994, for the nematicide/insecticid cadusafos.

[59 FR 39467, Aug. 3, 1994]

§ 180.462 Pyridate; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide pyridate (*O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol, expressed as pyridate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	0.03
Cabbage	0.03
Chickpea, seed	0.1
Collards	0.03
Corn, field, forage	0.03
Corn, grain	0.03
Corn, stover	0.03
Peanut	0.03
Peppermint, tops	0.20
Spearmint, tops	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[57 FR 54303, Nov. 18, 1992, as amended at 62 FR 44558, Aug. 22, 1997; 63 FR 53844, Oct. 7, 1998; 64 FR 46298, Aug. 25, 1999; 65 FR 25652, May 3, 2000; 67 FR 35049, May 17, 2002; 72 FR 35665, June 29, 2007]

§ 180.463 Quinclorac; tolerances for residues.

(a) *General.* Tolerances are established for residues of quinclorac (3,7-dichloro-8-quinoline carboxylic acid) in or the following food commodities:

Commodity	Parts per million
Barley, grain	2.0
Cattle, fat	0.7
Cattle, meat byproducts	1.5
Cattle, meat	0.05
Egg	0.05
Goat, fat	0.7
Goat, meat byproducts	1.5
Goat, meat	0.05
Grain, aspirated fractions	1200
Hog, fat	0.7
Hog, meat byproducts	1.5
Hog, meat	0.05
Horse, fat	0.7
Horse, meat byproducts	1.5
Horse, meat	0.05
Milk	0.05
Poultry, fat	0.05
Poultry, meat byproducts	0.1
Poultry, meat	0.05
Rice, bran	15.0
Rice, grain	5.0
Rice, straw	12.0
Sheep, fat	0.7
Sheep, meat byproducts	1.5
Sheep, meat	0.05
Sorghum, grain, forage	3.0
Sorghum, grain, grain	6.0
Sorghum, grain, stover	1.0
Wheat, forage	1.0
Wheat, germ	0.75
Wheat, grain	0.5
Wheat, hay	0.5
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[57 FR 47996, Oct. 21, 1992, as amended at 64 FR 6548, 6549, Feb. 10, 1999; 64 FR 14632, Mar. 26, 1999; 65 FR 33701, May 24, 2000; 67 FR 35049, May 17, 2002; 72 FR 55073, Sept. 28, 2007]

§ 180.464 Dimethenamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide dimethenamid, 1(R,S)-2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethylthien-3-yl)-acetamide, applied as either the 90:10 or 50:50 S:R isomers, in or on the following food commodities:

Commodity	Parts per million
Bean, dry, seed	0.01
Beet, garden, roots	0.01
Beet, garden, tops	0.01
Beet, sugar, dried pulp	0.01
Beet, sugar, molasses	0.01
Beet, sugar, roots	0.01
Beet, sugar, tops	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, forage	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01
Garlic	0.01
Grass, forage	0.15
Grass, hay	2.5
Grass, seed screenings	0.01
Grass, straw	0.01
Hop, dried cones	0.05
Horseradish	0.01
Leek	0.01
Onion, bulb	0.01
Onion, green	0.01
Onion, Welsh	0.01
Peanut	0.01
Peanut, hay	0.01
Radish, roots	0.01
Radish, tops	0.01
Rutabaga, roots	0.01
Rutabaga, tops	0.1
Shallot, bulb	0.01
Shallot, fresh leaves	0.01
Sorghum, grain, forage	0.01
Sorghum, grain, grain	0.01
Sorghum, grain, stover	0.01
Soybean, seed	0.01
Turnip, greens	0.1
Turnip, roots	0.01
Turnip, tops	0.1
Vegetable, tuberous and corm, subgroup 1C	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of dimethenamid, 1 (R,S)-2-chloro-N-[(1-methyl-2-methoxy) ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Pumpkin	0.01
Squash, winter	0.01

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 51551, Aug. 24, 2000, as amended at 67 FR 46884, July 17, 2002; 69 FR 29459, May 24, 2004; 69 FR 57207, Sept. 24, 2004; 70 FR 24712, May 11, 2005; 71 FR 25942, May 3, 2006; 71 FR 49354, Aug. 23, 2006; 72 FR 44388, Aug. 8, 2007; 72 FR 73630, Dec. 28, 2007]

§ 180.465 4-(Dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane.

(a) *General.* Tolerances are established for the residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, (CAS No. 71526–07–3) when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity [1]	Parts per million
Corn, field, forage	0.005
Corn, field, grain	0.005
Corn, field, stover	0.005
Corn, pop, grain	0.005
Corn, pop, stover	0.005

[1]There are no U.S. registered products containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane as of June 17, 2002.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 4392, Jan. 29, 2003]

§ 180.466 Fenpropathrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the pesticide chemical fenpropathrin (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethyl-cyclopropanecarboxylate) in or on the following agricultural commodities:

Commodity	Parts per million
Almond, hulls	4.5
Avocado	1.0
Brassica, head and stem, subgroup 5A	3.0
Bushberry subgroup 13B	3.0
Caneberry subgroup 13-07A	12
Canistel	1.0
Cattle, fat	1.0
Cattle, meat byproducts	0.1
Cattle, meat	0.1
Cherry, sweet	5.0
Cherry, tart	5.0
Citrus, dried pulp	4.0
Citrus, oil	75
Cotton, refined oil	3.0
Cotton, undelinted seed	1.0
Egg	0.05
Fruit, citrus, group 10	2.0
Fruit, pome, group 11	5.0
Fruit, stone, crop group 12, except cherry	1.4
Goat, fat	1.0
Goat, meat byproducts	0.1
Goat, meat	0.1
Grape	5.0
Grape, raisin	10.0
Hog, fat	1.0
Hog, meat byproducts	0.1
Hog, meat	0.1
Horse, fat	1.0
Horse, meat byproducts	0.1
Horse, meat	0.1
Juneberry	3.0
Lingonberry	3.0
Mango	1.0
Melon subgroup 9A	0.5
Milk, fat (reflecting 0.08 ppm in whole milk)	2.0
Nut, tree, crop group 14	0.10
Olive	5.0
Papaya	1.0
Pea, succulent	0.02
Peanut, hay	20.0
Peanut	0.01
Pistachio	0.10
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Salal	3.0
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sheep, fat	1.0
Sheep, meat byproducts	0.1
Sheep, meat	0.1
Squash/Cucumber subgroup 9B	0.5
Star apple	1.0
Strawberry	2.0
Vegetable, fruiting, group 8	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 63034, Nov. 26, 1997, as amended at 63 FR 48116, Sept. 9, 1998; 64 FR 3009, Jan. 20, 1999; 65 FR 11242, Mar. 2, 2000; 65 FR 24397, Apr. 26, 2000; 65 FR 48620, Aug. 9, 2000; 66 FR 64774, Dec. 14, 2001; 67 FR 35049, May 17, 2002; 70 FR 38789, July 6, 2005; 70 FR 55747, Sept. 23, 2005; 74 FR 12606, Mar. 25, 2009]

§ 180.467 Carbon disulfide; tolerances for residues.

Tolerances are established for the nematicide, insecticide, and fungicide carbon disulfide, from the application of sodium tetrathiocarbonate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond	0.1
Almond, hulls	0.1
Grapefruit	0.1
Grape	0.1
Lemon	0.1
Orange, sweet	0.1
Peach	0.1
Plum, prune, fresh	0.1

[58 FR 33771, June 21, 1993, as amended at 62 FR 26949, May 16, 1997]

§ 180.468 Flumetsulam; tolerances for residues.

Tolerances are established for residues of the herbicide flumetsulam, *N*-(2,6-difluorophenyl)-5-methyl-(1,2,4)-triazolo-[1,5a]-pyrimidine-2-sulfonamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Bean, dry	0.05
Corn, field, grain	0.05
Corn, field, forage	0.05
Corn, field, stover	0.05
Soybean	0.05

[58 FR 57967, Oct. 28, 1993, as amended at 71 FR 58518, Oct. 4, 2006]

§ 180.469 Dichlormid; tolerances for residues.

(a) *General.* Tolerances are established for residues of dichormid; (Acetamide, 2,2-dichloro-*N*,*N*-di-2-propenyl-) (CAS Reg. No. 37764–25–3) when used as an inert ingredient (herbicide safener) in pesticide formulations in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
Corn, field, forage	0.05	12/31/08
Corn, field, grain	0.05	12/31/08
Corn, field, stover	0.05	12/31/08
Corn, pop, grain	0.05	12/31/08
Corn, pop, stover	0.05	12/31/08
Corn, sweet, forage	0.05	12/31/08
Corn, sweet, kernel plus cob with husks removed	0.05	12/31/08
Corn, sweet, stover	0.05	12/31/08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 16149, Mar. 27, 2000, as amended at 67 FR 51105, Aug. 7, 2002; 69 FR 58290, Sept. 30, 2004; 70 FR 76699, Dec. 28, 2005]

§ 180.470 Acetochlor; tolerances for residues.

(a) *General.* Tolerances are established for residues of acetochlor; 2-chloro-2'-methyl-6-ethyl-*N*-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl aniline (HEMA) moiety, to be analyzed as acetochlor and expressed as acetochlor equivalents, in or on the following raw agricultural commodities.

Commodity	Parts per million
Corn, field, forage	4.5
Corn, field, grain	0.05
Corn, field, stover	2.5
Corn, pop, grain	0.05
Corn, pop, stover	2.5
Corn, sweet, forage	1.5
Corn, sweet, kernels plus cob with husks removed	0.05
Corn, sweet, stover	1.0
Sorghum, grain, forage	1.6
Sorghum, grain, grain	0.05
Sorghum, grain, stover	1.7

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of acetochlor; 2-chloro-2'-methyl-6-ethyl-*N*-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl aniline (HEMA) moiety, to be analyzed as acetochlor and expressed as acetochlor equivalents, in or on the following raw agricultural commodities when present therein as a result of application of acetochlor to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.3
Animal feed, nongrass, group 18, hay	3.5
Beet, sugar, root	0.05
Beet, sugar, tops	0.05
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, forage	0.5
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, hay	2.0
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, stover	0.1
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw	0.3
Grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain	0.05
Pea and bean, dried shelled, except soybean, subgroup 6C	0.05
Potato	0.05
Soybean, forage	0.7
Soybean, hay	1.0
Soybean, seed	0.1
Sunflower, seed	0.05
Wheat, forage	0.5
Wheat, grain	0.02
Wheat, hay	2.0
Wheat, straw	0.1

[72 FR 27468, May 16, 2007, as amended at 74 FR 29969, June 24, 2009]

§ 180.471 Furilazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of furilazole; 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine (CAS Reg. No. 121776–33–8) when used as an inert ingredient (safener) in pesticide formulations in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Sorghum, forage	0.01
Sorghum, grain	0.01
Sorghum, stover	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 8867, Feb. 23, 2000, as amended at 67 FR 15735, Apr. 3, 2002; 72 FR 57492, Oct. 10, 2007]

§ 180.472 Imidacloprid; tolerances for residues.

(a) *General.* Tolerances are established permitting the combined residues of the insecticide imidacloprid (1-[6-chloro-3-pyridinyl) methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on the following food commodities:

Commodity	Parts Per Million
Acerola	1.0
Almond, hulls	4.0
Apple	0.5
Apple, wet pomace	3.0
Aspirated grain fractions	240
Atemoya	0.30
Artichoke, globe	2.5
Avocado	1.0
Banana	0.50
Barley, grain	0.05
Barley, hay	0.5
Barley, straw	0.5
Beet, sugar, roots	0.05
Beet, sugar, tops	0.5
Beet, sugar, molasses	0.3
Biriba	0.30
Blueberry	3.5
Borage, seed	0.05
Caneberry, subgroup 13-A	2.5
Canistel	1.0
Canola, seed	0.05
Cattle, fat	0.3
Cattle, meat byproducts	0.3
Cattle, meat	0.3
Cherimoya	0.3
Citrus, dried pulp	5.0
Coffee, bean, green	0.80
Corn, field, forage	0.10
Corn, field, grain	0.05
Corn, field, stover	0.20
Corn, pop, grain	0.05
Corn, pop, stover	0.20
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.20
Cotton, gin byproducts	4.0
Cotton, undelinted seed	6.0
Cotton, meal	8.0
Crambe, seed	0.05
Cranberry	0.05
Currant	3.5
Custard apple	0.30
Egg	0.02
Elderberry	3.5
Feijoa	1.0
Flax, seed	0.05
Fruit, citrus, group 10	0.7
Fruit, pome, group 11	0.6
Fruit, stone, group 12	3.0
Goat, fat	0.3
Goat, meat byproducts	0.3
Goat, meat	0.3
Gooseberry	3.5
Grape, juice	1.5
Grape, pomace (wet or dried)	5.0
Grape, raisin	1.5
Grape, raisin, waste	15.0
Grape	1.0
Guava	1.0
Herbs subgroup 19A, dried herbs	48.0
Herbs subgroup 19-A, fresh herbs	8.0
Hog, fat	0.3
Hog, meat byproducts	0.3
Hog, meat	0.3
Hop, dried cones	6.0
Horse, fat	0.3
Horse, meat byproducts	0.3
Horse, meat	0.3
Huckleberry	3.5
Ilama	0.30
Jaboticaba	1.0
Juneberry	3.5
Kava, leaves	4.0
Kava, roots	0.40
Leaf petioles subgroup 4B	6.0
Leafy greens subgroup 4A	3.5
Lettuce, head and leaf	3.5
Lingonberry	3.5
Longan	3.0
Lychee	3.0
Mango	1.0
Milk	0.1
Millet, pearl, forage	2.0
Millet, pearl, grain	0.05
Millet, pearl, hay	6.0
Millet, pearl, straw	3.0
Millet, proso, forage	2.0
Millet, proso, grain	0.05
Millet, proso, hay	6.0
Millet, proso, straw	3.0
Mustard, black, seed	0.05
Mustard, field, seed	0.05
Mustard, Indian, seed	0.05
Mustard, rapeseed, seed	0.05
Mustard, seed	0.05
Nut, tree, group 14	0.05
Oat, forage	2.0
Oat, grain	0.05
Oat, hay	6.0
Oat, straw	3.0
Okra	1.0
Passionfruit	1.0
Papaya	1.0
Peanut	0.45
Peanut, hay	35
Peanut, meal	0.75
Pecan	0.05
Persimmon	3.0
Pistachio	0.05
Pomegranate	0.90
Potato, chip	0.4
Potato, processed potato waste	0.9
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Pulasan	3.0
Rambutan	3.0
Rapeseed, seed	0.05
Raspberry, wild	2.5

Commodity	Parts Per Million
Rye, forage	2.0
Rye, grain	0.05
Rye, hay	6.0
Rye, straw	3.0
Safflower, seed	0.05
Salal	3.5
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sheep, fat	0.3
Sheep, meat byproducts	0.3
Sheep, meat	0.3
Sorghum, forage	0.10
Sorghum, grain, grain	0.05
Sorgum, grain, stover	0.10
Soursop	0.30
Soybean, forage	8.0
Soybean, hay	35
Soybean, meal	4.0
Soybean, seed	3.5
Spanish lime	3.0
Star apple	1.0
Starfruit	1.0
Strawberry	0.50
Sugar apple	0.30
Sunflower, seed	0.05
Tomato, paste	6.0
Tomato, pomace (wet or dried)	4.O
Tomato, puree	3.0
Vegetable, brassica leafy, group 5	3.5
Vegetable, cucurbit, group 9	0.5
Vegetable, fruiting, group 8	1.0
Vegetable, leaves of root and tuber, group 2	4.0
Vegetable, legume, group 6, except soybean	4.0
Vegetable, root and tuber, group 1, except sugar beet	0.40
Watercress	3.5
Watercress, upland	3.5
Wax jambu	1.0
Wheat, forage	7.0
Wheat, grain	0.05
Wheat, hay	0.5
Wheat, straw	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent combined residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, when present therein as a result of the application of the pesticide to growing crops listed in this section and other non-food crops as follows:

Commodity	Parts Per Million
Corn, sweet, kernel plus cob with husks removed	0.05
Grain, cereal, forage, fodder and straw, group 16; forage	2.0
Grain, cereal, forage, fodder and straw, group 16; hay	6.0
Grain, cereal, forage, fodder and straw, group 16; stover	0.3
Grain, cereal, forage, fodder and straw, group 16; straw	3.0
Grain, cereal, group 15	0.05
Vegetable, foliage of legume, group 7	2.5
Vegetable, legume, group 6	0.3

[71 FR 46116, Aug. 11, 2006, as amended at 72 FR 33912, June 20, 2007]

§ 180.473 Glufosinate ammonium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide glufosinate-ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents, in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	0.50
Apple	0.05
Banana	0.30
Banana, pulp	0.20
Beet, sugar, molasses	5.0
Beet, sugar, roots	0.9
Beet, sugar, tops (leaves)	1.5
Bushberry subgroup 13B	0.15
Canola, meal	1.1
Canola, seed	0.40
Cattle, fat	0.40
Cattle, meat	0.15
Cattle, meat byproducts	6.0
Corn, field forage	4.0
Corn, field, grain	0.20
Corn, field, stover	6.0
Cotton, gin byproducts	15
Cotton, undelinted seed	4.0
Egg	0.15
Goat, fat	0.40
Goat, meat	0.15
Goat, meat byproducts	6.0
Grain aspirated fractions	25
Grape	0.05
Hog, fat	0.40
Hog, meat	0.15
Hog, meat byproducts	6.0
Horse, fat	0.40
Horse, meat	0.15
Horse, meat byproducts	6.0
Juneberry	0.10
Lingonberry	0.10
Milk	0.15
Nut, tree, group 14	0.10
Pistachio	0.10

Commodity	Parts per million
Potato	0.80
Potato, chips	1.6
Potato granules/flakes	2.0
Poultry, fat	0.15
Poultry, meat	0.15
Poultry, meat byproducts	0.60
Rice, grain	1.0
Rice, hull	2.0
Rice, straw	2.0
Salal	0.10
Sheep, fat	0.40
Sheep, meat	0.15
Sheep, meat byproducts	6.0
Soybean	2.0
Soybean, hulls	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide glufosinate ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt and its metabolite, 3-methylphosphinicopropionic acid in or on the following raw agricultural commodities when present therein as a result of the application of glufosinate ammonium to crops listed in paragraph (a) of this section:

Commodity	Parts per million
Barley, hay	0.40
Barley, straw	0.40
Buckwheat, fodder	0.40
Buckwheat, forage	0.40
Oat, forage	0.40
Oat, hay	0.40
Oat, straw	0.40
Rye, forage	0.40
Rye, straw	0.40
Teosinte	0.40
Triticale	0.40
Wheat, forage	0.40
Wheat, hay	0.40
Wheat, straw	0.40

[68 FR 55849, Sept. 29, 2003, as amended at 71 FR 25945, May 3, 2006; 72 FR 72625, Dec. 21, 2007]

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of the fungicide, tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities:

Commodity	Parts per million
Almond, hulls	6.0
Apple, wet pomace	0.1
Asparagus	0.05
Banana	0.05
Barley, grain	0.15
Barley, hay	7.0
Barley, straw	3.5
Bean, dry seed	0.1
Bean, succulent	0.1
Beet, garden, roots	0.70
Beet, garden, tops	7.0
Brassica, leafy greens, subgroup 5B	2.5
Cherry, sweet, pre- and post-harvest	5.0
Cherry, tart, pre- and post-harvest	5.0
Coffee, green bean [1]	0.15
Coffee, roasted bean [1]	0.3
Corn, field, forage	4.0
Corn, field, grain	0.05
Corn, field, stover	3.5
Corn, pop, grain	0.05
Corn, pop, stover	3.5
Corn, sweet, forage	7.0
Corn, sweet, kernel plus cob with husks removed	0.5
Corn, sweet, stover	6.0
Cotton, gin byproducts	25.0
Cotton, undelinted seed	2.0
Fruit, pome, group 11	0.05
Fruit, stone, group 12, except cherry	1.0
Grain, aspirated fractions	16.0
Grape	5.0
Grass, forage	8.0
Grass, hay	25.0
Grass, seed screenings	55.0
Grass, straw	30.0
Hop, dried cones	35.0
Lychee	1.6
Mango, postharvest	0.15
Nut, tree, group 14	0.05
Oat, forage	0.10
Oat, grain	0.05
Oat, hay	0.10
Oat, straw	0.10
Okra	1.2
Onion, bulb, subgroup 3-07A	0.2
Onion, green, subgroup 3-07B	1.3
Peach	1.0
Peanut	0.1
Pistachio	0.05
Plum, pre- and post-harvest	1.0
Soybean, forage	25
Soybean, hay	50
Soybean, seed	0.08
Sunflower, seed	0.05
Sunflower, meal	0.2
Sunflower, refined oil	0.2
Vegetable, cucurbit, group 9	0.09
Wheat, forage	3.0
Wheat, grain	0.05
Wheat, hay	7.0
Wheat, straw	1.5

[1] There are no U.S. registrations as of 7/31/2008.

(2) Tolerances are established for the combined residues of the fungicide, tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite.

Commodity	Parts per million
Cattle, meat byproducts	0.2
Goat, meat byproducts	0.2
Horse, meat byproducts	0.2
Milk	0.1
Sheep, meat byproducts	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations for the residues of the fungicide, tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities:

Commodity	Parts per million
Turnip, roots	0.5
Turnip, tops	7.0

(d) *Indirect or inadvertent residues.* [Reserved]

[59 FR 39464, Aug. 3, 1994]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.474, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	4.5
Banana [1]	0.2
Barley, grain	0.1
Barley, hay	0.05
Barley, straw	0.05
Beet, sugar	0.01
Beet, sugar, dried pulp	1.9
Canola, seed	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Fruit, pome group 11	1.0
Grape [1]	0.10
Papaya [1]	0.30
Potato, processed waste	0.04
Rye, grain [1]	0.1
Vegetable, fruiting, group 8	0.60
Vegetable, tuberous and corm, subgroup 1C	0.01

[1] There are no U.S. registrations.

(2) Tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, and its metabolite, CGA-205375, 1-[2-chloro-4-(4-chloro-phenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, liver	0.20
Cattle, meat	0.05
Cattle, meat byproduct (except liver)	0.10
Eggs	0.10
Goat, fat	0.10
Goat, liver	0.20
Goat, meat	0.05
Goat, meat byproduct (except liver)	0.10
Hog, fat	0.10
Hog, liver	0.20
Hog, meat	0.05
Hog, meat byproduct (except liver)	0.10
Horse, fat	0.10
Horse, liver	0.20
Horse, meat	0.05
Horse, meat byproduct (except liver)	0.10
Milk	0.01
Sheep, fat	0.10
Sheep, liver	0.20
Sheep, meat	0.05
Sheep, meat byproduct (except liver)	0.10

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the fungicide difenoconazole in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Almond	0.05	12/31/11
Almond, hulls	5.0	12/31/11
Cantaloupe	1.0	12/31/11
Cucumber	1.0	12/31/11
Watermelon	1.0	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 36254, July 6, 1999, as amended at 64 FR 47687, Sept. 1, 1999; 65 FR 55921, Sept. 15, 2000; 65 FR 82940, Dec. 29, 2000; 66 FR 64774, Dec. 14, 2001; 68 FR 37765, June 25, 2003; 70 FR 75739, Dec. 21, 2005; 71 FR 53984, Sept. 13, 2006; 73 FR 1508, Jan. 9, 2008; 73 FR 45629, Aug. 6, 2008]

§ 180.476 Triflumizole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1 *H* -imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as stoichiometric equivalent of the parent compound.

Commodity	Parts per million
Apple, pomace	2.0
Apple	0.5
Brassica, head and stem, subgroup 5A	8.0
Brassica, leafy greens, subgroup 5B	40
Canistel	2.5
Cherry, sweet	1.5
Cherry, tart	1.5
Cilantro, leaves	35
Grape	2.5
Grape pomace	15.0
Grape, raisin, waste	10.0
Hazelnut	0.05
Hop, dried cones	50
Leafy greens subgroup 4A, except spinach	35
Mango	2.5
Papaya	2.5
Pear	0.5
Pineapple	4.0
Sapodilla	2.5
Sapote, black	2.5
Sapote, mamey	2.5
Star apple	2.5
Strawberry	2.0
Swiss chard	18
Turnip, greens	40
Vegetable, cucurbit, Group 9	0.5

(2) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities of animal origin listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1 *H* -imidazole, the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate, and other metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound.

Commodity	Parts per million
Cattle, fat	0.5
Cattle, meat	0.05
Cattle, meat byproducts	0.5
Egg	0.05
Goat, fat	0.5
Goat, meat	0.05
Goat, meat byproducts	0.5
Hog, fat	0.5
Hog, meat	0.05
Hog, meat byproducts	0.5
Horse, fat	0.5
Horse, meat	0.05
Horse, meat byproducts	0.5
Milk	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.1
Sheep, fat	0.5
Sheep, meat	0.05
Sheep, meat byproducts	0.5

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for the residues triflumizole (1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1H-imidazole) and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/ revocation date
Cabbage, chinese, napa	20	12/31/09
Kohlrabi	20	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33702, May 24, 2000, as amended at 67 FR 40228, June 12, 2002; 67 FR 54587, Aug. 23, 2002; 70 FR 7047, Feb. 10, 2005; 70 FR 17915, Apr. 8, 2005; 71 FR 13279, Mar. 15, 2006; 71 FR 49358, Aug. 23, 2006; 74 FR 26543, June 3, 2009]

§ 180.477 Flumiclorac pentyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide flumiclorac pentyl, [2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)phenoxy]-acetate, in or on the raw agricultural commodities listed below.

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Cotton, gin byproducts	3.0
Cotton, undelinted seed	0.2
Soybean, hulls	0.02
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33702, May 24, 2000, as amended at 71 FR 11533, Mar. 8, 2006]

§ 180.478 Rimsulfuron; tolerances for residues

(a) *General.* Tolerances are established for residues of the herbicide rimsulfuron (*N*-((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)-3-(ethylsulfonyl)-2-pyridinesulfonamide in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.09
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Fruit, citrus, group 10	0.01
Fruit, pome, group 11	0.01
Fruit, stone, group 12	0.01
Grape	0.01
Nut, tree, group 14	0.01
Pistachio	0.01
Potato	0.1
Tomato	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 16696, Apr. 6, 1998, as amended at 72 FR 41913, Aug. 1, 2007]

§ 180.479 Halosulfuron-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidiny)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-caboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as halosulfuron-methyl equivalent in or on the raw agricultural commodities listed in the table in this unit.

Commodity	Parts per million
Cattle, meat byproducts	0.1
Goat, meat byproducts	0.1
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Sheep, meat byproducts	0.1

(2) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole- 4-carboxylate, in or on the raw agricultural commodities listed below.

Commodity	Parts per million
Alfalfa, forage	1.0
Alfalfa, hay	2.0
Almond, hulls	0.2
Asparagus	0.8
Bean, dry, seed	0.05
Bean, snap, succulent	0.05
Corn, field, forage	0.2
Corn, field, grain	0.05
Corn, field, stover	0.8
Corn, pop, grain	0.05
Corn, pop, stover	0.8
Corn, sweet, forage	0.2
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.8
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Melon subgroup 9A	0.1
Nut, tree, group 14	0.05
Pistachio	0.05
Rice, grain	0.05
Rice, straw	0.2
Sorghum, grain, forage	0.05
Sorghum, grain, grain	0.05
Sorghum, grain, stover	0.1
Squash/Cucumber subgroup 9B	0.5
Sugarcane, cane	0.05
Vegetable, fruiting, group 8	0.05

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of halosulfuron methyl, methyl 5-[(4,6-dimethoxy-2-

pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, in connection with use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA in or on the following commodity:

Commodity	Parts per million	Expiration/ revocation date
Sweet potato	1.0	12/31/08

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 25448, May 12, 1999, as amended at 65 FR 58433, Sept. 29, 2000; 66 FR 66340, Dec. 26, 2001; 66 FR 66786, Dec. 27, 2001; 67 FR 45649, July 10, 2002; 67 FR 59192, Sept. 20, 2002; 70 FR 51622, Aug. 31, 2005; 72 FR 8927, Feb. 28, 2007]

§ 180.480 Fenbuconazole; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the fungicide fenbuconazole, alpha–[2–(4–chlorophenyl)– ethyl]–alpha–phenyl–3–(1H–1,2,4–triazole)– 1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)– dihydro–3–phenyl–3–(1H–1,2,4– triazole–1–ylmethyl)–2–3 H–furanone, and RH–9130, trans–5–(4–chlorophenyl)dihydro–3–phenyl–3– (1H–1,2,4–triazole–1–ylmethyl)–2–3 H–furanone, expressed as fenbuconazole in or on the following agricultural commodities.

Commodity	Parts per million
Almond	0.05
Almond, hulls	1.0
Apple	0.4
Apple, wet pomace	1.0
Banana	0.3
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	0.4
Beet, sugar, roots	0.3
Beet, sugar, tops	9.0
Bushberry subgroup 13B	0.3
Cattle, meat byproducts	0.05
Citrus, dried pulp	5.0
Citrus, oil	40.0
Cranberry	0.5
Fruit, citrus, group 10	1.0
Fruit, stone, group 12	1.0
Goat, meat byproducts	0.05
Grain, aspirated fractions	6.0
Grape [1]	1.0
Horse, meat byproducts	0.05
Peanut	0.1
Pecan	0.05
Pepper	0.40
Sheep, meat byproducts	0.05
Wheat, forage	4.0
Wheat, grain	0.1
Wheat, hay	8.0
Wheat, straw	8.0

[1]There are no United States registrations for grape as of August 2006.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for fenbuconazole (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1 H -1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1 H -1,2,4-triazole-1-ylmethyl)-2-3 H -furanone and trans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1 H 1,2,4-triazole-1-ylmethyl-2-3 H -furanone, expressed as fenbuconazole in or on the following raw agricultural commodities in connection with use of the pesticide under a section 18 exemption granted by EPA. The time-limited tolerances will expire on the date specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Cattle, fat	0.01	12/31/08
Cattle, meat	0.01	12/31/08
Goat, fat	0.01	12/31/08
Goat, meat	0.01	12/31/08
Hog, fat	0.01	12/31/08
Hog, meat	0.01	12/31/08
Hog, meat byproducts	0.01	12/31/08
Horse, fat	0.01	12/31/08
Horse, meat	0.01	12/31/08
Sheep, fat	0.01	12/31/08
Sheep, meat	0.01	12/31/08

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[60 FR 11032, Mar. 1, 1995]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.480, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.481 Prosulfuron; tolerances for residues.

Tolerances that expire as indicated in the table below are established for residues of the herbicide prosulfuron 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration date
Cattle, fat	0.05	12/31/99
Cattle, kidney	0.05	Do.
Cattle, liver	0.05	Do.
Cattle, meat	0.05	Do.
Cattle, meat byproducts	0.05	Do.
Corn, forage	0.01	Do.
Corn, grain and fresh (including sweet kernels plus cobs with husks removed)	0.01	Do.
Corn, stover	0.01	Do.
Goat, fat	0.05	Do.
Goat, kidney	0.05	Do.
Goat, liver	0.05	Do.
Goat, meat	0.05	Do.
Goat, meat byproducts	0.05	Do.
Grain, cereal, forage, fodder and straw, group 16, except rice and wild rice; forage	0.10	Do.
Grain, cereal, forage, fodder and straw, group 16, except rice and wild rice; hay	0.20	Do.
Grain, cereal, forage, fodder and straw, group 16, except rice and wild rice; stover	0.01	Do.
Grain, cereal, forage, fodder and straw, group 16, except rice and wild rice; straw	0.02	Do.
Grain, cereal, group 15, except rice and wild rice	0.01	Do.
Hog, fat	0.05	Do.
Hog, kidney	0.05	Do.
Hog, liver	0.05	Do.
Hog, meat	0.05	Do.
Hog, meat byproducts	0.05	Do.
Horse, fat	0.05	Do.
Horse, kidney	0.05	Do.
Horse, liver	0.05	Do.
Horse, meat	0.05	Do.
Horse, meat byproducts	0.05	Do.
Milk	0.01	Do.
Sheep, fat	0.05	Do.
Sheep, kidney	0.05	Do.
Sheep, liver	0.05	Do.
Sheep, meat	0.05	Do.
Sheep, meat byproducts	0.05	Do.

[61 FR 26842, May 29, 1996, as amended at 61 FR 26844, May 29, 1996]

§ 180.482 Tebufenozide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	25
Apple, pomace	3.0
Apple	1.0
Berry group 13	3.0
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	10.0
Canola, refined oil	4.0
Canola, seed	2.0
Citrus, oil	15.0
Cotton	1.5
Cotton, gin byproducts	30
Cranberry	1.0
Fruit, citrus, group 10	0.80
Fruit, pome	1.5
Grape	3.0
Kiwifruit [1]	0.5
Leaf petioles subgroup 4B	2.0
Leafy greens subgroup 4A	10.0
Peppermint, tops	10.0
Spearmint, tops	10.0
Tree nut crop group including pistachio	0.1
Turnip, greens	9.0
Turnip, roots	0.3
Vegetable, fruiting, group 8	1.0
Vegetable, tuberous and corm, except potato, subgroup 1D	0.015
Walnut	0.1

[1]There are no U.S. registrations on kiwifruit as of June 15, 1999.

(2) Tolerances are established for the combined residues of tebufenozide and its metabolites benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-((4-carboxymethyl)benzoyl)hydrazide), benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, the stearic acid conjugate of benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and benzoic acid, 3-hydroxymethyl-5-methyl-1-(1,1-dimethylethyl)-2-(4-(1-hydroxyethyl)benzoyl)hydrazide.

Commodity	Parts per million
Fat of cattle, goat, hog, horse, and sheep	0.1
Meat of cattle, goat, hog, horse and sheep	0.08
Meat byproducts of cattle, goat, hog, horse and sheep	0.08
Milk	0.04

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide benzoic acid in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Beet, garden, roots	0.3	12/31/05
Beet, garden, tops	9.0	12/31/05
Grape	3.0	12/31/05
Sweet potato, roots	0.25	12/31/05

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent combined residues of tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on the raw agricultural commodities when present therein as a result of the application of tebufenozide to growing crops listed in paragraph (a) of this section to read as follows:

Commodity	Parts per million
Animal feed, nongrass, group 18	1.0
Grain, cereal, forage, fodder and straw, group 16	1.0
Grass, forage, fodder and hay, group 17	1.0
Vegetable, foliage of legume, group 7	0.20

[60 FR 29347, May 31, 1995]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.482, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.483 *O*-[2-(1,1-Dimethylethyl)-5-pyrimidinyl] *O*-ethyl-*O*-(1-methylethyl) phosphorothioate; tolerances for residues.

Time-limited tolerances are established for residues of the insecticide *O*-[2-(1,1-dimethylethyl)-5-pyrimidinyl] *O*-ethyl-*O*-(1-methylethyl) phosphorothioate in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration date
Corn, forage and fodder, field, pop, and sweet	0.01	7/6/99
Corn, grain, field and pop	0.01	Do.
Corn, sweet, kernel plus cob with husks removed	0.01	Do.

[60 FR 34873, July 5, 1995]

§ 180.484 Flutolanil (*N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide); tolerances for residues.

(a) *General.* Tolerances are established for residues of flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, kidney	1.00
Cattle, liver	2.00
Cattle, meat byproducts	0.05
Cattle, meat	0.05
Egg	0.05
Goat, fat	0.10
Goat, kidney	1.00
Goat, liver	2.00
Goat, meat byproducts	0.05
Goat, meat	0.05
Hog, fat	0.10
Hog, kidney	1.00
Hog, liver	2.00
Hog, meat byproducts	0.05
Hog, meat	0.05
Horse, fat	0.10
Horse, kidney	1.00
Horse, liver	2.00
Horse, meat byproducts	0.05
Horse, meat	0.05
Milk	0.05
Peanut	0.5
Peanut, hay	15.0
Peanut, meal	1.0
Potato	0.20
Potato, wet peel	0.30
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Rice, bran	10.0
Rice, grain	7.0
Rice, hulls	25.0
Rice, straw	10.0
Sheep, fat	0.10
Sheep, kidney	1.00
Sheep, liver	2.00
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil, in or on the following commodities:

Commodity	Parts per million
Soybean, forage	8.0
Soybean, hay	2.5
Soybean, seed	0.20
Wheat, bran	0.20
Wheat, forage	2.5
Wheat, grain	0.05
Wheat, hay	1.2

Commodity	Parts per million
Wheat, straw	0.20

[60 FR 42458, Aug. 16, 1995, as amended at 61 FR 33044, June 26, 1996; 63 FR 42256, 42257, Aug. 7, 1998; 66 FR 10825, Feb. 20, 2001; 71 FR 74818, Dec. 13, 2006; 72 FR 35665, June 29, 2007; 73 FR 33017, June 11, 2008]

§ 180.485 Cyproconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for the free and conjugated residues of the fungicide cyproconazole, α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on the following food commodities:

Commodity	Parts per million
Aspirated grain fractions	2.5
Cattle, fat	0.01
Cattle, meat byproducts (except liver)	0.01
Coffee bean, green (Imported) [1]	0.1
Corn, field, forage	0.60
Corn, field, grain	0.01
Corn, field, stover	1.2
Goat, fat	0.01
Goat, meat byproducts (except liver)	0.01
Horse, fat	0.01
Horse, meat byproducts (except liver)	0.01
Sheep, fat	0.01
Sheep, meat byproducts (except liver)	0.01
Soybean, forage	1.0
Soybean, hay	3.0
Soybean, oil	0.10
Soybean, seed	0.05
Wheat, forage	0.80
Wheat, grain	0.05
Wheat, grain, milled byproducts	0.10
Wheat, hay	1.3
Wheat, straw	0.90

[1]There are no U.S. registrations as of February 15, 2008 for use on coffee bean.

(2) A tolerance is established for the combined free and conjugated residues of cyproconazole α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-1*H*-1,2,4-triazole-1-ethanol] and its metabolite [δ-(4-chlorophenyl)-β,δ-dihydroxy-γ-methyl-1*H*-1,2,4-triazole-1-hexenoic acid in or on the following commodity:

Commodity	Parts per million
Milk	0.02

(3) Tolerances are established for the combined free and conjugated residues of cyproconazole α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-1*H*-1,2,4-triazole-1-ethanol and its metabolite 2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol in or on the following commodities:

Commodity	Parts per million
Cattle, liver	0.50
Goat, liver	0.50
Hog, liver	0.01
Horse, liver	0.50
Sheep, liver	0.50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 53835, Oct. 7, 1998, as amended at 71 FR 71058, Dec. 8, 2006; 73 FR 27760, May 14, 2008]

§ 180.486 Phosphorothioic acid, *0,0*-diethyl *0*-(1,2,2,2-tetrachloroethyl) ester; tolerances for residues.

Tolerances are established permitting the residue of the insecticide phosphorothioic acid, *0,0*-diethyl *0*-(1,2,2,2-tetrachloroethyl) ester in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01

[60 FR 49792, Sept. 27, 1995]

§ 180.487 Pyrithiobac sodium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, pyrithiobac sodium, (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate), resulting from the application of the pesticide chemical in or on the following foods/feeds:

Commodity	Parts per million
Cotton, gin byproducts	0.15
Cotton, undelinted seed	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 54783, Oct. 22, 1997, as amended at 64 FR 56469, Oct. 20, 1999; 67 FR 72110, Dec. 4, 2002]

§ 180.490 Imazapic-ammonium; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of the herbicide imazapic, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, both free and conjugated, in or on the following food commodities:

Commodity	Parts per million
Grass, forage	15
Grass, hay	30
Peanut	0.1

(2) Tolerances are also established for the combined residues of the herbicide imazapic, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its free metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, kidney	1.0
Cattle, meat byproducts, except kidney	0.1
Cattle, meat	0.1
Goat, fat	0.1
Goat, kidney	1.0
Goat, meat byproducts, except kidney	0.1
Goat, meat	0.1
Horse, fat	0.1
Horse, kidney	1.0
Horse, meat byproducts, except kidney	0.1
Horse, meat	0.1
Milk	0.1
Sheep, fat	0.1
Sheep, kidney	1.0
Sheep, meat byproducts, except kidney	0.1
Sheep, meat	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with reginal registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 54224, Oct. 6, 1999, as amended at 66 FR 64774, Dec. 14, 2001; 66 FR 66332, Dec. 26, 2001]

§ 180.491 Propylene oxide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of propylene oxide when used as a postharvest fumigant in or on the following food commodities:

Commodity	Parts per million
Cacao bean, dried bean	200
Cacao bean, cocoa powder	200
Fig	3.0
Garlic, dried	300
Grape, raisin	1.0
Herbs and spices, group 19, dried	300
Nut, tree, group 14	300
Onion, dried	300
Plum, prune, dried	2.0

(2) Tolerances are established for the reaction product, propylene chlorohydrin, from use of propylene oxide as a postharverst fumigant, in or on the following food commodities:

Commodity	Parts per million
Basil, dried leaves	6000
Cacao bean, dried bean	20.0
Cacao bean, cocoa powder	20.0
Fig	3.0
Garlic, dried	6000
Grape, raisin	4.0
Herbs and spices, group 19, dried, except basil	1500
Nut, tree, group 14	10.0
Onion, dried	6000
Plum, prune, dried	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33702, May 24, 2000, as amended at 68 FR 39430, July 1, 2003; 72 FR 49651, Aug. 29, 2007; 73 FR 54963, Sept. 24, 2008]

§ 180.492 Triflusulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, triflusulfuron methyl 2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-

methylbenzoate in or on the raw agricultural commodities:

Commodity	Parts per million
Beet, sugar, roots	0.05
Beet, sugar, tops	0.05
Chicory, roots	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 40196, June 12, 2002]

§ 180.493 Dimethomorph; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the fungicide dimethomorph, (*E,Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	20.0
Ginseng	0.90
Grape, raisin [1]	6.0
Hop, dried cones	60
Lettuce, head	10
Lettuce, leaf	10
Potato	0.05
Potato, wet peel	0.20
Taro, corm	0.5
Taro, leaves	6.0
Turnip, greens	20.0
Vegetable, bulb, group 3	2.0
Vegetable, cucurbit, group 9	0.5
Vegetable, fruiting, group 8	1.5

[1] There are no U.S. registrations as of March 4, 2009, for the use of dimethomorph on grapes grown for raisin production.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the fungicide dimethomorph, (*E,Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on the following commodities:

Commodity	Parts per million
Bean, lima, succulent	0.60
Grape	3.5

(d) *Indirect or inadvertent residues.* Time-limited tolerances are established for inadvertent or indirect residues of the fungicide dimethomorph in or on the following raw agricultural commodities when present therein as a result of the application of dimethomorph to growing crops. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Grain, cereal, forage, fodder and straw, group 16, forage	0.05	5/12/04
Grain, cereal, forage, fodder and straw, group 16, hay	0.10	5/12/04
Grain, cereal, forage, fodder and straw, group 16, stover	0.15	5/12/04
Grain, cereal, forage, fodder and straw, group 16, straw	0.15	5/12/04
Grain, cereal, group 15	0.05	5/12/04

[62 FR 26416, May 14, 1997, as amended at 62 FR 39961, July 25, 1997; 63 FR 8139, Feb. 18, 1998; 63 FR 32140, June 12, 1998; 64 FR 18369, Apr. 14, 1999; 64 FR 25455, May 12, 1999; 65 FR 58390, Sept. 29, 2000; 66 FR 37598, July 19, 2001; 67 FR 35049, May 17, 2002; 67 FR 60923, Sept. 27, 2002; 68 FR 55833, Sept. 29, 2003; 70 FR 7047, Feb. 10, 2005; 71 FR 76177, Dec. 20, 2006; 74 FR 9356, Mar. 4, 2009]

§ 180.494 Pyridaben; tolerance for residues.

(a) *General.* Tolerances are established for residues of the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the following plants, and of the insecticide pyridaben and its metabolites (2-tert-butyl-5-(4-(1-carboxy-1-methylethyl)benzylthio)-4-chloropyridazin-3(2H)-one] and (2-tert-butyl-5-[4(-1,1-dimethyl-2-hypdroxyethyl)benzylthio-4-chloropyridazinn-3(2H)-one) on animals, as indicated in the following table.

Commodity	Parts per million	Revocation/expiration date
Almond, hulls	4.0	None
Apple	0.5	None
Apple, wet pomace	0.75	None
Canistel	0.10	None
Cattle, fat	0.05	None
Cattle, meat	0.05	None
Cattle, meat byproducts	0.05	None
Citrus	0.5	None
Citrus, dried pulp	1.5	None
Citrus, oil	10.0	None
Fruit, stone, group 12	2.5	None
Goat, fat	0.0	None
Goat, meat	0.05	None

Commodity	Parts per million	Revocation/expiration date
Goat, meat byproducts	0.05	None
Grape	1.5	None
Hog, fat	0.05	None
Hog, meat	0.05	None
Hog, meat byproducts	0.05	None
Hop, dried cones	10.0	None
Horse, fat	0.05	None
Horse, meat	0.05	None
Horse, meat byproducts	0.05	None
Mango	0.10	None
Milk	0.01	None
Nut, tree, group 14	0.05	None
Papaya	0.10	None
Pear	0.75	None
Pistachio	0.05	None
Sapodilla	0.10	None
Sapote, black	0.10	None
Sapote, mamey	0.10	None
Sheep, fat	0.05	None
Sheep, meat	0.05	None
Sheep, meat byproduct	0.05	None
Star apple	0.10	None
Strawberry	2.5	None
Tomato	0.15	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the insecticide pyridaben [2-tert-butyl-5(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration Date
Cranberry	0.5	None

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 43712, July 14, 2000, as amended at 66 FR 33199, June 21, 2001; 70 FR 55769, Sept. 23, 2005]

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide spinosad in or on the food commodities in the table to this paragraph. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: Spinosyn A (Factor A: CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione.

Commodity	Parts per million
Acerola	1.5
Alfalfa, seed	0.15
Alfalfa, seed screenings	2.0
Almond, hulls	2.0
Amaranth, grain, grain	1.0
Amaranth, grain, stover	10
Animal feed, nongrass, group, 18	0.02
Animal feed, nongrass, group, 18, forage	35.0
Animal feed, nongrass, group, 18, hay	30.0
Apple pomace	0.5
Artichoke, globe	0.3
Asparagus	0.2
Atemoya	0.3
Avocado	0.3
Banana	0.25
Beet, sugar, molasses	0.75
Biriba	0.3
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10.0
Bushberry subgroup 13B	0.250
Caneberry subgroup 13A	0.7
Canistel	0.3
Cattle, fat	50
Cattle, liver	10
Cattle, meat	2.0
Cattle, meat byproducts, except liver	5.0
Cherimoya	0.3
Citrus, oil	3.0
Citrus, dried pulp	0.5
Coriander, leaves	8.0
Corn, sweet, kernel plus cob with husks removed	0.02
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.02
Cranberry	0.01
Custard apple	0.3
Egg	0.30
Feijoa	.05
Fig	0.10
Fish	4.0
Fish-shellfish, crustacean	4.0
Fish-shellfish, mollusc	4.0
Food commodities	0.02
Fruit, citrus, group 10	0.3
Fruit, pome, group 11	0.20
Fruit, stone, group 12	0.20
Goat, fat	50
Goat, liver	10
Goat, meat	2.0
Goat, meat byproducts, except liver	5.0
Grain, aspirated fractions	200
Grain, cereal, group 15	1.5
Grain, cereal, group 16, forage, except rice	2.5
Grain, cereal, group 16, hay, except rice	10.0
Grain, cereal, group, 16, stover, except rice	10.0
Grain, cereal, group, 16, straw, except rice	1.0
Grape	0.50
Grape, raisin	0.70
Grass, forage, fodder and hay, group 17, forage	10.0

Commodity	Parts per million
Grass, forage, fodder and hay, group 17, hay	5.0
Guava	0.3
Herb subgroup 19A, dried	22
Herb subgroup 19A, fresh	3.0
Hog, fat	33
Hog, meat byproducts	8.0
Hog, meat	1.5
Hop, dried cones	22
Horse, fat	50
Horse, liver	10
Horse, meat	2.0
Horse, meat byproducts, except liver	5.0
Ilama	0.3
Jaboticaba	0.3
Juneberry	0.25
Lingonberry	0.250
Longan	0.3
Lychee	0.3
Mango	0.3
Milk	7.0
Milk, fat	85
Nut, tree, group 14	0.02
Okra	0.40
Onion, green	2.0
Papaya	0.3
Passionfruit	0.3
Pea and bean, dried shelled, except soybean, subgroup 6C	0.02
Pea and bean, succulent shelled, subgroup 6B	0.02
Peanut	0.02
Peanut, hay	11.0
Peppermint, tops	3.5
Pineapple	0.02
Pineapple, process residue	0.08
Pistachio	0.020
Poultry, fat	1.3
Poultry, meat	0.10
Poultry, meat byproducts	0.10
Pulasan	0.3
Rambutan	0.3
Rice, hulls	4.0
Salal	0.250
Sapodilla	0.3
Sapote, black	0.3
Sapote, mamey	0.3
Sapote, white	0.3
Sheep, fat	50
Sheep, liver	10
Sheep, meat	2.0
Sheep, meat byproducts, except liver	5.0
Soursop	0.3
Soybean	0.02
Spanish lime	0.3
Spearmint, tops	3.5
Spice, subgroup 19B, except black pepper	1.7
Star apple	0.3
Starfruit	0.3
Strawberry	1.0
Sugar apple	0.3
Ti, leaves	10.0
Vegetable, bulb, group 3, except green onion	0.10
Vegetable, cucurbit, group 9	0.3
Vegetable, foliage of legume, group 7	8.0
Vegetable, fruiting, group 8	0.4
Vegetable, leafy, except brassica, group 4	8.0
Vegetable, leaves of root and tuber, group 2	10.0
Vegetable, legume, edible podded, subgroup 6A	0.30
Vegetable, root and tuber, group 1	0.10
Watercress	8.0
Wax jambu	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[72 FR 68540, Dec. 5, 2007]

§ 180.496 Thiazopyr; tolerances for residues.

Tolerances are established for combined residues of the herbicide thiazopyr (3-pyridinecaroxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester) and its metabolites determined as 2-(difluoromethyl)-6-(trifluoromethyl)-3,4,5-pyridinetricarboxylic acid, all expressed as the parent equivalents in or on the following raw agricultural commodities:

Commodities	Parts per million
Grapefruit	0.05
Orange, sweet	0.05

[62 FR 9978, Mar. 5, 1997]

§ 180.497 Clofencet; tolerances for residues.

(a) *Tolerances—general.* Tolerances are established for the plant growth regulator (hybridizing agent) clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5 dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid in or on the following raw agricultural commodities:

Commodities	Parts per million
Cattle, fat	0.04
Cattle, kidney	10.0
Cattle, meat byproducts, except kidney	0.5
Cattle, meat	0.15
Egg	1.0
Goat, fat	0.04
Goat, kidney	10.0
Goat, meat byproducts, except kidney	0.5
Goat, meat	0.15
Hog, fat	0.04
Hog, kidney	10.0
Hog, meat byproducts, except kidney	0.5
Hog, meat	0.15
Horse, fat	0.04
Horse, kidney	10.0
Horse, meat byproducts, except kidney	0.5
Horse, meat	0.15
Milk	0.02
Poultry, fat	0.04
Poultry, meat byproducts	0.20
Poultry, meat	0.15

Commodities	Parts per million
Sheep, fat	0.04
Sheep, kidney	10.0
Sheep, meat byproducts, except kidney	0.5
Sheep, meat	0.15
Wheat, forage	10.0
Wheat, grain	250.0
Wheat, hay	40.0
Wheat, straw	50.0

(b) *Tolerances for indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the plant growth regulator (hybridizing agent) clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid in or on the following raw agricultural commodities when present therein as a result of the application of clofencet to the growing crops in paragraph (a) of this section:

Commodities	Parts per million
Grain, cereal, forage, fodder and straw, group 16, except rice, sweet corn, wheat, and wild rice; forage	4.0
Grain, cereal, forage, fodder and straw, group 16, except rice, sweet corn, wheat, and wild rice; hay	15.0
Grain, cereal, forage, fodder and straw, group 16, except rice, sweet corn, wheat, and wild rice; stover	1.0
Grain, cereal, forage, fodder and straw, group 16, except rice, sweet corn, wheat, and wild rice; straw	4.0
Grain, cereal group 15, except rice, sweet corn, wheat, and wild rice	20.0
Soybean	30.0
Soybean, forage	10.0
Soybean, hay	10.0

[62 FR 9983, Mar. 5, 1997]

§ 180.498 Sulfentrazone; tolerances for residues.

(a)(1) *General.* A tolerance is established for combined residues of the herbicide sulfentrazone N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide and its major metabolite 3-hydroxymethyl sulfentrazone N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide in or on the following raw agricultural commodity:

Commodity	Parts per million
Soybean, seed	0.05

(2) Tolerances are established for combined residues of the herbicide sulfentrazone and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide in or on the following food commodities:

Commodity	Parts per million
Asparagus	0.15
Bean, lima, succulent	0.15
Cabbage	0.20
Corn, field, forage	0.20
Corn, field, grain	0.15
Corn, field, stover	0.30
Horseradish	0.20
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Peanut	0.20
Peanut, meal	0.40
Peppermint, tops	0.30
Potato	0.15
Spearmint, tops	0.30
Sugarcane, cane	0.15
Sugarcane, molasses	0.20
Sunflower, seed	0.20

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide *N*-[2,4-dichloro-5-[4- (difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-y-l]phenyl] methanesulfonamide and its metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances expire and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Bean, succulent seed without pod (lima bean & cowpea)	0.1	12/31/07
Flax, seed	0.20	12/31/10
Strawberry	0.60	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for inadvertent and indirect combined residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and 3-desmethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-l-yl]phenyl]methanesulfonamide) in or on the following raw agricultural commodities when present therein as a result of the application of sulfentrazone to growing crops.

Commodity	Parts per million
Grain, cereal (excluding sweet corn), Hulls	0.30
Grain, cereal, forage, fodder and atraw, group 16, except sweet corn; forage	0.2
Grain, cereal, forage, fodder and atraw, group 16, except sweet corn; hay	0.2
Grain, cereal, forage, fodder and atraw, group 16, except sweet corn; stover	0.1
Grain, cereal, forage, fodder and atraw, group 16, except sweet corn; straw	0.6
Grain, cereal, group 15, except sweet corn	0.1
Grain, cereal, group 15, except sweet corn; bran	0.15

[62 FR 10708, Mar. 10, 1997, as amended at 64 FR 51067, Sept. 21, 1999; 65 FR 67279, Nov. 9, 2000; 65 FR 82940, Dec. 29, 2000; 66 FR 39658, Aug. 1, 2001; 67 FR 46884, July 17, 2002; 67 FR 54118, Aug. 21, 2002; 68 FR 2247, Jan. 16, 2003; 68 FR 55280, Sept. 24, 2003; 69 FR 29459, May 24, 2004; 69 FR 71717, Dec. 10, 2004; 70 FR 7047, Feb. 10, 2005; 72 FR 71802, Dec. 19, 2007]

§ 180.499 Propamocarb hydrochloride, tolerances for residues.

(a) *General.* Tolerances are established for the residues of propyl[3-(dimethylamino)propyl]carbamate monohydrochloride also known as propamocarb hydrochloride in or on the following raw agricultural commodity:

Commodity	Parts per million
Lettuce, head	50
Lettuce, leaf	90
Potato	0.06
Tomato, paste	5.0
Vegetable, cucurbit, group 9	1.5
Vegetable, fruiting, group 8	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerance with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 15620, Apr. 2, 1997, as amended at 62 FR 26966, May 16, 1997; 63 FR 32136, June 12, 1998; 64 FR 16843, Apr. 7, 1999; 65 FR 58399, Sept. 29, 2000; 66 FR 37598, July 19, 2001; 66 FR 48585, Sept. 21, 2001; 67 FR 35049, May 17, 2002; 69 FR 47022, Aug. 4, 2004; 70 FR 7047, Feb. 10, 2005]

§ 180.500 Imazapyr; tolerances for residues.

(a) *General.* Tolerances are being established for residues of the herbicide imazapyr, [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid], applied as the acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.20
Cattle, meat	0.05
Cattle, meat byproducts, except kidney	0.05
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Fish	1.0
Goat, fat	0.05
Goat, kidney	0.20
Goat, meat	0.05
Goats, meat byproducts, except kidney	0.05
Grass, forage	100
Grass, hay	30
Horse, fat	0.05
Horse, kidney	0.20
Horse, meat	0.05
Horse, meat byproducts, except kidney	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, kidney	0.20
Sheep, meat	0.05
Sheep, meat byproducts, except kidney	0.05
Shellfish	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 55484, Sept. 26, 2003]

§ 180.501 Hydroprene; tolerances for residues.

(a) *General.* A tolerance of 0.2 part per million is established for residues of hydroprene [(S)-(Ethyl (2E,4E,7S)-

3,7,11-trimrthyl-2,4-dodecadienoate)], (CAS Reg. No. 65733–18–8) on food commodities in food-handling establishments in accordance with the following prescribed conditions:

(1) Application shall be limited to spot, crack and crevice, perimeter and ultra low volume (ULV) fogging treatment in food storage or food-handling establishments, including warehouses, food service, manufacturing, and processing establishments such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries where food and food products are held, processed, and served: Provided that the food is removed or covered prior to such use, and food-processing surfaces are covered during treatment or thoroughly cleaned before using, or in the case of point-source device treatments, devices must not come into direct contact with food preparation surfaces and must be in a minimum distance of 3 feet from exposed foods.

(2) To assure safe use of the insect growth regulator, the label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 61647, Nov. 19, 1997, as amended at 71 FR 74818, Dec. 13, 2006]

§ 180.502 Aminoethoxyvinylglycine hydrochloride (aviglycine HCl); tolerances for residues.

(a) *General.* Tolerances are established for residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl) in or on the following food commodities:

Commodity	Parts per million
Apple	0.08
Fruit, stone, group 12, except cherry	0.170
Pear	0.08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 24838, May 7, 1997, as amended at 64 FR 31129, June 10, 1999; 66 FR 36481, 36484, July 12, 2001; 69 FR 7606, Feb. 18, 2004]

§ 180.503 Cymoxanil, tolerance for residues.

(a) *General.* Tolerances are established for residues of the fungicide, cymoxanil, 2-cyano -N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide, in or on the following food commodities:

Commodity	Parts per million
Caneberry, subgroup 13A-07	4.0
Cilantro, leaves	19
Hop, dried cones	7.0
Leafy greens, subgroup 4A	19
Leaf petioles, subgroup 4B	6.0
Lychee [1]	1.0
Onion, bulb, subgroup 3-07A	0.05
Onion, green, subgroup 3-07B	1.1
Potato	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.2

[1] There is no U.S. registration for lychee.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with a regional registration.* Tolerances with a regional registration as defined in § 180.1(n) are established for the residues of the fungicide cymoxanil, 2-cyano -*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide) in or on the raw agricultural commodities:

Commodity	Parts per million
Grape	0.10

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 26411, May 14, 1997, as amended at 62 FR 39956, July 25, 1997; 63 FR 24949, May 6, 1998; 63 FR 66464, Dec. 2, 1998; 64 FR 6539, Feb. 10, 1999; 64 FR 47689, Sept. 1, 1999; 66 FR 37598, July 19, 2001; 67 FR 35049, May 17, 2002; 68 FR 41936, July 16, 2003; 70 FR 7047, Feb. 10, 2005; 72 FR 37646, July 11, 2007; 73 FR 58885, Oct. 8, 2008]

§ 180.504 [Reserved]

§ 180.505 Emamectin; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4′-deoxy-4′-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}) in or on the following commodities:

Commodity	Parts per million
Almond, hulls	0.20
Apple, wet pomace	0.075
Cotton, gin byproducts	0.050
Cotton, undelinted seed	0.025
Fruit, pome, group 11	0.025
Nut, tree, group 14	0.02
Pistachio	0.02
Tomato, paste	0.150
Turnip, greens	0.050
Vegetable, Brassica, leafy, group 5	0.050
Vegetable, fruiting, group 8	0.020
Vegetable, leafy, except Brassica, group 4	0.100

(2) Tolerances are also established for combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in/on the following commodities when present therein as a result of the application of emamectin to crops listed in the table in paragraph (a)(1) of this section:

Commodity	Parts per million
Cattle, fat	0.010
Cattle, liver	0.050
Cattle, meat	0.003
Cattle, meat byproducts, except liver	0.020
Goat, fat	0.010
Goat, liver	0.050
Goat, meat	0.003
Goat, meat byproducts, except liver	0.020
Hog, fat	0.003
Hog, liver	0.020
Hog, meat	0.002
Hog, meat byproducts (except liver)	0.005
Horse, fat	0.010
Horse, liver	0.050
Horse, meat	0.003
Horse, meat byproducts, except liver	0.020
Milk	0.003
Sheep, fat	0.010
Sheep, liver	0.050
Sheep, meat	0.003
Sheep, meat byproducts, except liver	0.020

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* [Reserved]

[71 FR 18649, Apr. 12, 2006, as amended at 74 FR 2873, Jan. 16, 2009]

§ 180.506 Cyclanilide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, cyclanilide, [1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid] determined as 2,4-dichloroaniline (calculated as cyclanilide) in or on the following food commodities and processed feed:

Commodity	Parts Per Million
Cattle, fat	0.10
Cattle, meat	0.02
Cattle, meat byproducts, except kidney	0.2
Cattle, kidney	2.0
Cotton, undelinted seed	0.60
Cotton, gin byproducts	25.0
Goat, fat	0.10
Goat, meat	0.02
Goat, meat byproducts, except kidney	0.20
Goat, kidney	2.0
Horse, fat	0.10
Horse, meat	0.02
Horse, meat byproducts, except kidney	0.20
Horse, kidney	2.0
Hog, fat	0.10
Hog, meat	0.02
Hog, meat byproducts, except kidney	0.20
Hog, kidney	2.0
Milk	0.04
Sheep, fat	0.10
Sheep, meat	0.20
Sheep, meat byproducts, except kidney	0.20
Sheep, kidney	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 28355, May 23, 1997; 62 FR 34182, June 25, 1997]

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide, azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate] in or on the following food commodities and processed food:

Commodity	Parts per million
Acerola	2.0
Almond, hulls	4.0
Animal feed, nongrass, forage, group 18	45
Animal feed, nongrass, hay, group 18	120
Artichoke, globe	4.0
Asparagus	0.04
Atemoya	2.0
Avocado	2.0
Banana (pre-harvest and post harvest)	2.0
(of which not more than 0.1 is contained in the pulp)	
Barley, bran	0.2
Barley, forage	25
Barley, grain	0.1
Barley, hay	15.0
Barley, straw	4.0
Biriba	2.0
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	25
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	5.0
Canistel	2.0
Canola, seed	1.0
Citrus, dried pulp	20.0
Citrus, oil	40.0
Cherimoya	2.0
Coriander, leaves	30.0
Corn, field, forage	12.0
Corn, field, grain	0.05
Corn, field, refined oil	0.3
Corn, field, stover	25.0
Corn, pop, grain	0.05
Corn, pop, stover	25.0
Corn, sweet, forage	12.0
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	25.0
Cotton, gin byproducts	45
Cotton, undelinted seed	0.6
Crambe, seed	0.5
Cranberry	0.50
Cucurbits	0.3
Custard apple	2.0
Feijoa	2.0
Flax, seed	0.5
Fruit, citrus, group 10	10.0
Fruit, stone	1.5
Grain, aspirated fractions	420
Grape	1.0
Grass, forage [1]	15
Grass, hay [1]	20
Guava	2.0
Herb Subgroup 19A, dried leaves	260
Herb Subgroup 19A, fresh leaves	50
Hop, dried cones	20.0
Ilama	2.0
Jaboticaba	2.0
Jackfruit	2.0
Juneberry	3.0
Lingonberry	3.0
Longan	2.0
Loquat	2.0
Lychee	2.0
Mango	2.0
Mustard, field, seed	0.5
Mustard, Indian, seed	0.5
Mustard, seed	0.5
Nut, tree, group 14	0.02
Okra	2.0
Onion, bulb	1.0
Onion, green	7.5
Passionfruit	2.0
Pawpaw	2.0
Papaya	2.0
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
Pea and bean, succulent shelled, subgroup 6B	0.5
Peanut	0.2
Peanut, refined oil	0.6
Peanut, hay	15.0
Pecan	0.01
Peppermint, tops	30
Persimmon	2.0
Pistachio	0.50
Potato	0.03
Pulasan	2.0
Rambutan	2.0
Rapeseed, Indian	0.5
Rapeseed, seed	0.5
Rice, grain	5.0
Rice, hulls	20
Rice, straw	12
Rice, wild, grain	5.0
Safflower, seed	0.5
Salal	3.0
Sapodilla	2.0
Sapote, black	2.0
Sapote, mamey	2.0
Sapote, white	2.0
Sorghum, forage	25
Sorghum, grain	11
Sorghum, stover	40
Soursop	2.0
Soybean, hay	55.0
Soybean, hulls	1.0
Soybean, seed	0.5
Spanish lime	2.0
Spearmint, tops	30
Spice Subgroup 19B, except black pepper	38
Star apple	2.0
Starfruit	2.0
Strawberry	10
Sugar apple	2.0
Sunflower, seed	0.5
Tamarind	2.0
Tomato	0.2
Tomato, paste	0.6
Turnip, greens	25
Vegetable, foliage of legume, group 7	30.0
Vegetable, fruiting, group 8, except tomato	2.0
Vegetable, leafy, except brassica, group 4	30.0
Vegetable, leaves of root and tuber, group 2	50.0
Vegetable, legume, edible podded, subgroup 6A, except soybean	3.0
Vegetable, root, subgroup 1A	0.5
Vegetable, tuberous and corm, subgroup 1C	0.03
Watercress	3.0
Wax jambu	2.0
Wheat, bran	0.20

Commodity	Parts per million
Wheat, forage	25
Wheat, grain	0.10
Wheat, hay	15
Wheat, straw	4.0

(2) Tolerances are established for residues of the fungicide, azoxystrobin [methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in or on the following food commodities.

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.01
Cattle, meat byproducts	0.07
Goat, fat	0.03
Goat, meat	0.01
Goat, meat byproducts	0.07
Hog, fat	0.010
Hog, meat	0.01
Hog, meat byproducts	0.010
Horse, fat	0.03
Horse, meat	0.01
Horse, meat byproducts	0.07
Milk.	0.006
Sheep, fat	0.03
Sheep, meat	0.01
Sheep, meat byproducts	0.07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 32235, June 13, 1997]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.507, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.509 Mefenpyr-diethyl; tolerance for residues.

(a) *General.* Tolerances are established for residues of the herbicide safener, mefenpyr-diethyl, 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester and its 2,4-dichlorophenyl-pyrazoline metabolites, when applied at a rate no greater than 0.053 pound safener per acre per growing season in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.2
Barley, straw	0.5
Canola, seed	0.02
Cattle, meat byproducts	0.1
Goat, meat byproducts	0.1
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Sheep, meat byproducts	0.1
Wheat, forage	0.2
Wheat, grain	0.05
Wheat, hay	0.2
Wheat, straw	0.5
Soybean, forage	0.1
Soybean, hay	0.1
Soybean, seed	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[73 FR 74977, Dec. 10, 2008]

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide pyriproxyfen 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxypyridine in or on the following food commodities:

Commodity	Parts per million
Acerola	0.10
Almond, hulls	2.0
Animal feed, nongrass, group 18, forage	0.70
Animal feed, nongrass, group 18, hay	1.1
Animal feed, nongrass, group 18, seed	2.0
Apple, wet pomace	0.8
Atemoya	0.20
Avocado	1.0
Banana	0.20
Beet, sugar, dried pulp	3.0
Biriba	0.20
Brassica, head and stem, subgroup 5A	0.70
Brassica, leafy greens, subgroup 5B	2.0
Bushberry subgroup 13B	1.0
Cacao bean, dried	0.02
Caneberry, subgroup 13-A	1.0
Canistel	1.0
Canola, seed	0.20
Cherimoya	0.20
Citrus, oil	20
Citrus, dried pulp	2.0
Citrus hybrids	0.30
Coffee, instant	0.10
Coffee, green bean	0.02
Cotton, gin byproducts	2.0
Cotton, undelinted seed	0.05
Cranberry	1.0
Custard apple	0.20
Date	0.30
Feijoa	0.10
Fig	0.30
Fig, dried fruit	1.0
Fruit, citrus	0.3
Fruit, pome	0.2

Commodity	Parts per million
Fruit, stone, group 12	1.0
Grain, cereal, group 15	1.1
Grain, cereal, forage, fodder and straw, group 16	1.1
Grape	2.5
Grass, forage, fodder, and hay, group 17, forage	0.70
Grass, forage, fodder, and hay, group 17, hay	1.1
Guava	0.10
llama	0.20
Jaboticaba	0.10
Juneberry	1.0
Lingonberry	1.0
Loganberry	0.30
Lychee	0.30
Mango	1.0
Nut, tree, group 14	0.02
Okra	0.02
Olive	1.0
Olive, oil	2.0
Onion, bulb	0.15
Papaya	1.0
Passionfruit	0.10
Pawpaw	1.0
Peanut	0.20
Pineapple	0.30
Pineapple, process residue	1.1
Pistachio	0.02
Pomegranate	0.20
Potato, chips	0.75
Potato, granules/flakes	0.75
Potato, wet peel	0.75
Pulasan	0.30
Rambutan	0.30
Rice, hulls	5.5
Safflower, seed	0.20
Salal	1.0
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sapote, white	0.30
Sesame, seed	0.02
Soursop	0.20
Spanish lime	0.30
Star apple	1.0
Starfruit	0.10
Strawberry	0.30
Sugar apple	0.20
Sugarcane	1.1
Tea	0.02
Vegetable, bulb, group 3, except onion, bulb	0.70
Vegetable, cucurbit, group 9	0.10
Vegetable, fruiting, group 8	0.2
Vegetable, legume, group 6	0.20
Vegetable, root and tuber, group 1	0.15
Walnut	0.02
Wax jambu	0.10

(2) A tolerance of 0.10 parts per million is established for all food commodities as a result of the proposed use of NYLAR in food handling establishments where food and food products are held, prepared, processed or served. Application is limited to space, general surface, spot, and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and served. Space and general surface application may be used only when the facility is not in operation provided exposed food is covered or removed from the area being treated prior to application. Spot, and/or crack and crevice treatment may be used while the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Food contact surfaces should be thoroughly washed with an effective cleaning compound and rinced with potable water after use of the product. To assure safe use of this additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insect growth regulator pyriproxyfen, in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Bean, succulent	0.10	6/30/08
Celery	2.50	6/30/07
Strawberry	0.30	12/31/07

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 10233, Mar. 3, 1999]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.510, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.511 Buprofezin; tolerances for residues.

(a) *General.* Tolerances are established for residues of buprofezin, 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4*H*-1,3,5-thiadiazin-4-one, in or on the following food commodities:

Commodity	Parts per million
Acerola	0.30
Almond	0.05
Almond, hulls	2.0

Commodity	Parts per million
Apricot	9.0
Atemoya	0.30
Avocado	0.30
Banana	0.20
Bean, snap, succulent	0.02
Berry, low growing, subgroup 13-07G	2.5
Birida	0.30
Canistel	0.90
Cattle, fat	0.05
Cattle, kidney	0.05
Cattle, liver	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cherimoya	0.30
Citrus, dried pulp	7.5
Citrus, oil	80
Cotton, gin byproducts	20.0
Cotton, undelinted seed	0.35
Custard apple	0.30
Feijoa	0.30
Fruit, citrus, group 10	2.5
Fruit, pome, group 11	4.0
Fruit, stone, group 12, except apricot and peach	1.9
Goat, fat	0.05
Goat, kidney	0.05
Goat, liver	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Grape	2.5
Guave	0.30
Hog, fat	0.05
Hog, kidney	0.05
Hog, liver	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, kidney	0.05
Horse, liver	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Llama	0.30
Jaboticaba	0.30
Lettuce, head	6.0
Loganberry	0.30
Lychee	0.30
Mango	0.90
Milk	0.01
Okra	4.0
Olive	3.5
Olive, oil	4.8
Papaya	0.90
Passionfruit	0.30
Peach	9.0
Pepper, nonbell	4.0
Pistachio	0.05
Pulasan	0.30
Radicchio	6.0
Rambutan	0.30
Sapodilla	0.90
Sapote, black	0.90
Sapote, mamey	0.90
Sheep, fat	0.05
Sheep, kidney	0.05
Sheep, liver	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soursop	0.30
Spanish lime	0.30
Star apple	0.90
Starfruit	0.30
Sugar apple	0.30
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8, except nonbell pepper	1.3
Vegetable, leafy, except Brassica, group 4, except head lettuce and radicchio	35
Wax jambu	0.30

(b) *Section 18 emergency exemption.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 40741, July 30, 1997, as amended at 63 FR 33585, June 19, 1998; 63 FR 41727, Aug. 5, 1998; 64 FR 45887, Aug. 23, 1999; 64 FR 59655, Nov. 3, 1999; 65 FR 52947, Aug. 31, 2000; 66 FR 46389, Sept. 5, 2001; 68 FR 37771, June 25, 2003; 70 FR 17907, Apr. 8, 2005; 71 FR 55313, Sept. 22, 2006; 72 FR 35187, June 27, 2007; 73 FR 19161, Apr. 9, 2008]

§ 180.512 [Reserved]

§ 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] in or on the following raw agricultural commodities:

Commodity	Parts per million
Vegetable, fruiting, group 8	1.0

(2) A tolerance of 0.01 parts per million is established for residues of chlorfenapyr in or on all food commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling areas where food/feed products are prepared, held, processed, or served and in accordance with the following prescribed conditions:

(i) Application shall be no greater than a 0.5% active ingredient solution for spot crack and crevice use in food/feed handling establishments, where food and food products are held, processed, prepared and/or served.

(ii) Application may only be undertaken when the facility is not in operation, and provided exposed food has been covered, or removed from the area being treated prior to application.

(iii) Food contact surfaces and equipment should be throughly washed with an effective cleaning compound, and rinsed with potable water after each use of the product.

(iv) Contamination of food or food contact surfaces shall be avoided. Application excludes any direct application to any food, food packaging, or any food contact surfaces.

(v) To assure safe use, the label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 55527, Sept. 26, 2003, as amended at 70 FR 3654, Jan. 26, 2005]

§ 180.514 Cloransulam-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, cloransulam-methyl, *N*-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro-(1,2,4)-triazolo[1,5c]-pyrimidine-2-sulfonamide, plus its acid, cloransulam, calculated as parent ester in or on the following raw agricultural commodities:

Commodity	Parts per million
Soybean, forage	0.1
Soybean, hay	0.2
Soybean, seed	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 49163, Sept. 19, 1997]

§ 180.515 Carfentrazone-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate) and its metabolite: carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[-4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on the following raw agricultural commodities:

Commodity	Parts per million
Acerola	0.10
Almond, hulls	0.20
Atemoya	0.10
Avocado	0.10
Banana	0.20
Barley, bran	0.80
Barley, flour	0.80
Berry group 13	0.10
Birida	0.10
Borage	0.10
Cacao bean, bean	0.10
Cactus	0.10
Caneberry subgroup 13A	0.1
Canistel	0.10
Canola	0.10
Cherimoya	0.10
Coconut	0.10
Coffee, bean, green	0.10
Corn, field, forage	0.20
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husk removed	0.10
Cotton, gin byproducts	10
Cotton, undelinted seed	0.20
Cotton, hulls	0.60
Cotton, meal	0.35
Cotton, refined oil	1.0
Crambe, seed	0.10
Custard apple	0.10
Date, dried fruit	0.10
Fat (cattle, goat, horse, and sheep)	0.10
Feijoa	0.10
Fig	0.10
Fish	0.30
Flax, seed	0.10
Fruit, citrus, group 10	0.10
Fruit, pome, group 11	0.10
Fruit, stone, group 12	0.10
Grain, aspirated grain fractions	1.8
Grain, cereal, forage, fodder and straw group 16, except corn and sorghum; forage	1.0
Grain, cereal, forage, fodder and straw, group 16, hay	0.30
Grain, cereal, forage, fodder and straw, group 16, stover	0.30
Grain, cereal, forage, fodder and straw, group 16, except rice; straw	0.10
Grain, cereal, group 15	0.10
Grain, cereal, group 15 (except rice grain and sorghum grain)	0.10
Grain, cereal, stover	0.80
Grain, cereal, straw	3.0
Grape	0.10
Grass, forage	5.0
Grass, hay	8.0
Guava	0.10
Herbs and spices group 19	2.0
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.10
Hop, dried cones	0.10
Horseradish	0.10
Ilama	0.10
Jaboticaba	0.10

Commodity	Parts per million
Juneberry	0.10
Kava, roots	0.10
Kiwifruit	0.10
Lingonberry	0.10
Longan	0.10
Lychee	0.10
Mango	0.10
Meat, (cattle, goat, horse, and sheep)	0.10
Meat, byproducts, cattle, goat, horse, and sheep)	0.10
Milk	0.05
Millet, flour	0.80
Mustard, seed	0.10
Noni	0.10
Nut, tree, group 14	0.10
Oat, flour	0.80
Okra	0.10
Olive	0.10
Palm heart	0.10
Palm heart, leaves	0.10
Papaya	0.10
Passionfruit	0.10
Pawpaw	0.10
Peanut	0.10
Peanut, hay	0.10
Persimmon	0.10
Pistachio	0.10
Pomegranate	0.10
Poultry, meat byproducts	0.10
Pulasan	0.10
Pummelo	0.10
Rambutan	0.10
Rapeseed, forage	0.10
Rapeseed, seed	0.10
Rice, grain	1.3
Rice, hulls	3.5
Rice, straw	1.0
Rye, bran	0.80
Rye, flour	0.80
Safflower, seed	0.10
Salal	0.10
Sapodilla	0.10
Sapote, black	0.10
Sapote, mamey	0.10
Shellfish	0.30
Sorghum, forage	0.20
Sorghum, grain	0.25
Sorghum, sweet	0.10
Soursop	0.10
Soybean, seed	0.10
Spanish lime	0.10
Star apple	0.10
Starfruit	0.10
Stevia	0.10
Strawberry	0.10
Strawberrypear	0.10
Sugar apple	0.10
Sugarcane	0.15
Sunflower, seed	0.10
Tea, dried	0.10
Ti, leaves	0.10
Ti, roots	0.10
Vanilla	0.10
Vegetable, brassica, leafy, group 5	0.10
Vegetable, bulb, group 3	0.10
Vegetable, cucurbit, group 9	0.10
Vegetable, foliage of legume, except soybean, subgroup 7A	0.10
Vegetable, fruiting, group 8	0.10
Vegetable, leafy, except brassica, group 4	0.10
Vegetable, leaves of root and tuber, group 2	0.10
Vegetable, legume, group 6	0.10
Vegetable, root and tuber, group 1	0.10
Wasaba, roots	0.10
Wax jambu	0.10
Wheat, bran	0.80
Wheat, flour	0.80
Wheat, germ	0.80
Wheat, middlings	0.80
Wheat, shorts	0.80

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide carfentrazone-ethyl and its chloropropionic acid metabolite in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Hop, dried cones	0.30	6/30/05
Tomato, paste	0.60	6/30/07
Tomato, puree	0.60	6/30/07
Vegetable, fruiting, group 8	0.10	6/30/07

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 52180, Sept. 30, 1998, as amended at 63 FR 65078, Nov. 25, 1998; 64 FR 45890, Aug. 23, 1999; 65 FR 48626, Aug. 9, 2000; 66 FR 39647, 39682, Aug. 1, 2001; 67 FR 35050, May 17, 2002; 67 FR 40211, June 12, 2002; 68 FR 37765, June 25, 2003; 69 FR 29459, May 24, 2004; 69 FR 58078, Sept. 29, 2004; 73 FR 9221, Feb. 20, 2008]

§ 180.516 Fludioxonil; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on the following commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18	0.01
Avocado	0.45
Bean, dry	0.4
Bean, succulent	0.4
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10
Bushberry subgroup 13B	2.0
Caneberry subgroup 13A	5.0
Canistel	0.45
Citrus, oil	500
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Flax, seed	0.05

Commodity	Parts per million
Fruit, citrus, group 10	10
Fruit, pome, group 11	5.0
Fruit, stone, group 12	5.0
Grain, cereal	0.02
Grain, cereal, forage, fodder, and straw, group 16	0.01
Grape	1.0
Grass, forage, fodder and hay, group 17	0.01
Herb subgroup 19A, dried	65
Herb subgroup 19A, fresh	10
Herbs and spices group 19	0.02
Juneberry	2.0
Kiwifruit	20
Leafy greens subgroup 4A, except spinach	30
Lingonberry	2.0
Longan	1.0
Lychee	1.0
Mango	0.45
Melon subgroup 9A	0.03
Onion, bulb	0.20
Onion, green	7.0
Papaya	0.45
Peanut	0.01
Peanut, hay	0.01
Pistachio	0.10
Pomegranate	5.0
Pulasan	1.0
Rambutan	1.0
Rapeseed, forage	0.01
Rapeseed, seed	0.01
Safflower, seed	0.01
Salal	2.0
Sapodilla	0.45
Sapote, black	0.45
Sapote, mamey	0.45
Spanish lime	1.0
Star apple	0.45
Strawberry	2.0
Sunflower, seed	0.01
Tomatillo	0.50
Tomato	0.50
Turnip, greens	10
Vegetable, bulb, group 3	0.02
Vegetable, cucurbit, crop group 9	0.45
Vegetable, foliage of legume, group 7	0.01
Vegetable, fruiting, group 8	0.01
Vegetable, leafy, except brassica, group 4	0.01
Vegetable, leaves of root and tuber, crop group 2	30
Vegetable, legume, group 6	0.01
Vegetable, root and tuber, group 1	0.02
Vegetable, root, except sugar beet, subgroup 1B	0.75
Vegetable, tuberous and corn, except potato, subgroup 1D	3.5
Watercress	7.0
Yam, true, tuber	8.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Starfruit	10	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 56082, Oct. 29, 1997]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.516, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.517 Fipronil; tolerances for residues.

(a) *General.* Therefore, tolerances are established for combined residues of the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) and its metabolites 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1H-pyrazole-3-carbonitrile and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile and its photodegradate 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)]-1H-pyrazole-3-carbonitrile in or on the following items at the levels specified:

Commodity	Parts per million
Corn, field, grain	0.02
Corn, field, stover	0.30
Corn, field, forage	0.15
Egg	0.03
Fat of cattle, goat, horse and sheep	0.40
Hog, fat	0.04
Hog, liver	0.02
Hog, meat	0.01
Hog, meat byproducts, except liver	0.01
Liver of cattle, goat, horse and sheep	0.10
Milk, fat (reflecting 0.05 ppm in whole milk)	1.50
Meat Byproducts, except liver of cattle, goat, horse and sheep	0.04
Meat of cattle, goat, horse and sheep	0.04
Potato	0.03
Potato, wet peel	0.10
Poultry, fat	0.05
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Rice, grain	0.04
Rice, straw	0.10

(b) *Section 18 emergency exemptions.*. Time-limited tolerances are established for combined residues of the insecticide, fipronil, 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile and its 2 metabolites MB45950 (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile) and MB46136 (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) and its photodegradate MB46513 (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)]-1H-pyrazole-3-carbonitrile), in connection with use of the pesticide under Section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the table for this paragraph.

Commodity	Parts per million	Expiration/revocation date
Rutabaga	1.0	12/31/10
Turnip	1.0	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for combined indirect or inadvertent residues of the insecticide fipronil and its metabolites and photodegradate in or on food commodities when present therein as a result of the application of fipronil to growing crops listed in paragraphs (a) and (b) of this section and other nonfood crops to read as follows:

Commodity	Parts per million
Wheat, forage	0.02
Wheat, grain	0.005
Wheat, hay	0.03
Wheat, straw	0.03

[62 FR 62979, Nov. 26, 1997, as amended at 63 FR 38495, July 17, 1998; 72 FR 46913, Aug. 22, 2007]

§ 180.518 Pyrimethanil; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of the fungicide pyrimethanil 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond	0.20
Almond, hulls	12
Apple, wet pomace	40
Banana	0.10
Citrus, oil	150
Fruit, citrus, group 10 postharvest	10
Fruit, pome, group 11 (pre-harvest and post-harvest)	14
Fruit, stone, group 12, except cherry	3.0
Grape	5.0
Grape, raisin	8.0
Onion, bulb	0.10
Onion, green	2.0
Pistachio	0.20
Strawberry	3.0
Tomato	0.50
Vegetable, tuberous and corm, subgroup 1C	0.05

(2) Tolerances are established for the combined residues of the fungicide pyrimethanil 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine and its metabolite 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, kidney	2.5
Cattle, meat	0.01
Cattle, meat byproducts, except kidney	0.01
Goat, fat	0.01
Goat, kidney	2.5
Goat, meat	0.01
Goat, meat byproducts, except kidney	0.01
Horse, fat	0.01
Horse, kidney	2.5
Horse, meat	0.01
Horse, meat byproducts, except kidney	0.01
Sheep, fat	0.01
Sheep, kidney	2.5
Sheep, meat	0.01
Sheep, meat byproducts, except kidney	0.01

(3) Tolerances are established for the combined residues of the fungicide pyrimethanil 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol in or on the following commodity:

Commodity	Parts per million
Milk	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[62 FR 63669, Dec. 2, 1997, as amended at 69 FR 52443, Aug. 26, 2004; 73 FR 64251, Oct. 29, 2008]

§ 180.519 Bromide ion and residual bromine; tolerances for residues.

(a) *General.* The food additives, bromide ion and residual bromine, may be present in water, potable in accordance with the following conditions:

(1) The food additives are present as a result of treating water aboard ships with a polybrominated ion-exchange resin (as a source of bromine) under the supervision of trained personnel.

(2) Residual bromine levels are controlled to not exceed 1.0 part per million (ppm) in the final treated water. Control is effected using calibrated recirculating or proportioning bromine feeder equipment and periodic checks of residual bromine using a bromine test kit. To assure safe use of the additives, the label and labeling of the disinfectant formulation containing the food additives shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

(3) No tolerance is established for bromide ion levels.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[41 FR 17893, Apr. 29, 1976. Redesignated at 41 FR 26568, June 28, 1976, and at 53 FR 24667, June 29, 1988. Redesignated and amended at 63 FR 34319, June 24, 1998; 71 FR 74818, Dec. 13, 2006]

§ 180.521 Fumigants for grain-mill machinery; tolerances for residues.

(a) *General.* Fumigants may be safely used in or on grain-mill machinery in accordance with the following prescribed conditions:

(1) The fumigants consist of methyl bromide.

(2) To assure safe use of the fumigant, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

(3) Residues of inorganic bromides (calculated as Br) in milled fractions derived from cereal grain from all fumigation sources, including fumigation of grain-mill machinery, shall not exceed 125 parts per million.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 49 FR 44459, Nov. 7, 1984. Further redesignated at 53 FR 24667, June 29, 1988, as amended at 54 FR 6130, Feb. 8, 1989. Further redesignated and amended at 63 FR 34319, June 24, 1998]

§ 180.522 Fumigants for processed grains used in production of fermented malt beverage; tolerances for residues.

(a) *General.* Fumigants for processed grain may be safely used, in accordance with the following conditions.

(1) *Methyl bromide.* Total residues of inorganic bromides (calculated as Br) from the use of this fumigant shall not exceed 125 parts per milion.

(2) Methyl bromide is used to fumigate corn grits and cracked rice in the production of fermented malt beverage.

(3) To assure safe use of the fumigant, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency, and the usage employed should conform with such label or labeling.

(4) The total residue of inorganic bromides in fermented malt beverage, resulting from the use of corn grits and cracked rice fumigated with the fumigant described in paragraph (a)(2) of this section plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under section 408 and/or 409 of the Act, does not exceed 25 parts per million bromide (calculated as Br).

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74818, Dec. 13, 2006]

§ 180.523 Metaldehyde; tolerances for residues.

(a) *General.* Tolerances are established for residues of the molluscicide metaldehyde in or on food commodities, as follows:

Commodity	Parts per million
Artichoke, globe	0.07
Berry group 13	0.15
Cactus	0.07
Fruit, citrus, group 10	0.26
Lettuce	1.73
Strawberry	6.25
Tomato	0.24
Vegetable, brassica, leafy, group 5	2.5
Watercress	3.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54963, Sept. 24, 2008]

§ 180.525 Resmethrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide resmethrin [5-(phenylmethyl)-3-furanyl] methyl 2,2-dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate in or on food commodities at 3.0 ppm resulting from use of the insecticide in food handling and storage areas as a space concentration for spot/or crack and crevice treatment and shall be limited to a maximum of 3.00 percent of the active ingredient by weight, and as a space treatment shall be limited to a maximum of 0.5 fluid ounce of 3.0 percent active ingredient by weight per 1000 cubic feet of space provided that the food is removed or covered prior to such use. To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74819, Dec. 13, 2006]

§ 180.526 Synthetic isoparaffinic petroleum hydrocarbons; tolerances for residues.

(a) *General.* Synthetic isoparaffinic petroleum hydrocarbons complying with 21 CFR 172.882 (a) and (b) may be safely used as a component of insecticide formulations for use on animal feed in an amount no greater than reasonably required to accomplish its intended effect as an adjuvant in the insecticide formulation and shall not be intended to accomplish any effect in animal feed. It is used or intended for use as a component of insecticide formulations used in compliance with regulations issued in 40 CFR part 180 and in this part.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[40 FR 14161, Mar. 28, 1975, as amended at 50 FR 2959, Jan. 23, 1985, and amended at 53 FR 24668, 24669, June 29, 1988. Redesignated and amended at 63 FR 34319, June 24, 1998]

§ 180.527 Flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-N-methylethyl benzenamine tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following commodities.

Commodity	Parts per million
Cattle, kidney	0.05
Corn, field, forage	0.4
Corn, field, grain	0.05
Corn, field, stover	0.4
Corn, sweet, forage	0.45
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.30
Goat, kidney	0.05
Hog, kidney	0.05
Horse, kidney	0.05
Sheep, kidney	0.05
Soybean, seed	0.1
Wheat, bran	0.80
Wheat, forage	6.0

Commodity	Parts per million
Wheat, grain	0.60
Wheat, hay	1.2
Wheat, straw	0.35

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances are established for combined residues of flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide, and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety, with regional registration.

Commodity	Parts per million
Grass, forage	7.0
Grass, hay	0.4

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities when present therein as a result of application of flufenacet to the growing crops in paragraph (a) of this section.

Commodity	Parts per million
Alfalfa, forage	0.1
Alfalfa, hay	0.1
Alfalfa, seed	0.1
Clover, forage	0.1
Clover, hay	0.1
Grain, cereal, group 15, except rice	0.1
Grain, cereal, forage, fodder, and straw, group 16, except rice	0.1
Grass, forage, fodder, and hay, group 17	0.1

[63 FR 26473, May 13, 1998, as amended by 63 FR 50791, Sept. 23, 1998; 64 FR 42846, Aug. 6, 1999; 65 FR 64366, Oct. 27, 2000; 68 FR 2247, Jan. 16, 2003; 68 FR 37759, June 25, 2003; 70 FR 37696, June 30, 2005; 71 FR 76200, Dec. 20, 2006; 72 FR 26310, May 9, 2007]

§ 180.530 2,2-Dimethyl-1,3-benzodioxol-4-ol methylcarbamate; tolerances for residues.

(a) *General.* (1) The insecticide 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate may be safely used in spot and/or crack and crevice treatments in animal feed handling establishments, including feed manufacturing and processing establishments, such as stores, supermarkets, dairies, meat slaughtering and packing plants, and canneries until the tolerance expiration/revocation date of April 26, 2005.

(2) The insecticide 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate may be safely used in spot and/or crack and crevice treatments in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries until the tolerance expiration/revocation date of April 26, 2005.

(3) To ensure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 34828, June 26, 1998, as amended at 69 FR 58083, Sept. 29, 2004]

§ 180.532 Cyprodinil; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the following food commodities:

Commodity	Parts per million
Almond	0.02
Almond, hulls	8.0
Apple, wet pomace	0.15
Avocado	1.2
Bean, dry	0.6
Bean, succulent	0.6
Brassica, head and stem, subgroup 5A	1.0
Brassica, leafy greens, subgroup 5B	10.0
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	10
Canistel	1.2
Cattle, meat byproducts	0.02
Citrus, dried pulp	8.0
Citrus, oil	340
Fruit, pome	0.1
Fruit, stone	2.0
Goat, meat byproducts	0.02
Grape	2.0
Grape, raisin	3.0

Commodity	Parts per million
Herb subgroup 19A, dried, except parsley	15.0
Herb subgroup 19A, fresh, except parsley	3.0
Horse, meat byproducts	0.02
Juneberry	3.0
Kiwifruit	1.8
Leafy greens subgroup 4A, except spinach	30
Lemon	0.60
Lime	0.60
Lingonberry	3.0
Longan	2.0
Lychee	2.0
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
Pistachio	0.10
Pulasan	2.0
Rambutan	2.0
Salal	3.0
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Sheep, meat byproducts	0.02
Spanish lime	2.0
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
Turnip, greens	10.0
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugarbeet, subgroup 1B	0.75
Watercress	20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 17706, Apr. 10, 1998]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.532, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.533 Esfenvalerate; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide esfenvalerate, ((*S*)-cyano-(3-phenoxyphenyl) methyl (*S*)-4-chloro-α-(1-methylethyl) benzeneacetate in or on the following raw agricultural commodities:

Commodity	Parts per million
Artichoke, globe	1.0
Beet, sugar, dried pulp	2.5
Beet, sugar, roots	0.5
Beet, sugar, tops	5.0
Egg	0.03
Kiwifruit	0.5
Kohlrabi	2.0
Lettuce, head	5.0
Mustard greens	5.0
Poultry, fat	0.3
Poultry, meat	0.03
Poultry, meat byproducts, except liver	0.3
Poultry, liver	0.03
Sorghum, forage	10.0
Sorghum, grain, grain	5.0
Sorghum, grain, stover	10.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 23401, Apr. 29, 1998, as amended at 63 FR 48615, Sept. 11, 1998]

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the following raw agricultural commodities.

Commodity	Parts per million
Barley, grain	0.5
Barley, hay	12.0
Barley, hay	20.0
Barley, straw	12.0
Cattle, fat	0.1
Cattle, kidney	1.5
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Corn, field, forage	1.0
Corn, field, grain	0.02
Corn, field, stover	0.5
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.02
Corn, sweet, stover	2.0
Fruit, pome, group 11	0.02
Garlic, bulb	0.03
Goat, fat	0.1
Goat, kidney	1.5
Goat, meat	0.1
Goat, meat byproducts	0.1
Grain, aspirated fractions	0.6
Grass, forage	120
Grass, hay	160
Hog, fat	0.1
Hog, kidney	1.5
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1

Commodity	Parts per million
Horse, kidney	1.5
Horse, meat	0.1
Horse, meat byproducts	0.1
Milk	0.3
Millet, forage	12.0
Millet, grain	0.5
Millet, hay	20.0
Millet, proso, straw	12.0
Oat, forage	12.0
Oat, grain	0.5
Oat, hay	20.0
Oat, straw	12.0
Onion, bulb	0.03
Shallot, bulb	0.03
Sheep, fat	0.1
Sheep, kidney	1.5
Sheep, meat	0.1
Sheep, meat byproducts	0.1
Sorghum, grain, forage	2.0
Sorghum, grain, grain	0.02
Sorghum, grain, stover	4.0
Wheat, forage	12.0
Wheat, grain	0.5
Wheat, hay	20.0
Wheat, straw	12.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 52169, Sept. 30, 1998, as amended at 64 FR 22799, Apr. 28, 1999; 66 FR 37598, July 19, 2001; 66 FR 47971, Sept. 17, 2001; 67 FR 46884, July 17, 2002; 67 FR 60146, Sept. 25, 2002; 68 FR 75438, Dec. 31, 2003; 69 FR 2074, Jan. 14, 2004; 70 FR 3649, Jan. 26, 2005; 70 FR 7047, Feb. 10, 2005; 71 FR 76204, Dec. 20, 2006; 72 FR 73635, Dec. 28, 2007]

§ 180.536 Triazamate; tolerances for residues.

(a) *General.* Time-limited tolerances are established for the combined residues of triazamate (RH-7988) ethyl(3-tert-butyl-1-dimethylcarbamoyl-1*H*-1,2,4-triazol-5-ylthio)acetate and its metabolite (RH0422) in or on the following commoditie(s):

Commodity	Parts per million	Expiration/ Revocation Date
Apple	0.1	12/31/01

(b) *Section 18 emergency exemptions.*

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 71026, Dec. 23, 1998]

§ 180.537 Isoxaflutole; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of isoxaflutole 5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione (RPA 202248), calculated as the parent compound, in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.04
Corn, field, grain	0.02
Corn, field, stover	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 50784, Sept. 23, 1998, as amended at 73 FR 75608, Dec. 12, 2008]

§ 180.538 Copper; tolerances for residues.

(a) *General.* A tolerance of 1 part per million is established in water, potable for residues of copper resulting from the use of the algicides or herbicides basic copper carbonate (malachite), copper sulfate, copper monoethanolamine, and copper triethanolamine to control aquatic plants in reservoirs, lakes, ponds, irrigation ditches, and other potential sources of potable water.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 74819, Dec. 13, 2006]

§ 180.539 d-Limonene; tolerances for residues.

(a) *General.* (1) The insecticide d-limonene may be safely used in insect-repellent tablecloths and in insect-repellent strips used in food- or feed-handling establishments.

(2) To assure safe use of the insect repellent, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33715, May 24, 2000, as amended at 70 FR 55268, Sept. 21, 2005]

§ 180.540 Fenitrothion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide fenitrothion, *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphorothioate, from the postharvest application of the insecticide to stored wheat in Australia, in or on the following food commodity:

Commodity	Parts per million
Wheat, gluten [1]	3.0

[1] There are no U.S. registrations on food commodities since 1987.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 54963, Sept. 24, 2008]

§ 180.541 Propetamphos; tolerances for residues.

(a) A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos ([(e)-]-methylethyl 3-[[(ethylamino) methoxyphosphinothioyl]oxy]-2-butenoate]) in food commodities exposed to the insecticide during treatment of food- or feed-handling establishments.

(1) Direct application shall be limited solely to spot and/or crack and crevice treatment in food-handling establishments where food and food products are held, processed, prepared, or served. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pin-stream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of food or food-contact surfaces.

(2) Direct application shall be limited solely to spot and/or crack and crevice treatment in feed-handling establishments where feed and feed products are held, processed, prepared, or sold. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pinstream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of feed or feed-contact surfaces.

(3) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33716, May 24, 2000]

§ 180.543 Diclosulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide diclosulam [*N*-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4] triazolo[1,5-*c*]pyrimidine-2-sulfonamide] in or on the following raw agricultural commodities as follows:

Commodity	Parts per million
Peanut	0.020
Soybean, seed	0.020

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 12134, Mar. 8, 2000]

§ 180.544 Methoxyfenozide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide methoxyfenozide per se; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the following food commodities:

Commodity	Parts per million
Acerola	0.4
Almond, hulls	25
Animal feed, nongrass, group 18, forage	50.0
Animal feed, nongrass, group 18, hay	150.0
Apple, wet pomace	7.0
Artichoke, globe	3.0
Avocado	0.6
Bean, dry, seed	0.24
Brassica, head and stem, subgroup 5A	7.0
Brassica, leafy greens, subgroup 5B	30
Bushberry subgroup 13-07B	3.0
Canistel	0.6
Cattle, fat	0.50
Cattle, meat	0.02
Coriander, leaves	30
Corn, field, forage	15
Corn, field, grain	0.05
Corn, field, refined oil	0.20
Corn, field, stover	125
Corn, sweet, forage	30
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	60
Cotton, gin byproducts	35
Cotton, undelinted seed	2.0
Cranberry	0.5
Feijoa	0.4
Fruit, pome, group 11	1.5
Fruit, stone, group 12, except plum, prune, fresh	3.0
Goat, fat	0.50
Goat, meat	0.02
Grain, aspirated fractions	2.0
Grape	1.0
Grape, raisin	1.5
Grass, forage, fodder and hay, group 17, forage	18.0
Grass, forage, fodder and hay, group 17, hay	30.0
Guava	0.4
Hog, fat	0.1
Hog, meat	0.02
Horse, fat	0.50
Horse, meat	0.02
Jaboticaba	0.4
Leaf petioles subgroup 4B	25
Leafy greens subgroup 4A	30
Longan	2.0
Lychee	2.0
Mango	0.6
Milk	0.10
Nut, tree, group 14	0.10
Okra	2.0
Onion, green, subgroup 3-07B	5.0
Papaya	0.6
Passionfruit	0.4
Pea and bean, succulent shelled, subgroup 6B	0.2
Pea, blackeyed, seed	4.0
Pea, southern, seed	4.0
Peanut	0.02
Peanut, hay	55.0
Peanut, oil	0.04
Peppermint, tops	7.0
Pistachio	0.10
Plum, prune, fresh	0.30
Poultry, fat	0.02
Poultry, meat	0.02
Pulasan	2.0
Rambutan	2.0
Sapodilla	0.6
Sapote, black	0.6
Sapote, mamey	0.6
Sheep, fat	0.50
Sheep, meat	0.02
Soybean, aspirated grain fractions	160
Soybean, forage	30
Soybean, hay	80
Soybean, hulls	2.0
Soybean, seed	1.0
Spanish lime	2.0
Spearmint, tops	7.0
Star apple	0.6
Starfruit	0.4
Strawberry	1.5
Turnip, greens	30
Vegetable, cucurbit, group 9	0.3
Vegetable, foliage of legume, except soybean, subgroup 7A	35
Vegetable, fruiting, group 8	2.0
Vegetable, leaves of root and tuber, group 2	30
Vegetable, legume, edible podded, subgroup 6A	1.5
Vegetable, root, subgroup 1A	0.5
Vegetable, tuberous and corm, except potato, subgroup 1D	0.02
Wax jambu	0.4

(2) For combined residues of the insecticide methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its glucuronide metabolite RH-141,518; β-D-Glucopyranuronic acid, 3-[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl-2-methylphenyl-] in the following commodities:

Commodity	Parts per million
Cattle, liver	0.40
Cattle, meat byproducts, except liver	0.10
Egg	0.02
Goat, liver	0.40
Goat, meat byproducts, except liver	0.10
Hog, liver	0.1
Hog, meat byproducts, except liver	0.02
Horse, liver	0.40
Horse, meat byproducts, except liver	0.10
Poultry, liver	0.10
Poultry, meat byproducts, except liver	0.02
Sheep, liver	0.40
Sheep, meat byproducts, except liver	0.10

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide methoxyfenozide *per se* (benzoic acid, 3-methoxy-2-methyl-,2-(3,5-

dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide), in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and will be revoked on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Sorghum, forage	30.0	12/31/12
Sorghum, grain	0.05	12/31/12
Sorghum, stover	60.0	12/31/12

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* (1) Tolerances are established for the indirect or inadvertent residues of the insecticide methoxyfenozide per se; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the following raw agricultural commodities, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section:

Commodity	Parts per million	Expiration/ revocation date
Vegetable, bulb, group 3-07	0.20	09/30/10
Vegetable, leaves of root and tuber, group 2	0.20	09/30/10
Vegetable, root and tuber, group 1	0.10	09/30/10

(2) Tolerances are established for the indirect or inadvertent combined residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its metabolites RH-117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N′*-(3-hydroxy-2-methylbenzoyl) hydrazide, RH-151,055 glucose conjugate of RH-117,236; 3,5-dimethyl benzoic acid *N*-tert-butyl-*N*-[3 (β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH-152,072 the malonylglycosyl conjugate of RH 117,236 in or on the following raw agricultural commodities, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section:

Commodity	Parts per million	Expiration/ revocation date
Animal feed, non-grass, group 18	10.0	09/30/10
Grain, cereal, forage, fodder and straw, group 16	10.0	09/30/10
Grass, forage, fodder and hay, group 17	10.0	09/30/10
Herb and spice, group 19	10.0	09/30/10
Vegetable, foliage of legume, group 7	10.0	09/30/10
Vegetable, legume, group 6	0.10	09/30/10

[67 FR 59203, Sept. 20, 2002, as amended at 68 FR 32389, May 30, 2003; 68 FR 37765, June 25, 2003; 69 FR 58097, Sept. 29, 2004; 70 FR 7047, Feb. 10, 2005; 70 FR 51604, Aug. 31, 2005; 70 FR 75739, Dec. 21, 2005; 71 FR 32853, June 7, 2006; 73 FR 11826, Mar. 5, 2008; 74 FR 22468, May 13, 2009]

§ 180.545 Prallethrin (*RS*)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1*RS*)-*cis, trans*-chrysanthemate; tolerances for residues.

(a) *General.* (1) A tolerance of 1.0 ppm is established for residues of the insecticide prallethrin (*RS*)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1*RS*)-*cis, trans*-chrysanthemate as follows:

(2) In or on food commodities in food handling establishments where food and food products are held, processed, prepared and/or served.

(3) Application shall be limited to space, general surface, and spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and/or served. General surface or space spray applications may be used only when the facility is not in operation provided exposed food has been covered or removed from the area being treated prior to application. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Spray concentrate shall be limited to a maximum of 2.0% active ingredient. Contamination of food or food contact surfaces shall be avoided. Food contact surfaces and equipment should be throughly washed with an effective cleaning compound and rinsed with potable water after use of the product.

(4) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall

be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 39313, June 26, 2000, as amended at 71 FR 74819, Dec. 13, 2006]

§ 180.546 Mefenoxam; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of (*R*)- and (*S*)-2-[(2,6-dimethyl(phenyl)-methoxyacetylamine]-propionic acid methyl ester, and its metabolites containing the 2,6 dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as mefenoxam equivalents, in or on the following food commodities:

Commodity	Parts per million
Artichoke, globe	0.05
Atemoya	0.20
Canistel	0.40
Custard apple	0.20
Herbs, dried	55
Herbs, fresh	8.0
Kiwifruit	0.10
Lingonberry	2.0
Mango	0.40
Papaya	0.40
Sapodilla	0.40
Sapote, black	0.40
Sapote, mamey	0.40
Star apple	0.40
Starfruit	0.20
Sugar apple	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[65 FR 57556, Sept. 25, 2000, as amended at 66 FR 48003, Sept. 17, 2001; 67 FR 35050, May 17, 2002]

§ 180.547 Prohexadione calcium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, kidney	0.10
Cattle, meat byproducts, except kidney	0.05
Fruit, pome, group 11	3.0
Goat, kidney	0.10
Goat, meat byproducts, except kidney	0.05
Grass, forage [1]	0.10
Grass, hay [1]	0.10
Grass, seed screenings [1]	3.5
Grass, straw [1]	1.2
Hog, kidney	0.10
Hog, meat byproducts, except kidney	0.05
Horse, kidney	0.10
Horse, meat byproducts, except kidney	0.05
Peanut	1.0
Peanut, hay	0.60
Sheep, kidney	0.10
Sheep, meat byproducts, except kidney	0.05

[1]Registration is limited to grass grown for seed.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 25660, May 3, 2000, as amended at 66 FR 29712, June 1, 2001]

§ 180.548 Tralkoxydim; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, tralkoxydim, 2-Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) in or on the raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.02
Barley, hay	0.02
Barley, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.02
Wheat, hay	0.02
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[63 FR 69199, Dec. 16, 1998, as amended at 68 FR 48302, Aug. 13, 2003; 70 FR 70739, Nov. 23, 2005]

§ 180.549 Diflufenzopyr; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of diflufenzopyr, 2-(1-[([3,5-

difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, and its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, expressed as diflufenzopyr, in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Corn, pop, grain	0.05
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.05
Grass, forage	22.0
Grass, hay	7.0

(2) Time-limited tolerances are established for combined residues of diflufenzopyr, 2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin- 5(6H)-one, and free and acid-released 8-hydroxymethylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione, expressed as diflufenzopyr, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, fat	0.30	7/31/05
Cattle, kidney	4.0	7/31/05
Cattle, meat	0.60	7/31/05
Cattle, meat byproducts, except kidney	0.50	7/31/05
Goat, fat	0.30	7/31/05
Goat, kidney	4.0	7/31/05
Goat, meat	0.60	7/31/05
Goat, meat byproducts, except kidney	0.50	7/31/05
Hog, fat	0.30	7/31/05
Hog, kidney	4.0	7/31/05
Hog, meat	0.60	7/31/05
Hog, meat byproducts, except kidney	0.50	7/31/05
Horse, fat	0.30	7/31/05
Horse, kidney	4.0	7/31/05
Horse, meat	0.60	7/31/05
Horse, meat byproducts, except kidney	0.50	7/31/05
Milk	3.0	7/31/05
Sheep, fat	0.30	7/31/05
Sheep, kidney	4.0	7/31/05
Sheep, meat	0.60	7/31/05
Sheep, meat byproducts, except kidney	0.50	7/31/05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 4308, Jan. 28, 1999, as amended at 67 FR 55338, Aug. 29, 2002]

§ 180.550 Arsanilic acid [(4-aminophenyl) arsonic acid]; tolerances for residues.

(a) *General.* A time-limited tolerance is established for residues of the plant growth regulator arsanilic acid [(4-aminophenyl) arsonic acid], in or on the following food commodities in connection with the use of the pesticide under section 5 experimental use permit. The tolerance will expire on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Grapefruit	2 (not to exceed 0.7 ppm total arsenic)	2/28/01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 14639, Mar. 26, 1999]

§ 180.551 Fluthiacet-methyl; tolerances for residues.

(a) *General.* (1) A tolerance is established for residues of the herbicide, fluthiacet-methyl, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester, in or on the food commodity:

Commodity	Parts per million
Corn, field, forage	0.050
Corn, field, grain	0.010
Corn, field, stover	0.050
Corn, pop, grain	0.010
Corn, pop, stover	0.050
Corn, sweet, forage	0.050
Corn, sweet, kernel plus cob with husks removed	0.010
Corn, sweet, stover	0.050
Soybean, seed	0.01

(2) A tolerance is established for the combined residues of the herbicide fluthiacet-methyland its acid metabolite: acetic acid, [[2-chloro-4-fluoro-5-[tetrahydro-3-oxo-1H,3H-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester, and its acid metabolite, acetic acid, [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1H,3H-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]- , in or on the following food commodities:

Commodity	Parts per million
Cotton, gin byproducts	0.20
Cotton, undelinted seed	0.020

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 18357, Apr. 14, 1999, as amended at 66 FR 65850, Dec. 21, 2001; 71 FR 77625, Dec. 27, 2006]

§ 180.552 Sulfosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide sulfosulfuron, 1–(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl) sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron in or on the raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.01
Cattle, meat byproducts	0.3
Goat, fat	0.02
Goat, meat	0.01
Goat, meat byproducts	0.3
Grass, forage, fodder and hay, group 17, forage	14
Grass, forage, fodder and hay, group 17, hay	25
Hog, fat	0.005
Hog, meat	0.005
Hog, meat byproducts	0.05
Horse, fat	0.02
Horse, meat	0.01
Horse, meat byproducts	0.3
Milk	0.02
Sheep, fat	0.02
Sheep, meat	0.01
Sheep, meat byproducts	0.3
Wheat, forage	4.0
Wheat, grain	0.02
Wheat, hay	0.3
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 27192, May 19, 1999, as amended at 70 FR 69464, Nov. 16, 2005; 72 FR 54574, Sept. 26, 2007]

§ 180.553 Fenhexamid; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the fungicide fenhexamid (N-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide) in or on the following commodities:

Commodity	Parts per million
Almond, hulls	2.0
Almond	0.02
Asparagus	0.02
Bushberry subgroup 13B	5.0
Caneberry subgroup 13A	20.0
Cilantro, leaves	30.0
Cucumber	2.0
Fruit, stone, group 12, except plum, prune, fresh, postharvest	10.0
Ginseng	0.3
Grape	4.0
Grape, raisin	6.0
Juneberry	5.0
Kiwifruit, postharvest	15.0
Leafy greens subgroup 4A, except spinach	30.0
Lingonberry	5.0
Pear	10
Pepper, nonbell	0.02
Pistachio	0.02
Plum, prune, dried	2.5
Plum, prune, fresh	1.5
Pomegranate	2.0
Salal	5.0
Strawberry	3.0
Vegetable, fruiting, group 8, except nonbell pepper	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 28924, May 28, 1999, as amended at 65 FR 19849, Apr. 13, 2000; 65 FR 69883, Nov. 21, 2000; 67 FR 19120, Apr. 18, 2002; 68 FR 2247, Jan. 16, 2003; 68 FR 55519, Sept. 26, 2003; 71 FR 15617, Mar. 29, 2006; 71 FR 43664, Aug. 2, 2006; 73 FR 19154, Apr. 9, 2008]

§ 180.554 Kresoxim-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the fungicide kresoxim-methyl (methyl (*E*)-2-[2-(2-methylphenoxy)-methyl]phenyl-2-(methoxyimido)acetate) and its metabolites as follows: (*E*)-2-[2-(2-methylphenoxy)methyl]-phenyl-2-(methoxyimido)acetic acid; (*E*)-2-[2-(2-hydroxymethylphenoxy)methyl]-phenyl-2-(methoxyimido)acetic acid (free and glucose conjugated); and (*E*)-2-[2-(4-hydroxy-2-methylphenoxy)-methyl]phenyl-2-(methoxyimido)acetic acid (free and glucose conjugated) in or on the following commodities:

Commodity	Parts per million
Apple, pomace	1.0
Fruit, pome	0.5
Grape	1.0
Grape, raisin	1.5
Pecan	0.15
Vegetable, cucurbit, group 9	0.40

(2) Tolerances are established in or on the following commodities for the residues of the metabolite (*E*)-2-[2-(2-methylphenoxy)methyl]-phenyl-2-(methoxyimido)acetic acid resulting from the use of the fungicide kresoxim-methyl:

Commodity	Parts per million
Cattle, meat byproducts	0.01
Goat, meat byproducts	0.01
Sheep, meat byproducts	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 31136, June 10, 1999, as amended at 71 FR 50359, Aug. 25, 2006]

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of trifloxystrobin (Benzeneacetic acid, (*E,E*)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA–321113 ((*E,E*)-methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid in or on the following commodities.

Commodity	Parts per million
Almond, hulls	3.0
Almond	0.04
Apple, wet pomace	5.0
Asparagus	0.07
Banana[1]	0.10
Barley, grain	0.05
Barley, hay	0.3
Barley, straw	5.0
Beet, sugar, dried pulp	0.4
Beet, sugar, molasses	0.2
Beet, sugar, roots	0.1
Beet, sugar, tops	4.0
Canistel	0.7
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Citrus, dried pulp	1.0
Citrus, oil	38
Corn, field, forage	0.2
Corn, field, grain	0.05
Corn, field, stover	7
Corn, field, refined oil	0.1
Corn, pop, grain	0.05
Corn, pop, stover	7
Corn, sweet, cannery waste	0.6
Corn, sweet, forage	0.6
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	0.25
Egg	0.04
Fruit, citrus, group 10	0.6
Fruit, pome	0.5
Fruit, stone, group 12	2
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Grain, aspirated fractions	5.0
Grape	2.0
Grape, raisin	5.0
Grass, forage	12
Grass, hay	17
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Hop, dried cones	11.0
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Leaf petioles subgroup 4B	3.5
Mango	0.7
Milk	0.02
Nut, tree, group 14	0.04
Oat, forage	0.3
Oat, grain	0.05
Oat, hay	0.3
Oat, straw	5.0
Papaya	0.7
Peanut, hay	4.0
Peanut	0.05
Pistachio	0.04
Potato	0.04
Poultry, fat	0.04
Poultry, meat	0.04
Poultry, meat byproducts	0.04
Radish, tops	10
Rice, grain	3.5
Rice, hulls	8
Rice, straw	7.5
Sapodilla	0.7

Commodity	Parts per million
Sapote, black	0.7
Sapote, mamey	0.7
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, forage	10.0
Soybean, hay	25.0
Soybean, seed	0.08
Star apple	0.7
Strawberry	1.1
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting	0.5
Vegetable, root, except sugar beet, subgroup 1B	0.1
Vegetable, root, except sugar beet, subgroup 1B, except radish	0.10
Wheat, bran	0.15
Wheat, forage	0.3
Wheat, grain	0.05
Wheat, hay	0.2
Wheat, straw	5.0

[1] There are no U.S. registrations as of September 27, 1999 for use on banana.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the fungicide trifloxystrobin, (benzeneacetic acid, (E,E)-[alpha]-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl] ethylidene]amino]oxy]methyl]-,methylester) and the free form of its acid metabolite CGA–321113 ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl]-phenyl]acetic acid) in connection with the use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the date specified in the table in this unit.

Commodity	Parts per million	Expiration/revocation date
Soybean, forage	4.0	12/31/09
Soybean, hay	6.5	12/31/09
Soybean, seed	0.04	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[64 FR 51907, Sept. 27, 1999, as amended at 65 FR 44453, July 18, 2000; 67 FR 35924, May 22, 2002; 68 FR 53304, Sept. 10, 2003; 70 FR 36532, June 24, 2005; 71 FR 15604, Mar. 29, 2006; 71 FR 55319, Sept. 22, 2006; 72 FR 53445, Sept. 19, 2007; 73 FR 57, Jan. 2, 2008]

§ 180.556 Pymetrozine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide pymetrozine 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene) amino] in or on the following raw agricultural commodities. The tolerance level for each commodity is expressed in terms of the parent insecticide only, which serves as an indicator of the use of pymetrozine on these raw agricultural commodities.

Commodity	Parts per million
Asparagus	0.04
Brassica, head and stem, subgroup 5A	0.5
Brassica, leafy greens, subgroup 5B	0.25
Cotton, gin byproducts	2.0
Cotton, undelinted seed	0.3
Hop, dried cones	6.0
Pecan	0.02
Turnip, greens	0.25
Vegetable, fruiting, group 8	0.2
Vegetable, cucurbit, group 9	0.1
Vegetable, leafy, execpt brassica, group 4	0.6
Vegetable, tuberous and corm, subgroup 1C	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 48634, Aug. 9, 2000, as amended at 66 FR 14846, Mar. 14, 2001; 66 FR 66794, Dec. 27, 2001; 70 FR 7047, Feb. 10, 2005; 70 FR 43298, July 27, 2005]

§ 180.557 Tetraconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide, tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole in or on the following commodities:

Commodity	Parts per million
Aspirated grain fractions	1.0
Beet sugar, dried pulp	0.15
Beet sugar, molasses	0.15
Beet sugar, root	0.05
Cattle, fat	0.02
Cattle, liver	0.20
Cattle, meat	0.01
Cattle, meat byproducts (except liver)	0.01
Eggs	0.02
Goat, fat	0.02
Goat, liver	0.20
Goat, meat	0.01
Goat, meat byproducts (except liver)	0.01
Grape	0.20
Hog, fat	0.01
Hog, liver	0.05
Hog, meat	0.01
Hog, meat byproducts (except liver)	0.01
Horse, fat	0.02

Commodity	Parts per million
Horse, liver	0.20
Horse, meat	0.01
Horse, meat byproducts (except liver)	0.01
Milk	0.01
Milk, fat	0.25
Peanut	0.03
Peanut, oil	0.10
Pecan	0.04
Poultry, fat	0.05
Poultry, meat	0.01
Poultry meat byproducts	0.01
Sheep, fat	0.02
Sheep, liver	0.20
Sheep, meat	0.01
Sheep, meat byproducts (except liver)	0.01
Soybean, refined oil	0.80
Soybean, seed	0.15

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 20830, Apr. 22, 2005, as amended at 70 FR 31359, June 1, 2005; 72 FR 18134, Apr. 11, 2007; 73 FR 67406, Nov. 14, 2008]

§ 180.558 *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride; tolerances for residues.

(a) *General.* A tolerance for residues of the plant growth regulator *N,N*-diethyl-2-(4-methylenzyloxy)ethylamine hydrochloride in or on raw agricultural commodities is established as follows:

Commodity	Parts per million
Orange, sweet	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 1814, Jan. 12, 2000]

§ 180.559 Clodinafop-propargyl; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of clodinafop-propargyl (propanoic acid, 2-[4-(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]-,2-propynyl ester, (2R)-) and its acid metabolite (propanoic acid, 2-[4-[(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]-, (2R)-), in or on wheat, grain at 0.1 ppm ; wheat, forage at 0.1 ppm; wheat, hay at 0.1 ppm; and wheat, straw at 0.50 ppm.

Commodity	Parts per million
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, hay	0.1
Wheat, straw	0.5

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 38774, June 22, 2000]

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	0.1
Barley, straw	0.1
Wheat, forage	0.2
Wheat, grain	0.1
Wheat, hay	0.5
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 38764, June 22, 2000, as amended at 70 FR 74688, Dec. 16, 2005; 73 FR 11820, Mar. 5, 2008]

§ 180.561 Acibenzolar-*S*-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, in or

on the following raw agricultural commodities:

Commodity	Parts per million
Banana[1]	0.1
Spinach	1.0
Tomato, paste	3.0
Vegetable, brassica, leafy, group 5	1.0
Vegetable, fruiting, group 8	1.0
Vegetable, leafy, group 4	0.25

[1]There are no United States registrations for banana.

(2) Tolerances are established for residues of acibenzolar-S-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-S-methyl ester, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those acibenzolar-S-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-S-methyl, in or on the commodity.

Commodity	Parts per million
Onion, bulb, subgroup 3–07A	0.1
Vegetable, cucurbit, group 9	2.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The time-limited tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Onion, green	0.05	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 50446, Aug. 18, 2000, as amended at 70 FR 7861, Feb. 16, 2005; 71 FR 76200, Dec. 20, 2006; 74 FR 24710, May 26, 2009]

§ 180.562 Flucarbazone-sodium; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2(trifluoromethoxy)phenyl] sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its N-desmethyl metabolite; and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on the following food commodities:

Commodity	Parts per million
Cattle, liver	1.50
Cattle, meat	0.01
Cattle, meat byproducts, except liver	0.01
Goat, liver	1.50
Goat, meat	0.01
Goat, meat byproducts, except liver	0.01
Hog, liver	1.50
Hog, meat	0.01
Hog, meat byproducts, except liver	0.01
Horse, liver	1.50
Horse, meat	0.01
Horse, meat byproducts, except liver	0.01
Milk	0.005
Sheep, liver	1.50
Sheep, meat	0.01
Sheep, meat byproducts, except liver	0.01
Wheat, forage	0.30
Wheat, grain	0.01
Wheat, hay	0.10
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[70 FR 67915, Nov. 9, 2005, as amended at 71 FR 76931, Dec. 22, 2006]

§ 180.563 Ethametsulfuron-methyl; tolerances for residues.

(a) *General.* A tolerance is established for residues of ethametsulfuron methyl (methyl 2- ((((4-ethoxy-6-(methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate) in or on the following raw agricultural commodities.

Commodity	Parts per million
Canola, seed	0.02
Crambe, seed	0.02
Rapeseed, seed	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect of inadvertent residues.* [Reserved]

[65 FR 57972, Sept. 27, 2000, as amended at 66 FR 18207, Apr. 6, 2001; 67 FR 35050, May 17, 2002]

§ 180.564 Indoxacarb; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-*e*][1,3,4][oxadiazine-4a(3*H*)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-*e*][1,3,4][oxadiazine-4a(3*H*)-carboxylate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace	3.0
Alfalfa, forage	10
Alfalfa, hay	50
Cattle, fat	1.5
Cattle, meat	0.05
Cattle, meat byproducts	0.03
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husk removed	0.02
Corn, sweet, stover	15
Cotton, gin byproducts	15
Cotton, undelinted seed	2.0
Cranberry	0.90
Fruit, pome, except pear, group 11	1.0
Fruit, stone, group 12	0.90
Goat, fat	1.5
Goat, meat	0.05
Goat, meat byproducts	0.03
Grain, aspirated fractions	45
Grape	2.0
Grape, raisin	5.0
Hog, fat	1.5
Hog, meat	0.05
Hog, meat byproducts	0.03
Horse, fat	1.5
Horse, meat	0.05
Horse, meat byproducts	0.03
Milk	0.15
Milk, fat	4.0
Okra	0.50
Pea, southern, seed	0.10
Peanut	0.01
Peanut, hay	40
Pear	0.20
Pear, oriental	0.20
Peppermint, tops	11
Sheep, fat	1.5
Sheep, meat	0.05
Sheep, meat byproducts	0.03
Soybean, hulls	4.0
Soybean, seed	0.80
Spearmint, tops	11
Turnip, greens	12
Vegetable, *Brassica*, leafy, group 5	12
Vegetable, cucurbit, group 9	0.60
Vegetable, fruiting, group 8	0.50
Vegetable, leafy, except *Brassica*, group 4	14
Vegetable, tuberous and corm, subgroup 1-C	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 58424, Sept. 29, 2000, as amended at 67 FR 41807, June 19, 2002; 67 FR 47309, July 18, 2002; 67 FR 58730, Sept. 18, 2002; 68 FR 25830, May 14, 2003; 68 FR 27746, May 21, 2003; 69 FR 28842, May 19, 2004; 69 FR 29459, May 24, 2004; 69 FR 32282, June 9, 2004; 72 FR 37641, July 11, 2007]

§ 180.565 Thiamethoxam; tolerances for residues.

(a) *General.* A tolerance is established for the combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine] (CAS Reg. No. 153719–23–4) and its metabolite [*N*-(2-chloro-thiazol-5-ylmethyl)-*N*′-methyl-*N*′-nitro-guanidine], calculated as parent equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	1.2
Artichoke, globe	0.45
Barley, grain	0.30
Barley, hay	0.40
Barley, straw	0.40
Bean, succulent	0.02
Borage, seed	0.02
Brassica, head and stem, subgroup 5-A	4.5
Brassica, leafy greens, subgroup 5-B	3.0
Bushberry subgroup 13B	0.20
Caneberry subgroup 13-A	0.35
Canola, seed	0.02
Cattle, meat byproducts	0.02
Cattle, meat	0.02
Citrus, dried pulp	0.60
ppm	
Coffee, bean, green [1]	0.05
Corn, field, forage	0.10
Corn, field, grain	0.020
Corn, field, stover	0.05
Corn, pop, forage	0.10
Corn, pop, grain	0.02
Corn, pop, stover	0.05
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husks removed	0.02

Commodity	Parts per million
Corn, sweet, stover	0.05
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.10
Crambe, seed	0.02
Cranberry	0.02
Flax, seed	0.02
Fruit, citrus, group 10	0.40
Fruit, pome, group 11	0.2
Fruit, stone, group 12	0.5
Goat, meat byproducts	0.02
Goat, meat	0.02
Grain, aspirated fractions	0.08
Grape	0.20
Grape, raisin	0.30
Hog, meat byproducts	0.02
Hog, meat	0.02
Hop, dried cones	0.10
Horse, meat byproducts	0.02
Horse, meat	0.02
Juneberry	0.20
Lingonberry	0.20
Milk	0.02
Mustard, seed	0.02
Nut, tree, group 14)	0.02
Peppermint, tops	1.5
Pistachio	0.02
Potato	0.25
Radish, tops	0.80
Rapeseed, seed	0.02
Safflower, seed	0.02
Salal	0.20
Sheep, meat byproducts	0.02
Sheep, meat	0.02
Sorghum, forage	0.02
Sorghum, grain	0.02
Sorghum, grain, stover	0.02
Soybean, hulls	2.0
Spearmint, tops	1.5
Strawberry	0.3
Sunflower	0.02
Tomato, paste	0.80
Vegetable, cucurbit, group 9	0.2
Vegetable, fruiting, group 8	0.25
Vegetable, leafy, except brassica, group 4	4.0
Vegetable, legume, group 6	0.02
Vegetable, root, except sugar beet, subgroup 1B	0.02
Vegetable, tuberous and corm, except potato, subgroup 1D	0.02
Wheat, forage	0.50
Wheat, grain	0.02
Wheat, hay	0.02
Wheat, straw	0.02

[1]There are no U.S. registrations as of September 17, 2003.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 79762, Dec. 20, 2000, as amended at 65 FR 80353, Dec. 21, 2000; 66 FR 28397, May 23, 2001; 67 FR 35050, May 17, 2002; 67 FR 66571, Nov. 1, 2002; 68 FR 51479, Aug. 27, 2003; 68 FR 54394, Sept. 17, 2003; 69 FR 55512, Sept. 15, 2004; 70 FR 719, Jan. 5, 2005; 70 FR 7182, Feb. 11, 2005; 72 FR 34409, June 22, 2007; 73 FR 21048, Apr. 18, 2008; 74 FR 15875, Apr. 8, 2009]

§ 180.566 Fenpyroximate; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl- 5-phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy]methyl] benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5- phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy] methyl]benzoate in or on the following commodities:

Commodity	Parts per million
Almond, hulls	3.0
Citrus, dried pulp	2.5
Citrus, oil	10
Cotton, gin byproducts	10
Cotton, undelinted seed	0.10
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.40
Grape	1.0
Hop, dried cones	10
Nut, tree, group 14	0.10
Peppermint, tops	7.0
Pistachio	0.10
Spearmint, tops	7.0

(2) Tolerances are established for residues of the insecticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5 -phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy]methyl] benzoate and its metabolites, (E)-4- [(1,3-dimethyl-5- phenoxypyrazol-4-yl)-methylene aminooxymethyl]benzoic acid and (E)-1,1-dimethylethyl-2-hydroxyethyl 4- [[[[(1,3-dimethyl -5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl] benzoate, calculated as the parent compound in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts, except kidney and liver	0.03
Goat, fat	0.03
Goat, meat	0.03
Goat, meat byproducts, except kidney and liver	0.03
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts, except kidney and liver	0.03
Milk	0.015
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts, except kidney and liver	0.03

(3) Tolerances are established for residues of the insecticide fenpyroximate,

(E)-1,1-dimethylethyl 4- [[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl] benzoate and its metabolite, (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylene aminooxymethyl]benzoic acid, calculated as the parent compound in the following commodities:

Commodity	Parts per million
Cattle, kidney	0.25
Cattle, liver	0.25
Goat, kidney	0.25
Goat, liver	0.25
Horse, kidney	0.25
Horse, liver	0.25
Sheep, kidney	0.25
Sheep, liver	0.25

(b) *Section 18 emergency exemptions.* Time-limited tolerance is established for the combined residues of fenpyroximate, (E)-1,1-dimethylethyl 4-[[[(E)-[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy] methyl]benzoate in or on honey at 0.10 ppm. This tolerance expires and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Honey	0.10	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 18568, Apr. 10, 2001, as amended at 69 FR 32464, June 10, 2004; 71 FR 49368, Aug. 23, 2006; 72 FR 26321, May 9, 2007]

§ 180.567 Zoxamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of zoxamide (3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) in or on the following commodities:

Commodity	Parts per million
Grape	3.0
Grape, raisin	15.0
Tomato	2.0
Vegetable, cucurbit, group 9	1.0

(2) Tolerances are established for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452) in or on the following commodities:

Commodity	Parts per million
Potato	0.060
Potato, granules/flakes	0.30
Potato, wet peel	0.10

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Revocation date
Ginseng	0.06	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 18733, Apr. 11, 2001, as amended at 66 FR 49118, Sept. 26, 2001; 69 FR 16805, Mar. 31, 2004; 71 FR 31104, June 1, 2006; 71 FR 76200, Dec. 20, 2006]

§ 180.568 Flumioxazin; tolerances for residues.

(a) *General.* Tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	8.0
Almond	0.02
Almond, hulls	0.70
Asparagus	0.02
Bean, dry seed	0.05
Bushberry subgroup 13–07B	0.02
Corn, field, forage	0.02
Corn, field, grain	0.02
Corn, field, stover	0.02
Cotton, gin byproducts	0.60
Cotton, undelinted seed	0.02
Fruit, pome, group 11	0.02
Fruit, stone, group 12	0.02
Garlic	0.02
Grape	0.02

Commodity	Parts per million
Melon, subgroup 9A	0.02
Nut, tree, group 14	0.02
Okra	0.02
Onion, bulb	0.02
Peanut	0.02
Peppermint, tops	0.04
Pistachio	0.02
Shallot, bulb	0.02
Soybean, seed	0.02
Spearmint, tops	0.04
Strawberry	0.07
Sugarcane, cane	0.20
Vegetable, fruiting, group 8	0.02
Vegetable, tuberous and corm, subgroup 1C	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 19878, Apr. 18, 2001, as amended at 68 FR 51471, Aug. 27, 2003; 69 FR 16831, Mar. 31, 2004; 69 FR 52198, Aug. 25, 2004; 71 FR 25956, May 3, 2006; 71 FR 61413, Oct. 18, 2006; 73 FR 11831, Mar. 5, 2008; 73 FR 39251, July 9, 2008]

§ 180.569 Forchlorfenuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the plant growth regulator forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N′*phenyl urea in or on the following commodities:

Commodity	Parts per million
Bushberry subgroup 13–07B	0.01
Grape	0.03
Grape, raisin	0.06
Kiwifruit	0.04

(2) Time-limited tolerances are established for residues of the plant growth regulator forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea in or on the food commodities:

Commodity	Parts per million	Expiration/ revocation date
Almond	0.01	12/31/11
Almond, hulls	0.15	12/31/11
Cherry, sweet	0.01	12/31/11
Fig	0.01	12/31/11
Pear	0.01	12/31/11
Pistachio	0.01	12/31/11
Plum, prune, fresh	0.01	12/31/11

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 22936, May 7, 2001, as amended at 69 FR 48805, Aug. 11, 2004; 69 FR 58322, Sept. 30, 2004; 73 FR 47846, Aug. 15, 2008]

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, (CAS No. 163520–33–0), and its metabolite: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid, when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.20
Corn, field, grain	0.08
Corn, field, stover	0.40
Corn, oil	0.50
Corn, pop, grain	0.04
Corn, pop, stover	0.25
Corn, sweet, forage	0.30
Corn, sweet, kernel plus cob with husk removed	0.04
Corn, sweet, stover	0.45

(2) Tolerances are established for the residues of isoxadifen-ethyl (3-isoxazolecarboxylic acid, 4,5-dihydro-5,5-diphenyl-, ethyl ester (CAS No. 164520–33–0)), and its metabolites 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benzenepropanenitrile when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.10
Rice, hulls	0.50
Rice, straw	0.25

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 33187, June 21, 2001, as amended at 66 FR 40141, Aug. 2, 2001; 67 FR 12878, Mar. 20, 2002; 69 FR 29890, May 26, 2004; 72 FR 63997, Nov. 14, 2007]

§ 180.571 Mesotrione; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the following commodities:

Commodity	Parts per million
Asparagus	0.01
Berry, group 13	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.5
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	1.5
Cranberry	0.02
Flax, seed	0.01
Grass, forage	0.01
Grass, hay	0.01
Grass, seed screenings	0.10
Grass, straw	0.10
Lingonberry	0.01
Millet, forage	0.01
Millet, grain	0.01
Millet, hay	0.02
Millet, straw	0.02
Oat, forage	0.01
Oat, grain	0.01
Oat, hay	0.01
Oat, straw	0.01
Okra	0.01
Rhubarb	0.01
Sorghum, grain, forage	0.01
Sorghum, grain, grain	0.01
Sorghum, grain, stover	0.01
Sorghum, sweet	0.01
Sugarcane, cane	0.01

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in connection with use of the herbicide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances will expire on the dates specified in the table.

Commodity	h	Parts per million
Corn, sweet, kernel plus cob with husks removed	0.01	06/30/04
Corn, sweet, forage	0.50	06/30/04
Corn, sweet, stover	2.0	06/30/04
Cranberry	0.01	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 33195, June 21, 2001, as amended at 67 FR 45656, July 10, 2002; 68 FR 273, Jan. 3, 2003; 69 FR 58310, Sept. 30, 2004; 70 FR 14551, Mar. 23, 2005; 72 FR 71802, Dec. 19, 2007; 73 FR 1512, Jan. 9, 2008; 73 FR 9226, Feb. 20, 2008]

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* (1) Tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on the following food commodities:

Commodity	Parts per million
Acerola	0.90
Almond, hulls	15
Apple, wet pomace	1.2
Black sapote	7.0
Caneberry subgroup 13-07A	5.0
Canistel	7.0
Cattle, fat	0.10
Cotton, gin byproducts	35
Cotton, undelinted seed	0.75
Feijoa	0.90
Fruit, pome, group 11	0.75
Fruit, stone, group 12, except plum	2.5
Goat, fat	0.10
Grape	0.75
Grape, raisin	1.2
Guave	0.90
Hog, fat	0.10
Hop, dried cones	15
Horse, fat	0.10
Jaboticaba	0.90
Longan	5.0
Lychee	5.0
Mango	7.0
Nut, tree, group 14	0.20
Okra	2.0
Papaya	7.0
Passionfruit	0.90
Pea and bean, succulent shelled, subgroup 6B	0.70
Peppermint, tops	25
Pistachio	0.20
Plum	0.20
Pulasan	5.0
Rambutan	5.0
Sapodilla	7.0
Sapote, mamey	7.0
Sheep, fat	0.10
Soybean, succulent shelled	0.70
Spanish lime	5.0
Spearmint, tops	25
Star apple	7.0
Starfruit	0.90
Strawberry	1.5
Vegetable, cucurbit, group 9	0.75
Vegetable, fruiting, group 8	2.0
Vegetable, legume, edible-podded, subgroup 6A	6.0
Vegetable, tuberous and corm, subgroup 1C	0.10
Wax jambu	0.90

(2) Tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl) hydrazinecarboxylate); diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1′-biphenyl, 4-ol; and 1,1′-biphenyl, 4-oxysulfonic acid (expressed as 1,1′-biphenyl, 4-ol) in or on the following food commodities:

Commodity	Parts per million
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Cherry, tart	5.0	12/31/09
Potato	0.05	12/31/06
Soybean, hulls	20	12/31/09
Soybean, meal	3.5	12/31/09
Soybean, refined oil	20	12/31/09
Soybean, seed	1.5	12/31/09
Timothy, forage	50	12/31/10
Timothy, hay	150	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 34569, June 29, 2001, as amended at 66 FR 42772, Aug. 15, 2001; 67 FR 4922, Feb. 1, 2002; 67 FR 46884, July 17, 2002; 68 FR 55502, Sept. 26, 2003; 69 FR 5297, Feb. 4, 2004; 70 FR 4037, Jan. 28, 2005; 70 FR 74695, Dec. 16, 2005; 71 FR 51505, Aug. 30, 2006; 72 FR 71802, Dec. 19, 2007; 73 FR 11837, Mar. 5, 2008]

§ 180.573 Tepraloxydim; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim in or on the following raw agricultural commodities.

Commodity	Parts per million
Cotton, undelinted seed	0.2
Cotton, gin byproducts	3.0
Flax, seed	0.10
Grain, aspirated fraction	1200.0
Lentil, seed	0.10
Pea, dry, seed	0.10
Soybean, seed	6.0
Soybean, hulls	8.0

(2) Tolerances are established for the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)-1,5-dioic acid), calculated as tepraloxydim in or on the following commodities

Commodity	Parts per million
Cattle, fat	0.15
Cattle, kidney	0.50
Cattle, meat	0.20
Cattle, meat byproducts, except kidney	0.20
Egg	0.20
Goat, fat	0.15
Goat, kidney	0.50
Goat, meat	0.20
Goat, meat byproducts, except kidney	0.20
Hog, fat	0.15
Hog, kidney	0.50
Hog, meat	0.20
Hog, meat byproducts, except kidney	0.20
Horse, fat	0.15
Horse, kidney	0.50
Horse, meat	0.20
Horse, meat byproducts, except kidney	0.20
Milk	0.10
Poultry, fat	0.30
Poultry, liver	1.00
Poultry, meat	0.20
Poultry, meat byproducts, except liver	0.20
Sheep, fat	0.15
Sheep, kidney	0.50
Sheep, meat	0.20
Sheep, meat byproducts, except kidney	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(n) is established for the combined residues of tepraloxydim and its metabolites convertible to GP and OH-GP, calculated as tepraloxydim in or on the following raw agricultural commodity:

Commodity	Parts per million
Canola, seed	0.50

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 40150, Aug. 2, 2001 as amended at 72 FR 54588, Sept. 26, 2007]

§ 180.574 Fluazinam; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of fluazinam, (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl) phenyl]-5-(trifluoromethyl)-2-pyridinamine) in or on the following commodities:

Commodity	Parts per million
Aronia berry	7.0
Buffalo currant	7.0
Bushberry subgroup 13B	7.0
Chilean guava	7.0
European barberry	7.0
Ginseng	4.5
Highbush cranberry	7.0
Honeysuckle, edible	7.0
Jostaberry	7.0
Juneberry	7.0
Lingonberry	7.0
Native currant	7.0
Pea and bean, dried shelled, except soybean, subgroup 6C, except pea	0.02
Pea and bean, succulent shelled, subgroup 6B, except pea	0.04
Peanut	0.02
Potato	0.02
Salal	7.0
Sea buckthorn	7.0
Turnip, greens	0.01
Vegetable, Brassica leafy, group 5	0.01
Vegetable, legume, edible-podded, subgroup 6A, except pea	0.10

(2) Tolerances are established for residues of fluazinam and its metabolite AMGT 3-[[4-amino-3-[[3-chloro-5-(trifloromethyl)-2-pyridinyl]amino]-2-nitro-6-(trifluoromethyl) phenyl] thio]-2-(beta-D-glucopyranosyloxy) propionic acid) in or on the following commodity:

Commodity	Parts per million
Grape, wine [1]	3.0

[1] No US registration as of March 15, 2002.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 46738, Sept. 7, 2001, as amended at 67 FR 19130, Apr. 18, 2002; 72 FR 60260, Oct. 24, 2007]

§ 180.575 Sulfuryl fluoride; tolerances for residues.

(a)(1) *General.* Tolerances are established for residues of sulfuryl fluoride in or on the following commodities from the postharvest fumigation with sulfuryl fluoride for the control of insects:

Commodity	Parts per million
All processed food commodities not otherwise listed	2.0
Barley, bran, postharvest	0.05
Barley, flour, postharvest	0.05
Barley, grain, postharvest	0.1
Barley, pearled barley, postharvest	0.05
Cacao bean, roasted bean, postharvest	0.2
Cattle, meat, dried	0.01
Cheese	2.0
Coconut, postharvest	1.0
Coffee, bean, roasted bean, postharvest	1.0
Corn, field, flour, postharvest	0.01
Corn, field, grain, postharvest	0.05
Corn, field, grits, postharvest	15.0
Corn, field, meal, postharvest	0.01
Corn, pop, grain, postharvest	0.05
Cotton, undelinted seed, postharvest	0.5
Egg, dried	1.0
Fruit, dried, postharvest	0.05
Ginger, postharvest	0.5
Grain, aspirated fractions, postharvest	0.05
Herbs and spices group 19, postharvest	0.5
Hog, meat	0.02
Milk, powdered	2.0
Millet, grain, postharvest	0.1
Nut, pine, postharvest	0.2
Nut, tree, Group 14, postharvest	3.0
Oat, flour, postharvest	0.05
Oat, grain, postharvest	0.1
Oat, groats/rolled oats, postharvest	0.1
Peanut, postharvest	0.5
Pistachio, postharvest	3.0
Rice, bran, postharvest	0.01
Rice, flour, postharvest	0.05
Rice, grain, postharvest	0.04
Rice, hulls, postharvest	0.1
Rice, polished rice, postharvest	0.01
Rice, wild, grain, postharvest	0.05
Sorghum, grain, grain, postharvest	0.1
Triticale, grain, postharvest	0.1
Vegetable, legume, group 6, postharvest	0.5
Wheat, bran, postharvest	0.05
Wheat, flour, postharvest	0.05

Commodity	Parts per million
Wheat, germ, postharvest	0.02
Wheat, grain, postharvest	0.1
Wheat, milled byproducts, postharvest	0.05
Wheat, shorts, postharvest	0.05

(2) To assure safe use of this pesticide commodities treated with sulfuryl fluoride must be aerated for at least 24 hours prior to entering commerce.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[67 FR 5740, Feb. 7, 2002, as amended at 69 FR 3257, Jan. 23, 2004; 70 FR 40908, July 15, 2005]

§ 180.576 Cyhalofop-butyl; tolerances for residues.

(a) *General.* Time-limited tolerances are established for combined residues of cyhalofop (cyhalofop-butyl, R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate, plus cyhalofop acid, R-(+)-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionic acid) and the di-acid metabolite, (2R)-4-[4-(1-carboxyethoxy)phenoxy]-3-fluorobenzoic acid, from the application of the herbicide cyhalofop-butyl in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.03
Rice, wild, grain	0.03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 43256, June 27, 2002, as amended at 74 FR 15880, Apr. 8, 2009]

§ 180.577 Bispyribac-sodium; tolerances for residues.

(a) *General.* Tolerances are established for residues of bispyribac-sodium, sodium 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.02
Rice, straw	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[66 FR 48097, Sept. 18, 2001]

§ 180.578 Acetamiprid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine in or on the following commodities:

Commodity	Parts per million
Almond, hulls	5.0
Berry, low growing subgroups 13–07G	0.60
Bushberry subgroup 13–07B	1.6
Caneberry subgroup 13–07A	1.6
Canola, seed	0.010
Citrus, dried pulp	1.20
Cotton, gin byproducts	20.0
Cotton, undelinted seed	0.60
Fruit, citrus, group 10	0.50
Fruit, pome, group 11	1.0
Fruit, stone, group 12, except plum, prune	1.20
Grape	0.20
Mustard, seed	0.010
Nut, tree, group 14	0.10
Onion, bulb, subgroup 3–07A	0.02
Onion, green, subgroup 3–07B	4.5
Pea and bean, succulent shelled, subgroup 6B	0.40
Pistachio	0.10
Plum, prune, dried	0.40
Plum, prune, fresh	0.20
Tomato, paste	0.40
Vegetable, brassica, leafy, group 5	1.20
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8	0.20
Vegetable, leafy, except brassica, group 4	3.00
Vegetable, legume, edible podded, subgroup 6A	0.60
Vegetable, tuberous and corm, group 1	0.01

(2) Tolerances are established for the combined residues of the insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine and N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-acetamidine in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.20

Commodity	Parts per million
Egg	0.010
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.20
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.20
Horse, fat	0.10
Horse, meat	0.10
Horse, meat byproducts	0.20
Milk	0.10
Poultry, fat	0.010
Poultry, liver	0.050
Poultry, meat	0.010
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 14659, Mar. 27, 2002, as amended at 68 FR 52352, Sept. 3, 2003; 70 FR 19293, Apr. 13, 2005; 72 FR 67262, Nov. 28, 2007; 73 FR 2811, Jan. 16, 2008]

§ 180.579 Fenamidone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-, (S)-) from the application of the fungicide fenamidone on the following raw agricultural commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	55
Carrot	0.15
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Garlic	0.20
Garlic, great headed	0.20
Grape (imported)	1.0
Leek	1.5
Onion, bulb	0.20
Onion, green	1.5
Onion, welsh	1.5
Pepper, nonbell	3.5
Shallot, bulb	0.20
Shallot, fresh leaves	1.5
Sunflower	0.02
Tomato, paste	2.2
Tomato, puree	2.0
Vegetable, cucurbit, group 9	0.15
Vegetable, fruiting, group 8, except nonbell pepper	1.0
Vegetable, leafy, except Brassica, group 4	60
Vegetable, tuberous and corm, subgroup 1C	0.02

(2) Tolerances are established for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.10
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.10
Milk	0.02
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.10

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide fenamidone, (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Carrot	0.20	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide fenamidone (4-H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methlthio)-5-phenyl-3-(phenylamino, (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on the following agricultural commodities when present therein as a result of application of fenamidone to the crops in paragraph (a)(1).

Commodity	Parts per million
Strawberry	0.15
Wheat, grain	0.10
Wheat, hay	0.50
Wheat, forage	0.15
Wheat, straw	0.35

[67 FR 60976, Sept. 27, 2002, as amended at 69 FR 58066, Sept. 29, 2004; 71 FR 55293, Sept. 22, 2006; 72 FR 60272, Oct. 24, 2007]

§ 180.580 Iodosulfuron-Methyl-Sodium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide *Iodosulfuron-Methyl-Sodium (methyl 4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5 triazin-2-yl)ureidosulfonyl]benzoate, sodium salt*) in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, grain	0.03
Corn, field, stover	0.05
Wheat, forage	0.10
Wheat, grain	0.02
Wheat, hay	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 57532, Sept. 11, 2002, as amended at 74 FR 23644, May 20, 2009]

§ 180.581 Iprovalicarb; tolerances for residues.

(a) *General.* Tolerances are established for residues of iprovalicarb, [2-methyl-1[[[(1S)-(4-methylphenyl) ethyl] amino]carbonyl] propyl]carbamic acid methylethylester, in or on the following commodities.

Commodity	Parts per million
Grape [1]	2.0
Tomato [1]	1.0

[1]There is no U.S. registration as of September 1, 2005.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 54359, Aug. 22, 2002, as amended at 70 FR 55281, Sept. 21, 2005]

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate), expressed as parent compound, in or on the following raw agricultural commodities.

Commodity	Parts per million
Almond, hulls	7.0
Apple, wet pomace	8.0
Avocado	0.6
Banana	0.04
Barley, grain	1.4
Barley, hay	25
Barley, straw	6.0
Bean, succulent shelled	0.5
Beet, sugar, dried pulp	1.0
Beet, sugar, roots	0.2
Beet, sugar, tops	8.0
Berry, group 13	4.0
Borage, seed	0.45
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	16.0
Canistel	0.6
Castor oil plant, seed	0.45
Chinese tallowtree, seed	0.45
Citrus, dried pulp	12.5
Citrus, oil	9.0
Corn, field, forage	5.0
Corn, field, grain	0.1
Corn, field, refined oil	0.2
Corn, field, stover	17.0
Corn, pop, grain	0.1
Corn, pop, stover	17.0
Corn, sweet, forage	5.0
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	23.0
Cotton, gin byproducts	30
Cotton, undelinted seed	0.3
Crambe, seed	0.45
Cuphea, seed	0.45
Echium, seed	0.45
Euphorbia, seed	0.45
Evening primrose, seed	0.45
Flax, seed	0.45
Fruit, citrus, group 10	2.0
Fruit, pome, group 11	1.5
Fruit, stone, group 12	0.9
Gold of pleasure, seed	0.45
Grain, aspirated fractions	2.5
Grape	2.0
Grape, raisin	7.0
Grass, forage	10
Grass, hay	4.5
Grass, seed screenings	27
Grass, straw grown for seed	14
Hare's ear mustard, seed	0.45
Hop, dried cones	23.0
Jojoba, seed	0.45
Lesquerella, seed	0.45
Lunaria, seed	0.45
Mango	0.6
Meadowfoam, seed	0.45
Milkweed, seed	0.45
Mustard, seed	0.45
Niger seed, seed	0.45
Nut, tree, group 14	0.04
Oat, grain	1.2

Commodity	Parts per million
Oat, hay	18
Oat, straw	15
Oil radish, seed	0.45
Papaya	0.6
Pea, succulent	0.2
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
Peanut	0.05
Peanut, refined oil	0.1
Peppermint, tops	8.0
Pistachio	0.7
Poppy, seed	0.45
Radish, tops	16
Rapeseed, seed	0.45
Rose hip, seed	0.45
Rye, grain	0.04
Rye, straw	0.5
Safflower, seed	0.45
Sapodilla	0.6
Sapote, black	0.6
Sapote, mamey	0.6
Sesame, seed	0.45
Soybean, forage	5.0
Soybean, hay	7.0
Soybean, hulls	0.06
Soybean, seed	0.04
Spearmint, tops	8.0
Star apple	0.6
Stokes aster, seed	0.45
Strawberry	1.2
Sunflower, seed	0.45
Sweet rocket, seed	0.45
Tallowwood, seed	0.45
Tea oil plant, seed	0.45
Vegetable, bulb, group 3	0.9
Vegetable, cucurbit, group 9	0.5
Vegetable, foliage of legume, except soybean, subgroup 7A	25.0
Vegetable, fruiting, group 8	1.4
Vegetable, leafy, except brassica, group 4	29.0
Vegetable, leaves of root and tuber, group 2, except sugar beet	16.0
Vegetable, legume, edible podded, subgroup 6A	0.5
Vegetable, root, except sugar beet, subgroup 1B	0.4
Vegetable, tuberous and corm, subgroup 1C	0.04
Vegetables, foliage of legume, group 7	25
Vernonia, seed	0.45
Wheat, grain	0.02
Wheat, hay	6.0
Wheat, straw	8.5

(2) Tolerances are established for combined residues of the fungicide pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound, in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.1
Cattle, liver	1.5
Cattle, meat	0.1
Cattle, meat byproducts, except liver	0.2
Goat, fat	0.1
Goat, liver	1.5
Goat, meat	0.1
Goat, meat byproducts, except liver	0.2
Hog, fat	0.1
Hog, liver	1.5
Hog, meat	0.1
Hog, meat byproducts, except liver	0.2
Horse, fat	0.1
Horse, liver	0.1
Horse, meat	0.1
Horse, meat byproducts, except liver	0.2
Milk	0.1
Sheep, fat	0.1
Sheep, liver	1.5
Sheep, meat	0.1
Sheep, meat byproducts, except liver	0.2

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for combined residues of the fungicide pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl]carbamate) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The time-limited tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Endive, Belgian	11.0	12/31/09
Sugarcane, cane	0.02	12/31/11
Sugarcane, molasses	0.4	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 60901, Sept. 27, 2002, as amended at 69 FR 63100, Oct. 29, 2004; 71 FR 17021, Apr. 5, 2006; 72 FR 54569, Sept. 26, 2007; 73 FR 15431, Mar. 24, 2008; 73 FR 21842, Apr. 23, 2008; 73 FR 44167, July 30, 2008; 74 FR 11499, Mar. 18, 2009]

§ 180.583 Triticonazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, from the treatment of seed prior to planting in

or on raw agricultural commodities as follows:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 60959, Sept. 27, 2002]

§ 180.584 Tolylfluanid; tolerances for residues.

(a) *General.* Tolerances are established for residues of tolylfluanid, 1,1-dichloro-N-[(dimethylamino)-sulfonyl]-1-fluoro-N-(4-methylphenyl)methanesulfenamide in or on the following commodities.

Commodity	Parts per million
Apple [1]	5.0
Grape [1]	11
Hop, dried cones [1]	30
Tomato [1]	2.0

[1] No U.S. registration as of August 31, 2002.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[67 FR 60141, Sept. 25, 2002]

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, pyraflufen-ethyl, ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent in or on the following food commodities:

Commodity	Parts per million	Expiration/revocation date
Cattle, meat byproducts	0.02	10/15/12
Corn, field, forage	0.01	None
Corn, field, grain	0.01	None
Corn, field, stover	0.01	None
Cotton, gin byproducts	1.5	None
Cotton, undelinted seed	0.04	None
Goat, meat byproducts	0.02	10/15/12
Grass, forage, group 17	1.0	None
Grass, hay, group 17	1.4	None
Horse, meat byproducts	0.02	10/15/12
Milk	0.02	10/15/12
Potato	0.02	None
Sheep, meat byproducts	0.02	10/15/12
Soybean, forage	0.05	None
Soybean, hay	0.10	None
Soybean, seed	0.01	None
Wheat, forage	0.02	None
Wheat, grain	0.01	None
Wheat, hay	0.01	None
Wheat, straw	0.01	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 23055, Apr. 30, 2003, as amended at 68 FR 27739, May 21, 2003; 69 FR 26312, May 12, 2004; 73 FR 51743, Sept. 5, 2008]

§ 180.586 Clothianidin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities:

Commodity	Parts per million
Beet, sugar, dried pulp	0.03
Beet, sugar, molasses	0.05
Beet, sugar, roots	0.02
Canola, seed	0.01
Corn, field, forage	0.10
Corn, field, grain	0.01
Corn, field, stover	0.10
Corn, pop, grain	0.01
Corn, pop, stover	0.10
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husk removed	0.01
Corn, sweet, stover	0.10
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Fruit, pome	1.0
Grape	0.60
Milk	0.01
Potato	0.05
Potato, granules/flakes	0.08
Sorghum, forage, grain, stover	0.01

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Beet, sugar, roots	0.02	12/31/09
Beet, sugar, tops	0.02	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* Tolerances are established for the indirect or inadvertent residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities when present therein as a result of the application of clothianidin to crops listed in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18	0.02
Grain, cereal, forage, fodder and straw, group 16	0.02
Grass, forage, fodder and hay, group 17	0.02
Soybean, forage	0.02
Soybean, hay	0.02

[68 FR 32399, May 30, 2003, as amended at 70 FR 7894, Feb. 16, 2005; 71 FR 74801, Dec. 13, 2006; 73 FR 6856, Feb. 6, 2008]

§ 180.587 Famoxadone; tolerance for residues.

(a) *General.* Tolerances are established for residues of the fungicide famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on the following commodities:

Commodity	Parts per million
Caneberry subgroup 13–07A	10
Cattle, fat	0.02
Cattle, liver	0.05
Cilantro, leaves	25
Goat, fat	0.02
Goat, liver	0.05
Grape, raisin [1]	4.0
Hop, dried cone	80
Horse, fat	0.02
Horse, liver	0.05
Milk, fat (reflecting negligible residues in whole milk)	0.06
Onion, bulb, subgroup 3–07A	0.45
Onion, green, subgroup 3–07B	40
Potato	0.02
Sheep, fat	0.02
Sheep, liver	0.05
Spinach	50
Tomato	1.0
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8, except tomato	4.0
Vegetable, leafy, except Brassica, group 4, except spinach	25

[1] There are no U.S. registrations as of May 15, 2003.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with a regional registrations.* Tolerances with a regional registration as defined in Sec. 180.1(n) are established for the residues of the fungicide famoxadone, 3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on the raw agricultural commodities:

Commodity	Parts per million
Grape	2.5

(d) *Indirect or inadvertant residues.* [Reserved]

[68 FR 39471, July 2, 2003, as amended at 72 FR 28881, May 23, 2007; 74 FR 9364, Mar. 4, 2009]

§ 180.588 Quinoxyfen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on the following raw agricultural commodities:

Commodity	Parts per million
Artichoke, globe	1.4
Fruit, stone, group 12	0.70
Hop, dried cones	3.0
Gourd, edible	0.20
Grape	0.60
Lettuce, head	7.0
Lettuce, leaf	19
Melon, subgroup 9A	0.08
Pepper, bell	0.35
Pepper, nonbell	1.7
Pumpkin	0.20
Squash, winter	0.20
Strawberry	0.90

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 55858, Sept. 29, 2003, as amended at 70 FR 4032, Jan. 28, 2005; 71 FR 50354, Aug. 25, 2006; 74 FR 14743, Apr. 1, 2009]

§ 180.589 Boscalid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4′-chloro[1,1′-biphenyl]-2-yl) in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	17
Apple, wet pomace	10
Avocado	1.5
Banana, import [1]	0.20
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	18.0
Bushberry, subgroup 13B	13.0
Caneberry, subgroup13A	6.0
Canistel	1.5
Canola, refined oil	5.0
Canola, seed	3.5
Cotton, gin byproducts	55.0
Cotton, undelinted seed	1.0
Cucumber	0.5
Cucumber	0.20
Fruit, pome, group 11	3.0
Fruit, stone, group 12	1.7
Grain, aspirated fractions	3.0
Grape	3.5
Grape, raisin	8.5
Hop, dried cones	35
Leaf petioles subgroup 4B	45
Leafy greens subgroup 4A, except head lettuce and leaf lettuce	60
Lettuce, head	6.5
Lettuce, leaf	11.0
Mango	1.5
Nut, tree, group 14	0.70
Papya	1.5
Pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea and grain lupin	2.5
Pea and bean, succulent shelled, subgroup 6B, except cowpea	0.6
Peanut	0.05
Peanut, meal	0.15
Peanut, refined oil	0.15
Peppermint, tops	30.0
Pistachio	0.70
Sapodilla	1.5
Sapote, black	1.5
Sapote, mamey	1.5
Soybean, hulls	0.2
Soybean, seed	0.1
Soybean, vegetable	2.0
Spearmint, tops	30.0
Star apple	1.5
Strawberry	4.5
Sunflower, seed	0.60
Vegetable, bulb, group 3	3.0
Vegetable, cucurbit, group 9, except cucumber	1.6
Vegetable, fruiting, group 8	1.2
Vegetable, legume, edible podded, subgroup 6A	1.6
Vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip	1.0
Vegetable, root, subgroup 1A , except sugar beet, garden beet, radish, and turnip	0.7
Vegetable, tuberous and corm, subgroup 1C	0.05

[1] No US registration as of January 31, 2006.

(2) Tolerances are established for the combined residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4′-chloro[1,1′-biphenyl]-2-yl) and metabolites 2-chloro-N-(4′-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide and glucuronic acid conjugate of 2-chloro-N-(4′-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.30
Cattle, meat	0.10
Cattle, meat byproducts	0.35
Egg	0.02
Goat, fat	0.30
Goat, meat	0.10
Goat, meat byproducts	0.35
Hog, fat	0.10
Hog, meat	0.05
Hog, meat byproducts	0.10
Horse, fat	0.30
Horse, meat	0.10
Horse, meat byproducts	0.35
Milk	0.10
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproduct	0.10
Sheep, fat	0.30
Sheep, meat	0.10
Sheep, meat byproducts	0.35

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residues of the fungicide boscalid, 2-chloro-N-(4’-chloro [1, 1’-biphenyl]-2-yl)-3-pyridinecarboxamide in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Endive, Belgian	16	12/31/09
Tangerine	2.0	12/31/08

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide boscalid, 3-

pyridinecarboxamide, 2-chloro-N-(4′-chloro[1,1′-biphenyl]-2-yl) in or on the following raw agricultural commodities when present therein as a result of application of boscalid to the growing crops in paragraph (a)(1) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.0
Animal feed, nongrass, group 18, hay	2.0
Animal feed, nongrass, group 18, seed	0.05
Beet, garden, roots	0.1
Beet, sugar, roots	0.1
Cotton, gin byproducts	0.30
Cotton, undelinted seed	0.05
Cowpea, seed	0.1
Flax, seed	3.5
Grain, cereal, forage, fodder and straw, group 16, forage	2.0
Grain, cereal, forage, fodder and straw, group 16, stover	1.5
Grain, cereal, forage, fodder and straw, group 16, straw	3.0
Grain, cereal, group 15	0.20
Grass, forage, fodder, and hay, group 17, forage	2.0
Grass, forage, fodder, and hay, group 17, hay	8.0
Grass, forage, fodder, and hay, group 17, seed screenings	0.20
Grass, forage, fodder, and hay, group 17, straw	0.30
Lupin, grain, grain	0.1
Pea, field, seed	0.1
Radish, roots	0.1
Rice, hulls	0.50
Turnip, roots	0.1
Vegetable, foliage of legume, group 7, forage	1.5
Vegetable, foliage of legume, group 7, hay	2.0
Vegetable, foliage of legume, group 7, vines	0.05
Vegetable, leafy, except brassica, group 4, except celery, lettuce and spinach	1.0
Vegetable, leaves of root and tuber, group 2	0.1

[68 FR 44651, July 30, 2003, as amended at 69 FR 19774, Apr. 14, 2004; 70 FR 55293, Sept. 21, 2005; 71 FR 6364, Feb. 8, 2006; 71 FR 25961, May 3, 2006; 71 FR 76190, Dec. 20, 2006; 73 FR 16558, Mar. 28, 2008]

§ 180.590 2, 6-Diisopropylnaphthalene (2, 6-DIPN); tolerances for residues.

(a) *General.* Time-limited tolerances are established for residues of 2, 6-DIPN in or on the following commodities resulting from post-harvest applications to potato, when 2, 6-DIPN is used in accordance with good agricultural practices:

Commodity	Parts per million	Expiration/revocation date
Cattle, fat	0.8	8/1/09
Cattle, liver	0.3	8/1/09
Cattle, meat	0.1	8/1/09
Cattle, meat byproducts	0.1	8/1/09
Goat, fat	0.8	8/1/09
Goat, liver	0.3	8/1/09
Goat, meat	0.1	8/1/09
Goat, meat byproducts	0.1	8/1/09
Hog, fat	0.8	8/1/09
Hog, liver	0.3	8/1/09
Hog, meat	0.1	8/1/09
Hog, meat byproducts	0.1	8/1/09
Horse, fat	0.8	8/1/09
Horse, liver	0.3	8/1/09
Horse, meat	0.1	8/1/09
Horse, meat byproducts	0.1	8/1/09
Milk	0.1	8/1/09
Potato	2.0	8/1/09
Potato, wet peel	6.0	8/1/09
Sheep, fat	0.8	8/1/09
Sheep, liver	0.3	8/1/09
Sheep, meat	0.1	8/1/09
Sheep, meat byproducts	0.1	8/1/09

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 52011, Sept. 1, 2006]

§ 180.591 Trifloxysulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide trifloxysulfuron, *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(2,2,2-trifluoroethoxy)-2-pyridinesulfonamide in or on the following raw agricultural commodities.

Commodity	Parts per million
Almond	0.02
Almond, hulls	0.01
Fruit, citrus, Group 10	0.03
Cotton, undelinted seed	0.05
Cotton, gin byproducts	1.0
Sugarcane	0.01
Tomato	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 54386, Sept. 17, 2003]

§ 180.592 Butafenacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-

(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cotton, gin byproducts	10
Cotton, undelinted seed	0.50

(2) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) and its metabolite CGA-293731 (1-carboxy-1-methylethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate), in or on the following livestock commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.50
Goat, kidney	0.05
Goat, liver	0.50
Hog, kidney	0.05
Hog, liver	0.50
Horse, kidney	0.05
Horse, liver	0.50
Sheep, kidney	0.05
Sheep, liver	0.50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* [Reserved]

[68 FR 54827, Sept. 19, 2003]

§ 180.593 Etoxazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	2.0
Apple, wet pomace	0.50
Cattle, fat	0.02
Cattle, liver	0.01
Cotton, gin byproducts	1.0
Cotton, undelinted seed	0.05
Cucumber	0.02
Fruit, pome, group 11	0.20
Fruit, stone, group 12, except plum	1.0
Goat, fat	0.02
Goat, liver	0.01
Grape	0.50
Grape, raisin	1.5
Hop, dried cones	7.0
Horse, fat	0.02
Horse, liver	0.01
Milk, fat	0.01
Nut, tree, group 14	0.01
Peppermint, oil	20
Peppermint, tops	10
Pistachio	0.01
Plum	0.15
Plum, prune, dried	0.30
Sheep, fat	0.02
Sheep, liver	0.01
Spearmint, oil	20
Spearmint, tops	10
Strawberry	0.50
Tangerine [1]	0.10
Tomato	0.20
Vegetable, cucurbit subgroup 9A	0.20

[1]There are no U.S. registrations for use of etoxazole on tangerines as of September 26, 2003.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* [Reserved]

[68 FR 55493, Sept. 26, 2003, as amended at 70 FR 41625, July 20, 2005; 72 FR 72963, Dec. 26, 2007; 74 FR 25160, May 27, 2009]

§ 180.594 Thiacloprid; tolerances for residues.

(a) *General.* Tolerances for combined residues of the insecticide thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat byproducts	0.050
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat byproducts	0.050
Milk	0.030

Commodity	Parts per million
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat byproducts	0.050

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 55512, Sept. 26, 2003]

§ 180.595 Flufenpyr-ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide, flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], in or on the following commodities:

Commodity	Parts per million
Corn, field, grain	0.01
Soybean, seed	0.01
Sugarcane, cane	0.01

(2) Tolerances are established for residues of the herbicide flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], and its metabolite, S-3153 acid-4-OH; [2-chloro-4-hydroxy-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated, in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, stover	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[68 FR 54842, Sept. 19, 2003]

§ 180.596 Fosthiazate; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of Fosthiazate (*O*-ethyl *S*-(1-methylpropyl)(2-oxo-3-thiazolidinyl)phosphonothioate and its metabolite *O*-ethyl *S*-(1-methylpropyl)[2-(methylsulfonyl)ethyl] phosphoramidothioate) (ASC–67131).

Commodity	Parts per million
Tomato	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 18275, Apr. 7, 2004]

§ 180.597 Mesosulfuron-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide mesosulfuron-methyl, (methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonyl]amino]sulfonyl] -4-[[(methylsulfonyl)amino] methyl]benzoate]) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.01
Goat, meat byproducts	0.01
Grain, aspirated fractions	0.60
Horse, meat byproducts	0.01
Sheep, meat byproducts	0.01
Wheat, forage	0.60
Wheat, germ	0.10
Wheat, grain	0.03
Wheat, hay	0.06
Wheat, straw	0.30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 18263, Apr. 7, 2004]

§ 180.598 Novaluron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy) ethoxyphenyl]amino]carbonyl]-2,6-difluorobenzamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace	8.0
Brassica, head and stem, subgroup 5A	0.50
Cattle, fat	11
Cattle, kidney	1.0
Cattle, liver	1.0
Cattle, meat	0.60
Cattle, meat byproducts, except kidney and liver	0.60
Cotton, gin byproducts	30
Cotton, undelinted seed	0.60
Egg	0.05
Fruit, pome, group 11	2.0
Goat, fat	11
Goat, kidney	1.0
Goat, liver	1.0
Goat, meat	0.60
Goat, meat byproducts except kidney and liver	0.60
Hog, fat	0.05
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	11
Horse, kidney	1.0
Horse, liver	1.0
Horse, meat	0.60
Horse, meat byproducts, except kidney and liver	0.60
Milk	1.0
Milk, fat	20
Poultry, fat	0.40
Poultry, meat	0.03
Poultry, meat byproducts	0.04
Sheep, fat	11
Sheep, kidney	1.0
Sheep, liver	1.0
Sheep, meat	0.60
Sheep, meat byproducts, except kidney and liver	0.60
Sugarcane, cane	0.50
Tomato	1.0
Vegetable, tuberous and corn, subgroup 1C	0.05

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy] phenyl]amino]carbonyl]-2,6-difluorobenzamide in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Strawberry	0.50	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[69 FR 31021, June 2, 2004, as amended at 71 FR 17014, Apr. 5, 2006; 71 FR 61911, Oct. 20, 2006; 73 FR 74982, Dec. 10, 2008; 74 FR 637, Jan. 7, 2009; 74 FR 20891, May 6, 2009]

§ 180.599 Acequinocyl; tolerances for residues.

(a) *General.* Tolerances for combined residues of the insecticide acequinocyl, 2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione, and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, expressed as acequinocyl equivalents in or on the following commodities:

Commodity	Parts per million
Almond, hulls	2.0
Apple, wet pomace	1.0
Cattle, fat	0.02
Cattle, liver	0.02
Citrus, oil	30
Fruit, citrus, group 10	0.20
Fruit, pome, group 11	0.40
Goat, fat	0.02
Goat, liver	0.02
Grape	1.6
Horse, fat	0.02
Horse, liver	0.02
Nut, tree, group 14	0.02
Pistachio	0.02
Sheep, fat	0.02
Sheep, liver	0.02
Strawberry	0.40

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 43533, July 21, 2004, as amended at 73 FR 17910, Apr. 2, 2008]

§ 180.600 Propoxycarbazone; tolerances for residues

(a) *General.* (1) Tolerances are established for combined residues of the herbicide propoxycarbazone methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate and its metabolite methyl 2-[[[(4,5-dihydro-3-(2-hydroxypropoxy)-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in/on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage	20
Grass, hay	25
Wheat, forage	17
Wheat, grain	0.02
Wheat, hay	0.15
Wheat, straw	0.05

(2) Tolerances are established for residues of the herbicide propoxycarbazone methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in/on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat	0.05
Cattle, meat byproducts	0.3
Goat, meat	0.05
Goat, meat byproducts	0.3
Horse, meat	0.05
Horse, meat byproducts	0.3
Milk	0.03
Sheep, meat	0.05
Sheep, meat byproducts	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 40781, July 7, 2004, as amended at 71 FR 52487, Sept. 6, 2006; 74 FR 9377, Mar. 4, 2009]

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cyazofamid, 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on the following commodities:

Commodity	Parts per million
Carrot, roots	0.09
Grape, wine,* import	1.5
Potato	0.02
Tomato	0.20
Vegetable, cucurbit, group 9	0.10

*No domestic registrations.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 58299, Sept. 30, 2004, as amended at 73 FR 21839, Apr. 23, 2008]

§ 180.602 Spiroxamine; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide spiroxamine (8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine) and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety, calculated as parent equivalent, in or on the following raw agricultural commodities:

Commodity	Parts per million
Banana (import)	3.0
Grape (import)	1.0
Hop, dried cones	50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 42570, July 16, 2004]

§ 180.603 Dinotefuran; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of Dinotefuran, [*N*-methyl-*N*′-nitro-*N*″-((tetrahydro-3-furanyl)methyl)guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran.

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	1.4
Cotton, undelinted seed	0.4
Cotton, gin byproducts	8.0
Grape	0.9
Grape, raisin	2.5
Potato	0.05
Potato, chips	0.1
Potato, granules/flakes	0.15
Tomato, paste	1.0
Vegetable, fruiting, group 8	0.7
Vegetable, cucurbit, group 9	0.5
Vegetable, leafy, except Brassica, group 4	5.0

(2) Tolerances are established for residues of dinotefuran *N*-methyl-*N′*-nitro-*N″*-tetrahydro-3-furanyl)methyl)guanidine in/on the following commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of Dinotefuran, [*N* -methyl- *N* ′-nitro- *N*″ -((tetrahydro-3-furanyl)methyl)guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Rice, grain	2.8	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 14546, Mar. 23, 2005, as amended at 74 FR 12601, Mar. 25, 2009]

§ 180.604 Mepanipyrim; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect of inadvertent residues.* [Reserved]

(e) *Revoked tolerances subject to the channel of trade provisions.* [Reserved]

(f) *Import tolerances.* Tolerances are established for the combined residues of mepanipyrim, 4-methyl-N-phenyl-6-(1-propynyl)-2-pyrimidinamine, and its metabolite, 4-methyl-N-phenyl-6-(2-hydroxypropylk)-2-pyrimidinamine, both free and conjugated in or on the following commodities:

Commodity	Parts per million
Grape	1.5
Grape, raisin	3.0
Strawberry	1.5
Tomato	0.5

[68 FR 60827, Oct. 13, 2004]

§ 180.605 Penoxsulam; tolerances for residues.

(a) *General.* Tolerances are established for the herbicide, penoxsulam (2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide) in/on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	0.01
Fish	0.01
Fish, shellfish, crustacean	0.01
Fish, shellfish, mollusc	0.02
Grape	0.01
Nut, tree, group 14	0.01
Pistachio	0.01
Rice, grain	0.02
Rice, straw	0.50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[69 FR 57197, Sept. 24, 2004, as amended at 72 FR 40763, July 25, 2007; 74 FR 18648, Apr. 24, 2009]

§ 180.607 Spiromesifen; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its

enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in or on the following primary crop commodities:

Commodity	Parts per million
Bean, dry	0.02
Bean, edible podded	0.80
Bean, succulent	0.10
Berry and small fruit, low growing berry, subgroup 13-07G	2.0
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	12
Corn, field, forage	5.0
Corn, field, grain	0.02
Corn, field, stover	8.0
Corn, pop, grain	0.02
Corn, pop, stover	4.0
Corn, sweet, forage	17
Corn, sweet, kernel plus cob with husks removed	0.02
Corn, sweet, stover	12
Cotton, gin byproducts	15
Cotton, undelinted seed	0.50
Cowpea, forage	30
Cowpea, hay	86
Leafy greens subgroup 4A	12
Tomato, paste	0.80
Vegetable, cucurbit, group 9	0.10
Vegetable, fruiting, group 8	0.45
Vegetable, tuberous and corm, subgroup 1C	0.02

(2) Tolerances are established for the combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), and its metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties, calculated as the parent compound equivalents in the following livestock commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.02
Cattle, meat byproducts	0.20
Goat, fat	0.10
Goat, meat	0.02
Goat, meat byproducts	0.20
Horse, fat	0.10
Horse, meat	0.02
Horse, meat byproducts	0.20
Milk	0.01
Milk, fat	0.25
Sheep, fat	0.10
Sheep, meat	0.02
Sheep, meat byproducts	0.20

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of spiromesifen, (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Soybean, forage	30	12/31/11
Soybean, hay	86	12/31/11
Soybean, seed	0.02	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the inadvertent or indirect combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1- oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in the following rotational crop commodities:

Commodity	Parts per million
Alfalfa, forage	1.5
Alfalfa, hay	3.0
Barley, grain	0.03
Barley, hay	0.25
Barley, straw	0.15
Beet, sugar, roots	0.03
Beet, sugar, tops	0.20
Oat, forage	0.20
Oat, grain	0.03
Oat, hay	0.25
Oat, straw	0.25
Wheat, forage	0.20
Wheat, grain	0.03
Wheat, hay	0.15
Wheat, straw	0.25

[70 FR 43283, July 27, 2005, as amended at 72 FR 3079, Jan. 24, 2007; 73 FR 13140, Mar. 12, 2008; 73 FR 52606, Sept. 10, 2008; 74 FR 8492, Feb. 25, 2009; 74 FR 15886, Apr. 8, 2009]

§ 180.608 Spirodiclofen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of spirodiclofen per se (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate) in or on the following plant commodities:

Commodity	Parts per million
Almond, hulls	20.0
Apple, wet pomace	2.0
Citrus, juice	0.60
Citrus, oil	20.0
Fruit, citrus, group 10	0.50
Fruit, pome, group 11	0.80
Fruit, stone, group 12	1.0
Grape	2.0
Grape, juice	2.4
Grape, raisin	4.0
Hop, dried cones	30
Nut, tree, group 14	0.10
Pistachio	0.10

(2) Tolerances are established for residues of spirodiclofen (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate) and its free enol metabolite BAJ 2510 (3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4,5]dec-3-en-2-one) in or on the following livestock commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat byproducts	0.10
Cattle, meat	0.02
Goat, fat	0.02
Goat, meat byproducts	0.1
Goat, meat	0.02
Horse, fat	0.02
Horse, meat byproducts	0.1
Horse, meat	0.02
Milk	0.01
Milk, fat	0.03
Sheep, fat	0.02
Sheep. meat byproducts	0.1
Sheep. meat	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 40211, July 13, 2005, as amended at 73 FR 25539, May 7, 2008]

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the following raw agricultural commodities:

Commodity	Parts per million
Leaf petioles subgroup 4B	4.0
Peanut	0.010
Peanut, hay	20.0
Peanut, refined oil	0.030
Tomato, paste	1.5
Vegetable, fruiting, group 8	1.0
Vegetable, tuberous and corm, subgroup 1C	0.010

(2) Tolerances are established for the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.05
Cattle, meat byproducts	0.10
Goat, fat	0.10
Goat, meat	0.05
Goat, meat byproducts	0.10
Horse, fat	0.10
Horse, meat	0.05
Horse, meat byproducts	0.10
Milk	0.02
Milk, fat	0.50
Sheep, fat	0.10
Sheep, meat	0.05
Sheep, meat byproducts	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-

methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the following raw agricultural commodities when present therein as a result of the application of fluoxastrobin to the growing crops listed in paragraph (a)(1) of this section:

Commodity	Parts per million
Alfalfa, forage	0.050
Alfalfa, hay	0.10
Cotton, gin byproducts	0.020
Grain, cereal, forage, fodder, and straw, group 16	0.10
Grass, forage	0.10
Grass, hay	0.50
Vegetable, foliage of legume, group 7	0.050

[70 FR 54650, Sept. 16, 2005]

§ 180.610 Aminopyralid; tolerances for residues.

(a) *General.* (1) Tolerances are established for free and conjugated residues of the herbicide, aminopyralid (2-pyridine carboxylic acid, 4-amino-3,6-dichloro-) calculated as aminopyralid in or on:

Commodity	Parts per million
Grain, aspirated fractions	0.2
Grass, forage	25
Grass, hay	50
Wheat, bran	0.1
Wheat, forage	2.0
Wheat, grain	0.04
Wheat, hay	4.0
Wheat, straw	0.25

(2) Tolerances are established for residues of the herbicide aminopyralid in or on:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, kidney	0.3
Cattle, meat	0.02
Cattle, meat byproducts, except kidney	0.02
Goat, fat	0.02
Goat, kidney	0.3
Goat, meat	0.02
Goat, meat byproducts, except kidney	0.02
Horse, fat	0.02
Horse, kidney	0.3
Horse, meat	0.02
Horse, meat byproducts, except kidney	0.02
Milk	0.03
Sheep, fat	0.02
Sheep, kidney	0.3
Sheep, meat	0.02
Sheep, meat byproducts, except kidney	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 46428, Aug. 10, 2005]

§ 180.611 Pinoxaden; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione (M2), and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione (M4), and 4-(7,9-dioxo-hexahydro-pyrazolo[1,2-d] [1,4,5]oxadiazepin-8-yl)-3,5-diethyl-benzoic acid (M6), calculated as pinoxaden, in/on the following commodities:

Commodity	Parts per million
Barley, bran	1.6
Barley, grain	0.9
Barley, hay	1.5
Barley, straw	1.0
Egg	0.06
Poultry, fat	0.06
Poultry, meat	0.06
Poultry, meat byproducts	0.06
Wheat, bran	3.0
Wheat, forage	3.5
Wheat, grain	1.3
Wheat, hay	2.0
Wheat, straw	1.5

(2) For the combined residues of pinoxaden, 8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate), and its metabolites M2, 8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione, and free and conjugated forms of M4, 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione, calculated as pinoxaden, in/on the following commodities:

Commodity	Parts per million
Cattle, fat	0.04
Cattle, meat	0.04
Cattle, meat byproducts	0.04
Milk	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 43322, July 27, 2005]

§ 180.612 Topramezone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide topramezone, [3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.15
Corn, field, forage	0.05
Corn, field, grain	0.01
Corn, field, stover	0.05
Corn, pop, grain	0.01
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.05
Goat, kidney	0.05
Goat, liver	0.15
Horse, kidney	0.05
Horse, liver	0.15
Sheep, kidney	0.05
Sheep, liver	0.15

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 46419, Aug. 10, 2005]

§ 180.613 Flonicamid; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [*N*-(4-trifluoromethylnicotinoyl)glycine] in or on the following raw agricultural commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	1.5
Brassica, leafy greens, subgroup 5B	16
Cotton, gin byproducts	6.0
Cotton, hulls	2.0
Cotton, meal	1.0
Cotton, undelinted seed	0.50
Fruit, pome, group 11	0.20
Fruit, stone, group 12	0.60
Hop, dried cones	7.0
Okra	0.40
Potato, granules/flakes	0.40
Radish, tops	16
Spinach	9.0
Tomato, paste	2.0
Tomato, puree	0.50
Turnip, greens	16
Vegetable, cucurbit, group 9	0.40
Vegetable, fruiting, group 8	0.40
Vegetable, leafy, except brassica, group 4, except spinach	4.0
Vegetable, root, except sugar beet, subgroup 1B	0.60
Vegetable, tuberous and corm, subgroup 1C	0.20

(2) Tolerances are established for combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide], and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.08
Cattle, meat byproducts	0.08
Egg	0.04
Goat, fat	0.03
Goat, meat	0.08
Goat, meat byproducts	0.08
Horse, fat	0.03
Horse, meat	0.08
Horse, meat byproducts	0.08
Milk	0.03
Poultry, fat	0.03
Poultry, meat	0.03
Poultry, meat byproducts	0.03
Sheep, fat	0.03
Sheep, meat	0.08
Sheep, meat byproducts	0.08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 51614, Aug. 31, 2005, as amended at 71 FR 15608, Mar. 29, 2006; 73 FR 17923, Apr. 2, 2008]

§ 180.614 Kasugamycin; tolerances for residues.

(a) *General.* Tolerances are established for residues of kasugamycin, 3-O-[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetradeoxy-α-D-arabino-hexopyranosyl]-D-chiro-inositol in or on the following raw agricultural commodity:

Commodity	Parts per million
Vegetable, fruiting, group 8[1]	0.04

[1]There is no U.S. registration as of September 1, 2005.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[70 FR 55752, Sept. 23, 2005]

§ 180.615 Amicarbazone; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide, amicarbazone [4-amino-4, 5-dihydro- N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, liver	1.0
Cattle, meat	0.01
Cattle, meat byproducts, except liver	0.10
Corn, field, forage	0.80
Corn, field, grain	0.05
Corn, field, stover	1.0
Goat, fat	0.01
Goat, liver	1.0
Goat, meat	0.01
Goat, meat byproducts, except liver	0.10
Hog, fat	0.01
Hog, liver	0.10
Hog, meat	0.01
Hog, meat byproducts, except liver	0.01
Horse, fat	0.01
Horse, liver	1.0
Horse, meat	0.01
Horse, meat byproducts, except liver	0.10
Milk	0.01
Sheep, fat	0.01
Sheep, liver	1.0
Sheep, meat	0.01
Sheep, meat byproducts, except liver	0.10
Poultry, liver	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of amicarbazone [4-amino-4, 5-dihydro-N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on the following commodities when present therein as a result of application of amicarbazone to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.10
Cotton, gin byproducts	0.30
Cotton, undelinted seed	0.07
Soybean, forage	1.50
Soybean, hay	5.0
Soybean, seed	0.80
Wheat, forage	0.50
Wheat, grain	0.10
Wheat, hay	1.0
Wheat, milled byproducts	0.15
Wheat, straw	0.50

[70 FR 55760, Sept. 23, 2005]

§ 180.616 Fenpropimorph; tolerances for residues.

Tolerances are established for the residues of the fungicide fenpropimorph (rel-(2R,6S)-4-[3-[4-(1,1-dimethylethyl)phenyl]-2-

methylpropyl]-2,6-dimethylmorpholine) in or on the following commodity:

Commodity	Parts per million
Banana*	2.0

*No U.S. registration as of February 10, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 15612, Mar. 29, 2006]

§ 180.617 Metconazole; tolerances for residues.

(a)(1) *General.* Tolerances are established for the residue of the fungicide metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) in or on the following commodity:

Commodity	Parts per million
Almond, hulls	4.0
Banana[1]	0.1
Barley, grain	2.5
Barley, hay	7.0
Barley, straw	7.0
Beet, sugar, dried pulp	0.70
Beet, sugar, molasses	0.08
Beet, sugar, roots	0.07
Cattle, meat byproducts	0.04
Fruit, stone, group 12	0.20
Goat, meat byproducts	0.04
Grain, aspirated grain fractions	7.0
Horse, meat byproducts	0.04
Nut, tree, group 14	0.04
Oat, grain	1.0
Oat, hay	17
Oat, straw	6.0
Peanut	0.04
Peanut, refined oil	0.05
Pistachio	0.04
Rye, grain	0.25
Rye, straw	14
Sheep, meat byproducts	0.04
Soybean, forage	3.0
Soybean, hay	6.0
Soybean, hulls	0.08
Soybean, seed	0.05
Wheat, grain	0.15
Wheat, hay	16
Wheat, milled byproducts	0.20
Wheat, straw	18

[1] No U.S. registration as of August 30, 2006.

(2) Tolerances are established for the residues of the fungicide metconazole, including its metabolites and degradates, in or on commodities in the following table. Compliance with the tolerance levels specified in the table is to be determined by measuring only metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) as the sum of its cis- and trans- isomers in or on the following commodities:

Commodity	Parts per million
Canola seed	0.04
Corn, field, forage	3.0
Corn, field, grain	0.02
Corn, field, stover	4.5
Corn, pop, grain	0.02
Corn, pop, stover	4.5
Corn, sweet, forage	3.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	4.5
Cotton, gin byproducts	8.0
Cotton, undelinted seed	0.25
Egg	0.04

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the fungicide metconazole, including its metabolites and degradates, in or on the commodities listed in the following table in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only metconazole (5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) as the sum of its cis- and trans-isomers in or on the following commodities:

Commodity	Parts per million	Expiration/revocation date
Sugarcane, cane	1.6	12/31/11
Sugarcane, molasses	3.2	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 56388, Sept. 27, 2006, as amended at 71 FR 76196, Dec. 20, 2006; 73 FR 22828, Apr. 28, 2008; 74 FR 21266, May 7, 2009]

§ 180.618 Benthiavalicarb-isopropyl; tolerance for residues.

(a) *General.* Tolerances are established for the combined residues of benthiavalicarb-isopropyl,

isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Grape, imported	0.25
Grape, raisin	1.0
Tomato	0.45

Note: There are no U.S. registrations as of July 30, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect of inadvertent residues.* [Reserved]

[71 FR 52003, Sept. 1, 2006]

§ 180.619 Epoxiconazole; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the fungicide epoxiconazole [(*rel*-1-[[(2R,3S)-3-(2-chlorophenyl)-2-(4-fluorophenyl)oxiranyl]methyl]-1*H*-1,2,4-triazole]) in or on the following commodities:

Commodity	Parts per million
Banana*	0.5
Coffee*	0.05

*No U.S. Registration as of August 4, 2006

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional Registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 53989, Sept. 13, 2006]

§ 180.620 Etofenprox; tolerances for residues.

(a) *General.* A tolerance is established for residues of the insecticide etofenprox [2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether] in or on the following raw agricultural commodity:

Commodity	Parts per million
Rice, grain	0.01

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Rice, grain	0.01	12/31/09
Rice, straw	0.02	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 54928, Sept. 20, 2006, as amended at 73 FR 75605, Dec. 12, 2008]

§ 180.621 Dithianon; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide dithianon, (5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile) in or on the following commodities:

Commodity	Parts per million
Fruit, pome, group 11[1]	5
Hop, dried cones[1]	100

[1]No U.S. registration as of September 5, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 54922, Sept. 20, 2006]

§ 180.622 Ethaboxam; tolerances for residues.

(a) *General.* Tolerances are established for residues of ethaboxam, *N*-(cyano-2-thienylmethyl)-4-ethyl-2-(ethlyamino)-5-thiazolecarboxamide in or on the following commodity:

Commodity	Parts per million
Grape[1]	6.0

[1] There is no U.S. registration as of September 27, 2006

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 56392, Sept. 27, 2006]

§ 180.623 Flufenoxuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide, flufenoxuron, 1-[4-(2-chloro-α,α,α-trifluoro-p-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea, in or on the following food commodities.

Commodity	Parts per million
Apple [1]	0.50
Cattle, fat [1]	4.5
Cattle, meat [1]	0.10
Cattle, meat byproducts [1]	0.50
Goat, fat [1]	4.5
Goat, meat [1]	0.10
Goat, meat byproducts [1]	0.50
Grape [1]	0.70
Grape, raisin [1]	2.0
Horse, fat [1]	4.5
Horse, meat [1]	0.10
Horse, meat byproducts [1]	0.50
Milk	0.20
Milk, fat [1]	4.0
Orange [1]	0.30
Orange, oil [1]	60
Pear [1]	0.50
Sheep, fat [1]	4.5
Sheep, meat [1]	0.10
Sheep, meat byproducts [1]	0.50

[1]There are no U.S. registrations as of September 30, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 57436, Sept. 29, 2006]

§ 180.624 Metrafenone; tolerances for residues.

(a) *General.* Tolerances are established for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on the following commodities.

Commodity	Parts per million
Grape	0.6 [1]

[1] There is no U.S. registration on grapes as of September 20, 2006.

(b) *Section 18 emergency exemption.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[71 FR 54917, Sept. 20, 2006]

§ 180.625 Orthosulfamuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of orthosulfamuron 1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-phenylsulfamoyl] urea) *per se* in or on the following commodities:

Commodity	Parts per million
Rice, grain	0.05
Rice, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* [Reserved]

[72 FR 8931, Feb. 28, 2007]

§ 180.626 Prothioconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, and prothioconazole-desthio, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol, calculated as parent in or on the following commodities:

Commodity	Parts per million
Barley, grain	0.35
Barley, hay	7.0
Barley, straw	4.0
Beet, sugar, roots	0.25
Grain, aspirated grain fractions	11
Pea and bean, dried shelled, except soybean, subgroup 6C	0.9
Peanut	0.02
Peanut, hay	6.0
Rapeseed, seed	0.15
Soybean, forage	4.5
Soybean, hay	17
Soybean, seed	0.15
Wheat, forage	8
Wheat, grain	0.07
Wheat, hay	4.5
Wheat, straw	5.0

(2) Tolerances are established for combined residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, and prothioconazole-desthio, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.02
Cattle, meat byproducts	0.2
Goat, fat	0.1
Goat, meat	0.02
Goat, meat byproducts	0.2
Hog, meat byproducts	0.05
Horse, fat	0.1
Horse, meat	0.02
Horse, meat byproducts	0.2
Milk	0.02
Poultry liver	0.02
Sheep, fat	0.1
Sheep, meat	0.02
Sheep, meat byproducts	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 11783, Mar. 14, 2007, as amended at 73 FR 14719, Mar. 19, 2008; 74 FR 14749, Apr. 1, 2009]

§ 180.627 Fluopicolide; tolerances for residues.

(a) *General.* Tolerances are established for residues of fluopicolide, 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide, as an indicator of combined residues of fluopicolide and its metabolite, 2,6-dichlorobenzamide (BAM).

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	5.0
Grape	2.0
Grape, raisin	6.0
Vegetable, bulb, crop group 3–07	7.0
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8	1.60
Vegetable, leafy, except brassica, group 4	25
Vegetable, leaves of root and tuber, group 2	15.0
Vegetable, root, subgroup 1A, except sugar beet and carrot	0.15
Vegetable, tuberous and corm (except potato), subgroup 1D	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 14447, Mar. 28, 2007, as amended at 73 FR 5455, Jan. 30, 2008; 73 FR 30498, May 28, 2008]

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) Tolerances are established for residues of the pesticide chlorantraniliprole (3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	5.0
Apple, wet pomace	0.60
Brassica, head and stem, subgroup 5A	4.0
Brassica, leafy greens, subgroup 5B	11
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Cotton, gin byproduct	30
Cotton, hulls	0.40
Cotton, undelinted seed	0.30
Fruit, pome, group 11	0.30
Fruit, stone, group 12	1.0
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproduct	0.01
Grape	1.2
Grape, raisin	2.5
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproduct	0.01
Milk	0.01
Nut, tree, group 14	0.04
Pistachio	0.04
Potato	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproduct	0.01
Vegetable, cucurbit, group 9	0.25
Vegetable, fruiting, group 8	0.70
Vegetable, leafy, except brassica, group 4	13

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residues of the insecticide chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino) carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1

H-pyrazole-5-carboxamide, in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Corn, sweet, cannery waste	6.0	12/31/11
Corn, sweet, forage	6.0	12/31/11
Corn, sweet, kernel plus cob with husks removed	0.01	12/31/11
Corn, sweet, stover	6.0	12/31/11
Milk	0.03	12/31/11
Rice, grain	0.10	12/31/11
Rice, straw	0.25	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Time-limited tolerances are established for indirect or inadvertent residues of the insecticide chlorantraniliprole (3-bromo- *N* -[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide) in or on the following commodities. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Animal feed, nongrass, group 18	0.20	04/10/10
Cowpea, forage	0.20	04/10/10
Cowpea, hay	0.20	04/10/10
Field pea, hay	0.20	04/10/10
Field pea, vine	0.20	04/10/10
Grain, cereal, forage, fodder and straw, group 16	0.20	04/10/10
Grass, forage, fodder and hay, group 17	0.20	04/10/10
Leek	0.20	04/10/10
Okra	0.70	04/10/10
Onion, green	0.20	04/10/10
Onion, Welsh	0.20	04/10/10
Peanut, hay	0.20	04/10/10
Shallot	0.20	04/10/10
Soybean, forage	0.20	04/10/10
Soybean, hay	0.20	04/10/10
Strawberry	1.20	04/10/10
Sugarcane	0.20	04/10/10
Vegetable, leaves of root and tuber, group 2	0.20	04/10/10

[72 FR 27455, May 16, 2007, as amended at 73 FR 25523, May 7, 2008; 73 FR 51731, Sept. 5, 2008; 74 FR 30474, June 26, 2009]

§ 180.629 Flutriafol; tolerance for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances specifed in the above table are established for residues of the fungicide flutriafol *per se* (2,4'-difluoro-α-(1H -1,2,4-triazol-1-yl-methyl)-benzhydryl alcohol) in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

	Parts per million	Expiration/ revocation date
Soybean	0.10	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 49665, Aug. 29, 2007]

§ 180.630 Flusilazole; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide, flusilazole, (1-[[bis(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole) in connection with use of the pesticide under Section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Soybean, aspirated grain fractions	2.6	12/31/10
Soybean, seed	0.04	12/31/10
Soybean, oil	0.10	12/31/10

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[72 FR 49660, Aug. 29, 2007]

§ 180.631 Pyrasulfotole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pyrasulfotole and pyrasulfotole-desmethyl, (5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone,

and its metabolite, 5-hydroxy-3-methyl-1*H*-pyrazol-4-yl) [2-methylsulfornyl)-4-(trifluoromethyl)phenyl]methanone, in or on the following agricultural commodities:

Commodity	Parts per million
Aspirated grain fractions	0.40
Barley, grain	0.02
Barley, hay	0.30
Barley, straw	0.20
Cattle, fat	0.02
Cattle, liver	0.35
Cattle, meat	0.02
Cattle, meat byproducts, except liver	0.06
Eggs	0.02
Goat, fat	0.02
Goat, liver	0.35
Goat, meat	0.02
Goat, meat byproducts, except liver	0.06
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, liver	0.35
Horse, meat	0.02
Horse, meat byproducts, except liver	0.06
Milk	0.01
Oat, forage	0.10
Oat, grain	0.08
Oat, hay	0.50
Oat, straw	0.20
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Rye, forage	0.20
Rye, grain	0.02
Rye, straw	0.20
Sheep, fat	0.02
Sheep, liver	0.35
Sheep, meat	0.02
Sheep, meat byproducts, except liver	0.06
Wheat, forage	0.20
Wheat, grain	0.02
Wheat, hay	0.80
Wheat, straw	0.20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 45649, Aug. 15, 2007]

§ 180.632 Fenazaquin; import tolerances for residues.

(a) *General.* Import tolerances are established for residues of the insecticide and miticide, fenazaquin, 4-tert-butylphenethyl quinazolin-4-yl ether, in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple	0.2
Citrus Oil	10
Fruit, Citrus, Group 10, except Grapefruit	0.5
Pear	0.2

(b) *Section is emergency exempotions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 44393, Aug. 8, 2007]

§ 180.633 Florasulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide florasulam N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide in or on the following commodities:

Commodity	Parts per million
Barley, grain	0.01
Barley, hay	0.05
Barley, straw	0.05
Oat, forage	0.05
Oat, grain	0.01
Oat, hay	0.05
Oat, straw	0.05
Rye, forage	0.05
Rye, grain	0.01
Rye, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.01
Wheat, hay	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 55077, Sept. 28, 2007]

§ 180.634 Tembotrione; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione and its metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione in or on the following commodities:

Commodity	Parts per million
Cattle, liver	0.40
Cattle, meat byproducts, except liver	0.07
Corn, field, forage	0.60
Corn, field, grain	0.02
Corn, field, stover	0.45
Corn, pop, grain	0.02
Corn, pop, stover	0.35
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	1.2
Goat, liver	0.40
Goat, meat byproducts, except liver	0.07
Horse, liver	0.40
Horse, meat byproducts, except liver	0.07
Poultry, liver	0.07
Sheep, liver	0.40
Sheep, meat byproducts, except liver	0.07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[72 FR 55085, Sept. 28, 2007]

§ 180.635 Spinetoram; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide spinetoram, expressed as a combination of XDE-175-J: 1-H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl) oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl] oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9, 10,11,12,13,14,16a,16b-hexadecahydro 14-methyl-, (2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR); XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O- ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9, 10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aR,5aS,5bS,9S, 13S,14R,16aS,16bS); ND-J: (2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR)-9-ethyl-14-methyl-13-[[(2S,5S,6R)-6- methyl-5-(methylamino)tetrahydro- 2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9, 10,11,12,13,14,15,16a,16b- octadecahydro-1H-as- indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranoside; and NF-J: (2R,3S,6S)-6-([(2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR)- 2-[(6-deoxy-3-O-ethyl-2,4-di-O- methyl-alpha-L-mannopyranosyl) oxy]-9-ethyl-14-methyl-7,15-dioxo-2, 3,3a,4,5,5a,5b,6,7,9, 10,11,12,13,14,15,16a,16b- octadecahydro-1H-as- indaceno[3,2-d]oxacyclododecin-13-yl] oxy)-2-methyltetrahydro- 2H-pyran-3-yl(methyl)formamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Acerola	0.30
Almond, hulls	2.0
Amaranth grain, grain	1.0
Apple, wet pomace	0.50
Artichoke, globe	0.30
Asparagus	0.04
Atemoya	0.30
Avocado	0.30
Banana	0.25
Beet, sugar, molasses	0.75
Biriba	0.30
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10
Bushberry, subgroup 13B	0.25
Caneberry, subgroup 13A	0.70
Canistel	0.30
Cattle, fat	5.5
Cattle, liver	0.85
Cattle, meat	0.20
Cattle, meat byproducts (except liver)	0.60
Cherimoya	0.30
Citrus, dried pulp	0.50
Citrus, oil	3.0
Corn, sweet, kernel plus cob with husks removed	0.04
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.04
Cranberry	0.04
Custard apple	0.30
Egg	0.04
Feijoa	0.30
Fig	0.10
Fruit, citrus, group 10	0.30
Fruit, pome, group 11	0.20
Fruit, stone, group 12	0.20
Goat, fat	5.5
Goat, liver	0.85
Goat, meat	0.20
Goat, meat byproducts (except liver)	0.60
Grain, aspirated fractions	20
Grain, cereal, group 15, except rice, sorghum, pearl millet and proso millet	0.04
Grain, cereal, group 16, forage	3.5
Grain, cereal, group 16, hay	10
Grain, cereal, group 16, stover	10
Grain, cereal, straw, group 16, except rice	1.0
Grape	0.50
Grape, raisin	0.70
Guava	0.30
Herb, dried, subgroup 19A	22
Herb, fresh, subgroup 19A	3.0
Hog, fat	0.40
Hog, meat	0.04
Hog, meat byproducts	0.04
Horse, fat	5.5
Horse, liver	0.85
Horse, meat	0.20
Horse, meat byproducts (except liver)	0.60
Ilama	0.30
Jaboticaba	0.30

Commodity	Parts per million
Juneberry	0.25
Lingonberry	0.25
Longan	0.30
Lychee	0.30
Mango	0.30
Milk	0.30
Milk, fat	7.5
Millet, pearl, grain	1.0
Millet, proso, grain	1.0
Nut, tree, group 14	0.04
Okra	0.40
Onion, green	2.0
Papaya	0.30
Passionfruit	0.30
Pea and bean, dried shelled, except soybean, subgroup 6C	0.04
Pea and bean, succulent shelled, subgroup 6B	0.04
Peanut	0.04
Peanut, hay	11
Peppermint, tops	3.5
Pistachio	0.04
Poultry, fat	0.10
Poultry, meat	0.04
Poultry, meat byproducts	0.04
Pulasan	0.30
Rambutan	0.30
Salal	0.25
Sapodilla	0.30
Sapote, black	0.30
Sapote, mamey	0.30
Sapote, white	0.30
Sheep, fat	5.5
Sheep, liver	0.85
Sheep, meat	0.20
Sheep, meat products (except liver)	0.60
Sorghum, grain, grain	1.0
Soursop	0.30
Soybean, seed	0.04
Spanish lime	0.30
Spearmint, tops	3.5
Star apple	0.30
Star fruit	0.30
Strawberry	1.0
Sugar apple	0.30
Ti, leaves	10
Vegetable, bulb, group 3, except green onion	0.10
Vegetable, cucurbit, group 9	0.30
Vegetable, foliage of legume, group 7	8.0
Vegetable, fruiting, group 8	0.40
Vegetable, leafy, except Brassica, group 4	8.0
Vegetable, leaves of root and tuber, group 2	10
Vegetable, legume, edible podded, subgroup 6A	0.30
Vegetable, root and tuber, group 1	0.10
Watercress	8.0
Wax jambu	0.30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registration.* [Reserved]

(d) *Indirect and invertent residues.* [Reserved]

[72 FR 57499, Oct. 10, 2007, as amended at 73 FR 14714, Mar. 19, 2008]

§ 180.636 1,3-dichloropropene; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide *cis*- and *trans*-1,3-dichloropropene and its metabolites *cis*- and *trans*-3-chloroacrylic acid, and *cis*- and *trans*-3-chloroallyl alcohol in or on the following commodities.

Commodity	Parts per million
Grape	0.018

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 8218, Feb. 13, 2008]

§ 180.637 Mandipropamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide mandipropamid, 4-chloro-N-[2-(3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide in or on the following commodities.

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	3
Brassica, leafy greens, subgroup 5B	25
Grape	1.4
Grape, raisin	3.0
Okra	1.0
Onion, dry bulb	0.05
Onion, green	4
Potato, wet peel	0.03
Vegetable, cucurbit, group 9	0.6
Vegetable, fruiting, group 8	1.0
Vegetable, leafy except Brassica, group 4	20
Vegetable, tuberous and corm, subgroup 1C	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent tolerances.* [Reserved]

[73 FR 2816, Jan. 16, 2008]

§ 180.638 Pyroxsulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pyroxsulam, N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide in or on the raw agricultural commodities:

Commodity	Parts per million
Wheat, forage	0.06
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 10402, Feb. 27, 2008]

§ 180.639 Flubendiamide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide flubendiamide *per se,* N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	9.0
Apple, wet pomace	2.0
Brassica, head and stem, subgroup 5A	0.60
Brassica, leafy greens, subgroup 5B	5.0
Cattle, fat	0.30
Cattle, kidney	0.30
Cattle, liver	0.30
Cattle, muscle	0.05
Corn, field, forage	8.0
Corn, field, grain	0.02
Corn, field, stover	15
Corn, pop, grain	0.02
Corn, pop, stover	15
Corn, sweet, forage	9.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	25
Cotton, gin byproducts	60
Cotton, undelinted seed	0.90
Egg	0.01
Fruit, pome, group 11	0.70
Fruit, stone, group 12	1.6
Goat, fat	0.30
Goat, kidney	0.30
Goat, liver	0.30
Goat, muscle	0.05
Grain, aspirated fractions	5.0
Grape	1.4
Horse, fat	0.30
Horse, kidney	0.30
Horse, liver	0.30
Horse, muscle	0.05
Milk	0.04
Milk, fat	0.30
Nut, tree, group 14	0.06
Okra	0.30
Poultry, fat	0.02
Poultry, liver	0.01
Poultry, muscle	0.01
Sheep, fat	0.30
Sheep, kidney	0.30
Sheep, liver	0.30
Sheep, muscle	0.05
Vegetable, cucurbit, group 9	0.20
Vegetable, fruiting, group 8	0.60
ppm	
Vegetable, leafy, except Brassica, group 4	11

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the insecticide flubendiamide *per se,* N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on the following raw agricultural commodities when present therein as a result of the application of flubendiamide *per se* to the growing crops listed in paragraph (a) of this section:

Commodity	Parts per million
Alfalfa, forage	0.15
Alfalfa, hay	0.04
Barley, hay	0.04
Barley, straw	0.07
Buckwheat	0.07
Clover, forage	0.15
Clover, hay	0.04
Grass, forage	0.15
Grass, hay	0.04
Millet, pearl, forage	0.15
Millet, pearl, hay	0.04
Millet, proso, forage	0.15
Millet, proso, hay	0.04
Millet, proso, straw	0.07
Oats, forage	0.15
Oats, hay	0.04
Oats, straw	0.07
Rye, forage	0.15
Rye, straw	0.07
Sorghum, grain, forage	0.03
Sorghum, grain, stover	0.06
Soybean, forage	0.02
Soybean, hay	0.04
Teosinte, forage	0.15
Teosinte, hay	0.04
Teosinte, straw	0.07
Triticale, forage	0.15
Triticale, hay	0.04
Triticale, straw	0.07
Wheat, forage	0.15
Wheat, hay	0.03
Wheat, straw	0.03

[73 FR 47062, Aug. 13, 2008]

§ 180.640 Pyridalyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of pyridalyl, pyridine,2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl, in or on the following raw agricultural commodities:)

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	3.5
Mustard greens	30
Turnip greens	30
Vegetable, fruiting, group 8	1.0
Vegetables, leafy, except *Brassica*, group 4	20

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 25533, May 7, 2008]

§ 180.641 Spirotetramat; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolites BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), BYI 08330-ketohydroxy (cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro 4.5 decane-2,4-dione), BYI08330-enol-Glc (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro 4.5 dec-3-en-4-yl beta-D-glucopyranoside), and BYI 08330-mono-hydroxy (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 decan-2-one), calculated as spirotetramat equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	9.0
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy, subgroup 5B	8.0
Citrus, oil	6.0
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.70
Fruit, stone, group 12	4.5
Grape, raisin	3.0
Hop, dried cones	10.0
Nut, tree, group 14	0.25
Onion, bulb, subgroup 3A-07	0.3
Potato, flakes	1.6
Small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F	1.3
Strawberry	0.40
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8	2.5
Vegetable, leafy, except brassica, group 4	9.0
Vegetable, tuberous and corm, subgroup 1C	0.60

(2) Tolerances are also established for the combined residues of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolite BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), calculated as spirotetramat equivalents, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.01
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[73 FR 39256, July 9, 2008]

§ 180.642 Gentamicin; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of gentamicin in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Apple	0.10	12/31/10

(c) *Tolerance with regional restrictions.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[73 FR 44162, July 30, 2008]

§ 180.643 Uniconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide/plant growth regulator uniconazole-P, (E)-(S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pent-1-en-3-ol, its *R*-enantiomer and its *Z*-isomer in or on the following raw agricultural commodities:

Commodity	Parts per million
Vegetable, fruiting, group 8	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[73 FR 51736, Sept. 5, 2008]

§ 180.644 Cyprosulfamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide safener cyprosulfamide, *N*-[[4-[(cyclopropylamino)carbonyl] phenyl]sulfonyl]-2-methoxybenzamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.20
Corn, field, grain	0.01
Corn, field, stover	0.20
Corn, pop, grain	0.01
Corn, pop, stover	0.20
Corn, sweet, forage	0.40
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.35

(2) Tolerances are established for residues of the herbicide safener cyprosulfamide, *N*-[[4-[(cyclopropylamino)carbonyl] phenyl]sulfonyl]-2-methoxybenzamide, and its metabolite 4-(aminosulfonyl)-*N*-cyclopropylbenzamide, calculated as cyprosulfamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.02
Goat, meat byproducts	0.02
Horse, meat byproducts	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[73 FR 60974, Oct. 15, 2008]

§ 180.645 Thiencarbazone-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of thiencarbazone-methyl [methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)-carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate], *per se*, in or on the following food and feed commodities:

Commodity	Parts per million
Corn, field, forage	0.04
Corn, field, grain	0.01
Corn, field, stover	0.02
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.05
Wheat, forage	0.10
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.01

(2) Tolerances are established for combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT [5-methoxy-4-methyl-2,4-dihydro-3*H*-1,2,4-triazol-3-one], calculated as the parent compound, in or on the following food commodities of animal origin:

Commodity	Parts per million
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT-glucoside [2-hexopyranosyl-5-methoxy-4-methyl-2,4-dihydro-3*H*-1,2,4-triazol-3-one], calculated as the parent compound, in or on the following food commodities:

Commodity	Parts per million
Soybean, forage	0.04
Soybean, hay	0.15

[73 FR 60968, Oct. 15, 2008]

§ 180.646 Ipconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of ipconazole, (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1H-1,2,4-triazole-1-ylmethyl) cyclopentanol) from seed treatment in or on the following commodities:

Commodity	Parts per million
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Grain, cereal, forage, fodder and straw, group 16, except rice	0.01
Grain, cereal group 15, except rice	0.01
Pea and bean, dried shelled, except soybean, subgroup 6C	0.01
Peanut	0.01
Soybean, forage	0.01
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[73 FR 69559, Nov. 19, 2008]

Subpart D—Exemptions From Tolerances

§ 180.900 Exemptions from the requirement of a tolerance.

An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.

[69 FR 23117, Apr. 28, 2004]

§ 180.905 Pesticide chemicals; exemptions from the requirement of a tolerance.

(a) When applied to growing crops, in accordance with good agricultural practice, the following pesticide chemicals are exempt from the requirement of a tolerance:

(1) [Reserved]

(2) *N*-Octylbicyclo(2,2,1)-5-heptene-2,3-dicarboximide.

(3) Petroleum oils.

(4) Piperonyl butoxide.

(5) [Reserved]

(6) Pyrethrum and pyrethrins.

(7) Rotenone or derris or cube roots.

(8) Sabadilla.

(b) These pesticides are not exempted from the requirement of a tolerance when applied to a crop at the time of or after harvest.

[69 FR 23117, Apr. 28, 2004]

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Residues of the following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest:

Inert ingredients	Limits	Uses
Acetic acid		Catalyst
Acetic anhydride		Solvent, cosolvent
Acetone		Do.
Alkanoic and alkenoic acids, mono- and diesters of α-hydro-ω-hydroxypoly (oxyethylene) with molecular weight (in amu) range of 200 to 6,000.		Emulsifiers

Inert ingredients	Limits	Uses
Alkyl (C_8-C_{24}) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.	.....	Surfactants, related adjuvants of surfactants
α-Alkyl (C_9-C_{18}-ω-hydroxypoly(oxyethylene) with poly(oxyethylene) content of 2-30 moles.	.....	Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α-Alkyl (C_6-C_{14})-ω-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 4-12 moles; average molecular weight (in amu) is approximately 635.	.....	Do.
α-alkyl (C_{12}-C_{15})-ω-hydroxypoly (oxypropylene) poly (oxyethylene) copolymers (where the poly (oxypropylene) content is 3–60 moles and the poly (oxyethylene) content is 5–80 moles).	Not more than 20% of pesticide formulations	Surfactant
Alkyl (C_8-C_{18}) sulfate and its ammonium, calcium, isopropylamine, magnesium, potassium, sodium, and zinc salts.	.....	Surfactants.
Aluminum hydroxide	.....	Diluent, carrier
Aluminum oxide	.....	Diluent
Aluminum stearate	.....	Surfactant
Ammonium bicarbonate	.....	Surfactant, suspending agent, dispersing agent
Ammonium carbamate	.....	Synergist in aluminum phosphide formulations
Ammonium chloride	.....	Intensifier when used with ammonium nitrate as a dessicant or defoliant. Fire suppressant in aluminum phosphide and magnesium phosphide formulations
Ammonium hydroxide	.....	Solvent, cosolvent, neutralizer, solubilizing agent
Ammonium stearate	.....	Surfactant
Ammonium sulfate	.....	Solid diluent, carrier
Ammonium thiosulfate	.....	Intensifier when used with ammonium nitrate as desiccant or defoliant
Amyl acetate	.....	Solvent, cosolvent, attractant
Ascorbyl palmitate	.....	Preservative
Attapulgite-type clay	.....	Solid diluent, carrier, thickener
Bacillus thuringiensis fermentation solids and/or solubles.	.....	Diluent, carrier
Bentonite	.....	Solid diluent, carrier
Benzoic acid	.....	Preservative for formulation
Bicyclo[3.1.1]hept–2–ene, 2,6,6–trimethyl–, homopolymer (Alpha-pinene, homopolymer)(CAS Reg. No. 25766–18–1).	.....	Surfactants, related adjuvants of surfactants
Bicyclo[3.1.1]heptane, 6,6–dimethyl–2–methylene–, homopolymer (Beta-pinene, homopolymer) (CAS Reg. No. 25719–60–2).	.....	Surfactants, related adjuvants of surfactants
Bicyclo[3.1.1]hept–2–ene, 2,6,6–trimethyl–, polymer with 6,6– dimethyl–2– methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3).	.....	Surfactants, related adjuvants of surfactants
2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7).	0.04% or less by weight of the total pesticide formulation.	In-can preservative
Butane	.....	Propellant
n-Butanol (CAS Reg. No. 71–36–3)	.....	Solvent, cosolvent
Butylated hydroxyanisole	.....	Antioxidant
Butylated hydroxytoluene	.....	Do.
Calcareous shale	.....	Solid diluent carrier
Calcite	.....	Do.
Calcium carbonate	.....	Do.
Calcium chloride	.....	Stabilizer
Calcium phosphate	.....	Solid diluent, carrier
Calcium hydroxide	.....	Do.
Calcium hypochlorite	.....	Sanitizing and bleaching agent
Calcium lactate pentahydrate (CAS Reg. No. 5743–47–5).	.....	Nutrient, stabilizer
Calcium oxide	.....	Solid diluent, carrier
Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210.	.....	Coating agent
Calcium silicate	.....	Solid diluent, carrier
Calcium stearate	.....	Do.
Carrageenan, conforming to 21 CFR 172.620	Minimum molecular weight (in amu): 100,000.	Thickener

Inert ingredients	Limits	Uses
Cetyl alcohol (CAS Reg. No. 36653–82–4)	Not more than 5.0% of pesticide formulation.	Evaporation retardant
Charcoal, activated	Meets specifications in the Food Chemical Codex.	Carrier
Coconut shells		Solid diluent and carrier
Cod liver oil		Solvent, cosolvent
Croscarmellose sodium (CAS Reg. No. 74811–65–7).		Disintegrant, solid diluent, carrier, and thickener
Dialkyl (C_8-C_{18}) dimethyl ammonium chloride	Not more than 0.2% in silica, hydrated silica.	Flocculating agent in the manufacture of silica, hydrated silica for use as a solid diluent, carrier
Diatomite (diatomaceous earth)		Solid diluent carrier
Diethylene glycol abietate		Surfactants, related adjuvants of surfactants
1,1-Difluoroethane (CAS Reg. No. 75–37–6)	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.	Aerosol propellant
1,2-Dihydro-6-ethoxy-2,2,4-trimethylquinolene	Not more than 0.02% of pesticide formulation.	Antioxidant
Dimethyl ether (methane, oxybis-) (CAS Reg. No. 115–10–6).		Propellant
3,6-Dimethyl-4-octyn-3,6-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Dipropylene glycol		Solvent, cosolvent
Disodium phosphate		Anticaking agent, conditioning agent
Disodium zinc ethylenediaminetetraacetate dihydride.		Sequestrant
Dolomite		Solid diluent, carrier
Epoxidized linseed oil		Surfactants, related adjuvants of surfactants
Epoxidized soybean oil		Do.
Ethyl acetate		Solvent, cosolvent
Ethyl alcohol		Do.
Ethyl esters of fatty acids derived from edible fats and oils.		Solvent, cosolvent
Ethyl maltol (CAS Reg. No.4940–11–8)	Not more than 0.2 % of the pesticide formulation.	Odor masking agent
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.		Surfactants, related adjuvants of surfactants
Ethylenediaminetetraacetic acid	3% of pesticide formulation	Sequestrant
Ethylenediaminetetraacetic acid, tetrasodium salt.	5% of pesticide formulation	Sequestrant
2-Ethyl-1-hexanol	Not more than 2.5% of pesticide formulation.	Solvent, adjuvant of surfactants
Fatty acids, conforming to 21 CFR 172.860		Binder, defoaming agent, lubricant
FD&C Blue No. 1	Not more than 0.2% of pesticide formulation.	Dye
FD&C Red No. 40 (CAS Reg. No. 25956–17–6) conforming to 21 CFR 74.340.	Not to exceed 0.002% by weight of pesticide formulation.	Dye, coloring agent
Ferric Citrate (CAS Reg. No. 2338–05–8)		Stabilizer
Ferric sulfate		Solid diluent, carrier
Furcelleran		Thickener
D-glucopyranose, oligomeric, C_{10-16}-alkyl glycosides (CAS Reg. No. 110615–47–9).		Surfactant
Glycerides, edible fats and oils derived from plants and animals, reaction products with sucrose (CAS Reg. Nos. 100403–38–1, 100403–41–6, 100403–39–2, 100403–40–5).		Emulsifier, dispersing agent
Glycerol mono-, di-, and triacetate		Solvent, cosolvent
Glyceryl monostearate		Emulsifier
Granite		Do.
Graphite		Solid diluent, carrier
Gum arabic (acacia)		Surfactant, suspending agent, dispersing agent
Gypsum		Solid diluent, carrier
Hexamethylenetetramine	For use in citrus washing solutions only at not more than 1%.	Preservative
3-hexen-1-ol, (3Z)- (CAS Reg. No. 928-96-1)	Not more than 0.4% of the pesticide formulation.	Odorant, alerting agent
n-Hexyl alcohol (CAS Reg. No. 111–27–3)		Solvent, cosolvent
Hydrochloric acid		Solvent, neutralizer

Inert ingredients	Limits	Uses
Hydroxyethylidine diphosphonic acid (HEDP) (CAS Reg. No. 2809–21–4).	For use in antimicrobial pesticide formulations at not more than 1 percent.	Stabilizer, chelator
Iron oxide		Solid diluent, carrier
Isopropyl myristate (CAS Reg. No. 110–27–0)		Solvent
Kaolinite-type clay		Solid diluent, carrier
Lactic acid		Solvent
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).		Solvent
Lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1).		Solvent
Lactic acid, n-propyl ester, (S); (CAS Reg. No. 53651–69–7).		Solvent
Lauryl alcohol		Surfactant
α-Lauryl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α-Lauryl-ω-hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.		Surfactants, related adjuvants of surfactants
Lignin (CAS Reg. No. 9005–53–2)		Surfactant, related adjuvants of surfactants
Lignin, alkali (CAS Reg. No. 8068–05–1)		Do.
Lignin, alkali, oxidized, sodium salt (CAS Reg. No. 68201–23–0).		Do.
Lignin alkali reaction products with disodium sulfite and formaldehyde (CAS Reg. No. 105859–97–0).		Do.
Lignin alkali reaction products with formaldehyde and sodium bisulfite (CAS Reg. No. 68512–35–6).		Do.
Lignosulfonic acid (CAS Reg. No. 8062–15–5)		Do.
Lignosulfonic acid, ammonium calcium salt (CAS Reg. No. 12710–04–2).		Do.
Lignosulfonic acid, ammonium magnesium salt (CAS Reg. No. 123175–37–1).		Do.
Lignosulfonic acid, ammonium salt (CAS Reg. No. 8061–53–8).		Do.
Lignosulfonic acid, ammonium sodium salt (CAS Reg. No. 166798–73–8).		Do.
Lignosulfonic acid, calcium magnesium salt (CAS Reg. No. 55598–86–2).		Do.
Lignosulfonic acid, calcium salt (CAS Reg. No. 8061–52–7).		Do.
Lignosulfonic acid, calcium sodium salt (CAS Reg. No. 37325–33–0).		Do.
Lignosulfonic acid, ethoxylated, sodium salt (CAS Reg. No. 68611–14–3).		Do.
Lignosulfonic acid, magnesium salt (CAS Reg. No. 8061–54–9).		Do.
Lignosulfonic acid, potassium salt (CAS Reg. No. 37314–65–1).		Do.
Lignosulfonic acid, sodium salt (CAS Reg. No. 8061–51–6).		Do.
Lignosulfonic acid, sodium salt, oxidized (CAS Reg. No. 68855–41–4).		Do.
Lignosulfonic acid, sodium salt, polymer with formaldehyde and phenol (CAS Reg. No. 37207–89–9).		Do.
Lignosulfonic acid, sodium salt, sulfomethylated (CAS Reg. No. 68512–34–5).		Do.
Lignosulfonic acid, zinc salt (CAS Reg. No. 57866–49–6).		Do.
d-Limonene (CAS Reg. No. 5989–27–5)		Solvent, fragrance
Magnesium carbonate		Anticaking agent, conditioning agent
Magnesium chloride		Safener
Magnesium lime		Solid diluent, carrier
Magnesium oxide		Do.
Magnesium silicate		Do.
Magnesium stearate		Surfactant
Magnesium sulfate		Solid diluent, carrier, safener
Methyl alcohol		Solvent
Methyl *n*-amyl ketone (CAS Reg. No. 110–43–0)		Solvent, cosolvent
Methylated silicones		Antifoaming agent
Methyl esters of fatty acids derived from edible fats and oils.		Solvent, cosolvent

Inert ingredients	Limits	Uses
Methyl esters of higher fatty acids conforming to 21 CFR 573.640.	.....	Antidusting agent, surfactant
Methyl isobutyl ketone	.....	Solvent
Mica	.....	Solid diluent, carrier
Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a) (CAS Reg. No. 8012–95–1).	.....	Diluent, carrier, and solvent
Monoammonium phosphate	No more than 3.75% by weight in formulation.	Postharvest fumigation in formulation with aluminum phosphide
Mono- and diglycerides of C_8-C_{18} fatty acids	.....	Surfactants, related adjuvants of surfactants
Montmorillonite-type clay	.....	Solid diluent, carrier
Nonyl, decyl, and undecyl glycoside mixture with a mixture of nonyl, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65% solids) from the reaction of primary alcohols (containing 15 to 20% secondary alcohol isomers) in a ratio of 20% C_9, 40% C_{10}, and 40% C_{11} with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).	.....	Surfactant.
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles.	.....	Surfactants, related adjuvants of surfactants
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-90.	.....	Do.
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.	.....	Do.
1-Octanal (CAS Reg. No. 124–13–0)	Not more than 0.2% of the pesticide formulation	Odor masking agent
Octyl and decyl glucosides mixture with a mixture of octyl and decyloligosaccharides and related reaction products (primarily *n*-decanol) produced as an aqueous-based liquid (68-72% solids) from the reaction of straight chain alcohols (C_8(45%), C_{10} (55%)) with anhydrous glucose.	.....	Surfactants, related adjuvants of surfactants
Oleic acid	.....	Diluent
Oleic acid diester of α-hydro-ω-hydroxypoly (oxyethylene); the poly(oxyethylene) having average molecular weight (in amu) 400.	.....	Surfactants, related adjuvants of surfactants
α-Oleoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.	.....	Emulsifier
Oleyl alcohol (CAS Reg. No. 143–28–2	15%	Cosolvent
Oxalic acid	No more oxalic acid should be used than is necessary to chelate calcium and in no case should more than 2 lb oxalic acid per acre be used.	Calcium chelating hard water inhibitor
Palmitic acid	.....	Diluent
Pentaerythritol ester of maleic anhydride modified wood rosin.	.....	Plasticizer
Petrolatum, conforming to 21 CFR 172.880	.....	Coating agent
Petroleum hydrocarbons, light odorless conforming to 21 CFR 172.884.	.....	Solvent, diluent.
Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882.	.....	Do.

Inert ingredients	Limits	Uses
Petroleum naphtha, conforming to 21 CFR 172.250(d).		Component of coating agent
Petroleum wax, conforming to 21 CFR 172.886(d).		Coating agent
Phosphoric acid		Buffer
Polyethylene, conforming to 21 CFR 177.1520(c).		Binder, carrier, and coating agent
Polyethylene glycol[α-hydro-ω-hydroxypoly(oxyethylene)]; mean molecular weight (in amu) 194 to 9,500 conforms to 21 CFR 178.3750.		Surfactants, related adjuvants of surfactants
Polyglycerol esters of fatty acids conforming to 21 CFR 172.854.		Surfactants, related adjuvants of surfactants
Polyglyceryl phthalate ester of coconut oil fatty acids.		Do.
Poly(oxy-1,2-ethanediyl), α-(carboxymethyl)-ω-(nonylphenoxy) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide. The molecular weight (in amu) ranges are 454-894 and 1598-4238.		Surfactant
Polyoxyethylene (20) sorbitan monostearate		Surfactants, related adjuvants of surfactants
[Poly[oxy(methyl-1,2-ethanediyl)], α-[2-bis(2-hydroxyethyl)amino]propyl]-ω-hydroxy,-ether with α-hydro-ω-hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C_{12-16} alkyl ethers, (CAS Reg. No. 176022–82–5).	Not to exceed 15% in the formulated product; only for use with glyphosate.	Surfactant
Polysorbate 65, conforming to 21 CFR 172.838		Emulsifier
Potassium aluminum silicate		Solid diluent, carrier
Potassium hydroxide		Neutralizer
Potassium phosphate		Buffer
Potassium sulfate		Solid diluent
Propane		Propellant
n-Propanol		Solvent, cosolvent
2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Registration No. 55989–05–4), minimum number average molecular weight (in amu), 18,900.		Encapsulating agent, dispensers, resins, fibers and beads
Propylene glycol		Solvent, cosolvent.
Propylene glycol alginate (as defined in 21 CFR 172.858).		Defoaming agent
Propyl gallate		Antioxidant
Propyl *p*-hydroxybenzoate		Preservative for formulations
Pyrophyllite		Solid diluent, carrier
Rhizobium inoculants (e.g. *Sinorhizobium, Bradyrhizobium & Rhizobium*).		All leguminous food commodities
Rosin, partially dimerized (as defined in 21 CFR 172.615).		Surfactants, related adjuvants of surfactants
Rosin, partially hydrogenated (as defined in 21 CFR 172.615).		Do.
Rosin, wood		Do.
Salts of fatty acids, conforming to 21 CFR 172.863.		Binder, emulsifier, anticaking agent
Sand		Solid diluent, carrier
Shellac, bleached; refined, food grade, arsenic and rosin-free.		Coating agent
Soapstone		Solid diluent
Sodium acid pyrophosphate		Surfactant, suspending agent, dispersing agent, buffer
Sodium α-olefinsulfonate (sodium C_{14}-C_{16}) (Olefin sulfonate).		Surfactants, related adjuvants of surfactants
Sodium aluminum silicate		Solid diluent, carrier
Sodium diisobutylnaphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium dioctylsulfosuccinate		Do.
Sodium dodecylphenoxybenzenedisulfonate		Do.
Sodium hexametaphosphate		Surfactant, emulsifier, wetting agent, suspending agent, dispersing agent, buffer
Sodium hydroxide		Neutralizer
Sodium metasilicate		Surfactants, emulsifiers, wetting agents, dispersing agents, buffer

Inert ingredients	Limits	Uses
Sodium monoalkyl and dialkyl (C_8-C_{16}) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.		Surfactants, related adjuvants of surfactants
Sodium mono- and dimethyl naphthalenesulfonates, molecular weight (in amu) 245-260.		Do.
Sodium mono-, di-, and tributyl naphthalenesulfonates.		Do.
Sodium mono-, di-, and triisopropyl naphthalenesulfonate.		Do.
Sodium *N*-oleoyl-*N*-methyltaurine		Do.
Sodium salt of sulfated oleic acid		Surfactants, related adjuvants of surfactants
Sodium silicate		Surfactant, emulsifier, wetting agent, stabilizer, inhibitor
Sodium starch glycolate (CAS Reg. No. 9063–38–1).	Granular and tableted products only; not to exceed 8% of the formulated product.	Disintegrant
Sodium sulfate		Solid diluent, carrier
Sodium tripolyphosphate		Buffer, surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
Sorbic acid (CAS Reg. No. 110–44–1)		Preservative for formulations
Sorbitan fatty acid esters (fatty acids limited to C_{12}, C_{14}, C_{16}, and C_{18} containing minor amounts of associated fatty acids) and their derivatives; the poly(oxyethylene) content averages 5-20 moles.		Surfactants, related adjuvants or surfactants.
Soybean flour	Expires May 24, 2005.	Surfactant
Soybean oil-derived fatty acids		Solvent, cosolvent
Sperm oil conforming to 21 CFR 172.210		Coating agent
Stearic acid		Diluent
α-Stearoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α-Stearoyl-ω-hydroxypoly(oxyethylene); the poly(oxyethylene) content averages either 8, 9, or 40 moles; if a blend of products is used, the average number of moles ethylene oxide reacted to produce any product that is a component of the blend shall be either 8, 9, or 40.		Surfactants, related adjuvants of surfactants
Sucrose octaacetate		Adhesive
Sulfite liquors and cooking liquors, spent, oxidized (CAS Reg. No. 68514–09–0).		Surfactant, related adjuvants of surfactants
Sulfuric acid (CAS Reg. No.7664–93–9)	Not to exceed 10% of the pesticide formulation; non-aerosol formulations only.	pH Control agent
Synthetic paraffin and its succinic derivatives conforming to 21 CFR 172.275.		Carrier, binder, and carrying agent
Synthetic petroleum wax, conforming to 21 CFR 172.888.		Binder, carrier, and coating agent
Talc		Solid diluent, carriers
Tall oil; fatty acids not less than 58%, rosin acids not more than 44%, unsaponifiables not more than 8%.		Surfactants, related adjuvants of surfactants
Tartrazine		Dye
Terpenes and terpenoids, turpentine oil, alpha-pinene fraction, polymd. (CAS Reg. No. 70750–57–1).		Surfactants, related adjuvants of surfactants
1,1,1,2-Tetrafluoroethane, (CAS Reg. No. 811–97–2).		Aerosol propellant
Tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No 97–99–4).	Expires February 9, 2008	Solvent/cosolvent
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.		Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
2,4,7,9-Tetramethyl-5-decyn-4, 7-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Tetrasodium pyrophosphate		Anticaking agent, conditioning agent
Thiosulfuric acid, disodium salt, anhydrous. (CAS Reg. No 7772–98–7).		Dechlorinator, reducing agent
Thiosulfuric acid, disodium salt, pentahydrate. (CAS Reg. No. 10102–17–7).		Do.
d-Alpha tocopherol (CAS Reg. No. 9–02–9	None	Safener
d-Alpha tocopheryl acetate (CAS Reg. No. 58–95–7).	None	Do.
dl-Alpha tocopherol (CAS Reg. No.10191–41–0)	None	Do.
dl-Alpha tocopheryl acetate (CAS Reg. No. 7695–91–2).	None	Do.
Tricalcium phosphate		Surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
Trisodium phosphate		Surfactant, emulsifier, wetting agent
Vermiculite		Solid diluent, carrier.
Vitamin E (CAS Reg. No. 1406–18–4)	None	Safener
Walnut shells		Leaching inhibitor, binder for water-dispersible aggregates, sticker and suspension stabilizer
Wintergreen oil		Attractant
Wood flour	Derived from wood free of chemical preservatives.	Solid diluent and carrier
Xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight).	Not more than 0.5% of pesticide formulation.	Surfactant
Xylene meeting the specifications listed in 21 CFR 172.884(b)(4).	In pesticide formulations for grain storage only.	Solvent, cosolvent
Zeolite (hydrated alkali aluminum silicate)		Solid diluent, carrier
Zinc oxide		Coating agent
Zinc sulfate (basic and monohydrate)		Do.
Zinc sulfate (basic and monohydrate)		Solid diluent, carrier

[69 FR 23117, Apr. 28, 2004, as amended at 69 FR 33578, June 16, 2004; 69 FR 34949, June 23, 2004; 69 FR 40786, July 7, 2004; 69 FR 47025, Aug. 4, 2004; 69 FR 58304, 58314, Sept. 30, 2004; 70 FR 28443, 28451, May 18, 2005; 70 FR 31364, June 1, 2005; 70 FR 37692, June 30, 2005; 70 FR 38786, July 6, 2005; 70 FR 43311, July 27, 2005; 70 FR 44496, Aug. 3, 2005; 70 FR 51628, Aug. 31, 2005; 70 FR 54286, Sept. 14, 2005; 70 FR 55296, Sept. 21, 2005; 70 FR 55733, Sept. 23, 2005; 70 FR 67910, Nov. 9, 2005; 71 FR 14414, Mar. 22, 2006; 71 FR 30810, May 31, 2006; 71 FR 43660, Aug. 2, 2006; 71 FR 45414, 45421, Aug. 9, 2006; 73 FR 9217, Feb. 20, 2008; 73 FR 17913, Apr. 2, 2008; 74 FR 22460, May 13, 2009]

EFFECTIVE DATE NOTE: At 71 FR 45421, Aug. 9, 2006, in §180.910, the table was amended by removing the following entries, effective Aug. 9, 2008. At 73 FR 45312 and 45316, Aug. 4, 2008, the effective date was delayed until Aug. 9, 2009:

a. α-Alkyl (C_9-C_{18}-ω-hydroxypoly(oxyethylene) with poly(oxyethylene) content of 2-30 moles.

c. α-Alkyl (C_6-C_{14})-ω-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 4-12 moles; average molecular weight (in amu) is approximately 635.

i. Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.

j. α-Lauryl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.

k. α-Lauryl-ω-hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.

m. α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 4-14 moles or 30 moles.

n. α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.

o. Polyglyceryl phthalate ester of coconut oil fatty acids.

s. Sodium diisobutylnaphthalenesulfonate.

t. Sodium dodecylphenoxybenzenedisulfonate.

w. Sodium monoalkyl and dialkyl (C_8-C_{16}) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.

x. Sodium mono- and dimethylnaphthalenesulfonates, molecular weight (in amu) 245-260.

y. Sodium mono-, di-, and tributyl naphthalenesulfonates.

z. Sodium mono-, di-, and triisopropyl naphthalenesulfonate.

aa. Sodium *N*-oleoyl-*N*-methyltaurine.

cc. α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.

§ 180.920 Inert ingredients used preharvest; exemptions from the requirement of a tolerance.

The following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only:

Inert ingredients	Limits	Uses
Acetophenone		Attractant
Adenosine (CAS Reg. No. 58–61–7)	Maximum of 0.5% of formulation.	Synergist
Alder bark		Seed germination stimulator
α-Alkyl (C_{12}-C_{18})-ω-hydroxypoly(oxyethylene) copolymers with poly(oxypropylene); polyoxyethylene content averages 3-12 moles and polyoxypropylene content 2-9 moles.		Surfactants, related adjuvants of surfactants
α-Alkyl (C_{10}-C_{16})-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles.		Surfactants, related adjuvants of surfactants
α-Alkyl(C_{12}-C_{18})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content averages 13-17 moles and the oxypropylene content averages 2-6 moles.		Do.
α-Alkyl (C_{10}-C_{16})-ω-hydroxypoly (oxyethylene)poly(oxypropylene) mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the combined poly(oxyethylene) poly(oxypropylene) content averages 3-20 moles.		Do.
α-Alkyl (C_{12}-C_{18})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-12 moles and the oxypropylene content is 3-7 moles.		Do.
α-Alkyl (C_{12}-C_{15})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α-Alkyl (C_{21}-C_{71})-ω-hydroxypoly (oxyethylene) in which the poly(oxyethylene) content is 2 to 91 moles and molecular weight range from 390 to 5,000.	Not to exceed 10%	Wetting agent or granule coating
n-Alkyl(C_8-C_{18})amine acetate		Surfactants, related adjuvants of surfactants
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 10213–78–2, 25307–17–9, 26635–92–7, 26635–93–8, 288259–52–9, 58253–49–9, 61790–82–7, 61791–14–8, 61791–24–0, 61791–26–2, 61791–31–9, 61791–44–4, 68155–33–9, 68155–39–5, 68155–40–8,70955–14–5, 73246–96–5).	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
N,N–Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 68213–26–3, 68153–97–9, 75601–76–2).	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, related adjuvants of surfactants
N,N-Bis[α-ethyl-ω-hydroxypoly(oxyethylene) alkylamine; the poly(oxyethylene) content averages 3 moles; the alkyl groups (C_{14}-C_{18}) are derived from tallow, or from soybean or cottonseed oil acids.	.....	Surfactants for preemergence use with herbicides on sugarcane only
N,N-Bis(2-hydroxyethyl)alkylamine, where the alkyl groups (C_8-C_{18}) are derived from coconut, cottonseed, soya, or tallow acids.	.....	Surfactants, related adjuvants of surfactants
N,N-Bis 2-(ω-hydroxypolyoxyethylene) ethyl) alkylamine; the reaction product of 1 mole *N,N*-bis(2-hydroxyethyl)alkylamine and 3-60 moles of ethylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.	.....	Do.
N,N-Bis-2-(ω-hydroxypolyoxyethylene/polyoxypropylene) ethyl alkylamine; the reaction product of 1 mole of *N,N*-bis(2-hydroxyethyl alkylamine) and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.	.....	Surfactant, related adjuvants of surfactants
Aluminum sulfate	.....	Safener adjuvant
Amine salts of alkyl(C_8-C_{24}) benzenesulfonic acid (butylamine, dimethylaminopropylamine, mono- and diisopropylamine, mono-, di-, and triethanolamine).	.....	Surfactants, related adjuvants of surfactants
Ammonium nitrate (CAS Reg. No. 6484–52–2) ..	.....	Adjuvant/ intensifier for herbicides
Ammonium polyphosphate (CAS Reg. No. 68333–79–9).	.....	Sequestrant, buffer, or surfactant
Barium sulfate	.....	Carrier
1,2-Benzisothiazolin-3-one	Not more than 0.1% of formulation. Not more than 0.02 lb to be applied per acre.	Preservative/stabilizer
Boric acid	.....	Sequestrant
Buffalo gourd root powder (*Cucurbita foetidissima* root powder); or, Zucchini juice (*Cucurbita pepo* juice) or Hawkesbury melon *Citrullus lanatus*..	No more than 2.5 lbs/acre/season (3.4 gm/acre/season of Cucurbitacin).	Gustatory stimulant
Butyl stearate	.....	Defoamer
γ-Butyrolactone	.....	Solvent
C.I. Pigment Blue #15 (CAS Reg. No. 147–14–8; containing no more than 50 ppm polychlorinated biphenyls (PCBs)).	For seed treament use only	Dye, coloring agent
C.I. Pigment Green #7 (CAS Reg. No. 1328–53–6; containing no more than 50 ppm polychlorinated biphenyls (PCBs)).	For seed treatment use only.	Dye, coloring agent
C.I. Pigment Violet #23 (CAS Reg. No. 6358–30–1; containing no more than 20 ppb of polychlorinated dibenzo-*p*-dioxins and/or polychlorinated dibenzofurans).	For seed treatment use only.	Dye, coloring agent
Camphor (CAS Reg. No. 76–22–2)	Not more than 5% weight to weight (w/w) of pesticide formulations.	Deodorant, melting point adjustment
Carbonic acid, dipotassium salt (CAS Reg. No. 584–08–7).	.....	Buffering agent
Carbonic acid, dipotassium salt, trihydrate (CAS Reg. No. 18662–52–7).	.....	Buffering agent
Carous chloride	10 ppm in formulation	Tagging agent
Carrageenan, conforming to 21 CFR 172.260	Not more than 0.15% of pesticide formulation.	Thickener and stabilizer for pesticide formulations applied to seeds before planting
Chlorobenzene	Contains not more than 1% impurities. Not for use after edible parts of plant begin to form. Do not graze livestock in treated areas within 48 hours after application.	Solvent, cosolvent

Inert ingredients	Limits	Uses
5-Chloro-2-methyl-4-isothiazolin-3-one (in combination with 2-methyl-4-isothiazolin-3-one).	Not more than 0.0022% (22.5 ppm) in the formulation; 0.00022% (or 2.25 ppm) in the final solution applied to growing crops.	Preservative
Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229–78–8).	Maximum of 0.14% by weight of formulation.	Preservative
Copper naphthenate	Not more than 2.5% of formulation; application limited to before edible portions of plants begin to form.	Mercaptan scavenger in technical pesticide
Cyclohexane		Solvent, cosolvent
Cyclohexanone		Do.
Cysteine (CAS Reg. No. 52–90–4)	Maximum of 0.5% of formulation.	Synergist
D&C Green No. 6		Dye
D&C Red No. 17, technical grade		Dye
D&C Red No. 33 (CAS Reg. No. 3567–66–6); meeting the specifications listed in 21 CFR 74.1333.		Dye
D&C Violet No. 2, technical grade	Not more than 0.005% of pesticide formulation.	Dye
Decanamide, N,N-dimethyl (CAS Reg. No. 14433–76–2).		Emulsifier, solvent, cosolvent
n-Decyl alcohol		Dye
Diammonium phosphate (CAS Reg. No. 7783–28–0).		Buffer, surfactant
α-(Di-*sec*-butyl)phenylpoly(oxypropylene) block polymer with poly(oxyethylene); the poly(oxypropylene) content averages 4 moles, the poly(oxyethylene) content averages 5 to 12 moles, the molecular.		Surfactants, related adjuvants of surfactants
Diethanolamine		Stabilizer, inhibitor for formulations used before crop emerges from soil
Diethylene glycol		Deactivator, adjuvant for formulations used before crop emerges from soil
Diethylene glycol and diethylene glycol monobutyl, monoethyl, and monomethyl ethers.		Deactivator for formulations used before crop emerges from soil, stabilizer
3,6-Dimethyl-4-octyn-3,6-diol	In pesticide formulations, for soil prior to planting or to plants before edible parts form.	Surfactants, related adjuvants of surfactants
Dimethyl sulfoxide		Solvent or cosolvent for formulations used before crop emerges from soil or prior to formation of edible parts of food plants
Dipotassium hydrogen phosphate		Buffering agent
Dipropylene glycol monomethyl ether		Stabilizer
Douglas-fir bark, ground		Solid diluent, carrier
Dysprosium chloride	10 ppm in formulation	Tagging agent
(S,S)–Ethylenediaminedisuccinic acid (CAS Reg. No. 20846–91–7).		Sequestrant or chelating agent
Ethylene glycol		Antifreeze, deactivator for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges
Ethylene glycol monobutyl ether		
2-Ethylhexanol		Cosolvent, defoamer, solvent for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges
Europic chloride	10 ppm in formulation	Tagging agent
FD&C Blue No. 1, methyl-polyethylene glycol derivative (CAS Reg. No. 9079–34–9).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent
FD&C Blue No. 1, polyethylene glycol derivative (CAS Reg. No. 9079–33–8).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent

Inert ingredients	Limits	Uses
FD&C Red No. 40 (CAS Reg. No. 25956–17–6)	For seed treatment use only. Not to exceed 2% by weight of the pesticide formulation.	Dye, coloring agent
Ferric chloride		Not greater than 2% of suspending, dispersing agent, pesticide formulation
Fluoroapatite		Solid diluent, carrier
Folic acid (CAS Reg. No. 59–30–3)	Maximum of 0.5% of formulation.	Synergist
Gluconic acid (and sodium salt)		Sequestrant
l-Glutamic acid (C_5 H_9 $NO_{4\pm}$ CAS Reg. No. 56–86–0).	Seet treatment use only	Plant nutrient
[alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5).		Surfactant
[alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0).		Surfactant
Glutamine (CAS Reg. No. 56–85–9)	Maximum of 0.5% of formulation.	Synergist
Glycerol—propylene oxide polymer (CAS Reg. No. 25791-96-2).		Component in water-soluble film
Glyceryl triacetate		Stabilizer
Glyceryl tris-12-hydroxystearate		Flow control agent
Graphite		Treatment aid for seeds
Hexamethylenetetramine		Stabilizer for carriers in solid pesticide formulations
2-Hydroxy-4-*n*-octoxybenzophenone (CAS Reg. No. 1843–05–6).	Not more than 0.2 pt of pesticide formulation.	Light stabilizer
Hydroxypropyl guar gum		Thickener
Isobornyl acetate		Solvent
Isobutyl alcohol		Do.
Isobutylene-butene copolymers	For soil application only	Binder
Isooctadecanol	Not more than 2% of pesticide formulation.	Defoaming agent
Lanthanum chloride	10 ppm in formulation	Tagging agent.
Linoleic diethanolamide (CAS Reg. No. 56863–02–6).		Surfactant
Magnesium nitrate (in combination with 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one).	None	Preservation
Maleic acid and maleic anhydride	For pesticide formulations applied to apples with a minimum preharvest interval of 21 days.	Stabilizer
Manganese carbonate		Plant nutrient
Mesityl oxide	Not for use after edible parts of plant begin to form. Do not graze livestock in treated areas within 48 hours after application.	Solvent, cosolvent
Methionine (CAS Reg. No. 59–51–8)	Maximum of 0.5% of formulation.	Synergist
Methyl alcohol		Do.
Methyl bis(2-hydroxyethyl)alkyl ammonium chloride, where the carbon chain (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.		Surfactant
Methyl ethyl ketone		Surfactant
Methyl *p*- hydroxybenzoate		Preservative for formulations
Methyl isobutyl ketone		Solvent, cosolvent
2-Methyl-4-isothiazolin-3-one (in combination with 5-chloro-2-methyl-4-isothiazolin-3-one).	Not more than 0.0022% (22.5 ppm) in the formulation; 0.00022% (or 2.25 ppm) in the final solution applied to growing crops.	Preservative
Methylnaphthalenesulfonic acid—formaldehyde condensate, sodium salt.		Dispersant
Methyl oleate		Surfactant
2-Methyl-2,4-pentanediol		Solvent for formulations used before crop emerges from soil

Inert ingredients	Limits	Uses
Methyl poly(oxyethylene) alkyl ammonium chloride, where the poly(oxyethylene) content is 3-15 moles and the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.	.....	Surfactant
N-Methylpyrrolidone (CAS Reg. No. 872-504)	.....	Solvent, cosolvent
Mixed phytosterols (consisting of campesterol, sitosterol and stigmasterol, with minor amounts of associated plant sterols) derived from edible vegetable oils.	.....	Surfactant
Mono- and bis-(1*H*, 1*H*, 2*H*, 2*H*-perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C_6-C_{12} range.	Not more than 0.5% of pesticide formulation. Expires February 9, 2008.	Surfactant, related adjvants of surfactants
Mono- and dialkyl (C_8-C_{18}) methylated ammonium chloride compounds, where the alkyl group(s) (C_8-C_{18}) are derived from coconut, cottonseed, soya, tallow, or hogfat fatty acids.	.....	Surfactants, related adjuvants of surfactants
Morpholine 4-C_{6-12} Acyl Derivatives (CAS Reg. No. 887947–29–7).	.....	As a solvent
Naphthalenesulfonic acid-formaldehyde condensate, ammonium and sodium salts.	.....	Surfactants, related adjuvants of surfactants
Nicotinamide (CAS Reg. No. 98–92–0)	Maximum of 0.5% of formulation.	Synergist
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene); produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-100 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4-14 or 30-100.	.....	Surfactant
Octanamide, N,N-dimethyl (CAS Reg. No. 1118–92–9).	.....	Emulsifier, solvent, cosolvent
n- Octyl alcohol	.....	Solvent, cosolvent
α-Oleoyl-ω-(oleoyloxy) poly(oxyethylene) derived from α-hydro-ω-hydroxypoly(oxyethylene) (molecular weight 600 amu).	.....	Component of defoamers
Oxo-decyl acetate (CAS reg. No. 108419–33–6)	.....	Solvent
Oxo-heptyl acetate (CAS Reg. No. 90438–79–2)	.....	Solvent
Oxo-hexyl acetate (CAS Reg. No. 88230–35–7)	.....	Solvent
Oxo-nonyl acetate (CAS Reg. No. 108419–34–7).	.....	Solvent
Oxo-octyl acetate (CAS Reg. No. 108419–32–5)	.....	Solvent
Oxo-tridecyl acetate (CAS Reg. No. 108419–35–8).	.....	Solvent
Partial sodium salt of *N*- lauryl-α-iminodipropionic acid.	Not more than 1% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Phenol	.....	Solvent, cosolvent
Phenolsulfonic acid—formaldehyde—urea condensate and its sodium salt.	Applied to growing plants only.	Dispersant surfactant
(Phthalocyaninato (2)) copper; (C.I. pigment blue No. 15).	When used as a colorant in low-density plastic films.	Coloring agent, pigment
Pigment red 48	For seed treatment use only.	Dye
α-Pinene	Not more than 2% of formulation by weight.	Stabilizer
Poly(oxyethylene) adducts of mixed phytosterols (such sterols to consist of campesterol, stigmasterol and sitosterol with minor amounts of associated plant sterols) derived from edible vegetable oils; polyoxyethylene content averaging 5-26 moles.	.....	Surfactant, related adjuvants
Poly(oxyethylene) (5) sorbitan monooleate	.....	Surfactants, related adjuvants of surfactants
Polysorbate 60, conforming to 21 CFR 172.836	.....	Surfactant
Potassium dihydrogen phosphate	.....	Buffering agent
Primary *n*-alkylamines, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.	.....	Surfactant
2-Propanamine, compound with α-phosphono-ω-butoxypoly (oxy-1,2-ethanediyl) (2:1) (CAS Reg. No. 431040–31–2).	Not more than 15% in the formulated product.	Surfactant

Inert ingredients	Limits	Uses
2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C_{8-10}- alkyl ether (2:1) (CAS Reg. No. 431062–72–5).	Not more than 15% in the formulated product.	Surfactant
Propylene glycol monomethyl ether		Solvent
Pyridoxine (CAS Reg. No. 65–23–6)	Maximum of 0.5% of formulation.	Synergist
Rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v)).		Surfactants, related adjuvants of surfactants
Rosin, gum		Do.
Rosin, tall oil		Do.
Scandium chloride	10 ppm in formulation	Tagging agent
Sodium bisulfate (CAS Reg. No. 7681–38–1)		Acidifying/buffering agent
Sodium 1,4-dicyclohexyl sulfosuccinate		Surfactants, related adjuvants of surfactants
Sodium 1,4-dihexyl sulfosuccinate		Do.
Sodium dihydrogen phosphate (CAS Reg. No. 7558–80–7) conforming to 21 CFR 182.6778.		Buffering agent
Sodium 1,4-diisobutyl sulfosuccinate		Surfactants, related adjuvants of surfactants
Sodium 1,4-dipentyl sulfosuccinate		Do.
Sodium metaborate		Sequestrant
Sodium molybdate		Plant nutrient
Sodium nitrate		Solid diluent
Sodium nitrite	Not more than 3% of pesticide formulation.	Stabilizer, inhibitor.
Sodium *o*-phenylphenate	Not more than 0.1% of pesticide formulation.	Preservative for formulation
Sodium salt of the insoluble fraction of rosin		Surfactants, related adjuvants of surfactants
Sodium tetraborate	Not more than 2% of pesticide formulation.	Buffering agent; corrosion inhibitor
Tannin		Dispersing agent
Tertiary butylhydroquinone		Antioxidant
1-Tetradecanamine, *N,N*-dimethyl-, *N*-oxide (CAS Reg. No. 3332–27–2).		Component in water-soluble film
N,N,N′,N″-Tetrakis-(2-hydroxypropyl) ethylenediamine.		Stabilizer for formulations used before crop emerges from soil
2,4,7,9-Tetramethyl-5-decyne 4,7-diol	In pesticide formulations, for application to soil prior to planting or to plants before edible parts form.	Surfactants, related adjuvants of surfactants
Tetrapotassium pyrophosphate (CAS Reg. No. 7320–345).	Not to exceed 10% of formulation.	Sequestrant, anticaking agent, conditioning agent
Titanium dioxide (CAS Reg. No. 13463–67–7)		Pigment/coloring agent in plastic bags used to wrap growing banana (preharvest), colorant on seeds for planting
Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Solvent, cosolvent
Triethanolamine		Stabilizer, inhibitor for formulations used before crop emerges from soil
Triethanolamine (CAS Reg. No. 102–71–6)		Stabilizer, inhibitor
Triethylene glycol		Deactivator
Triethyl phosphate		Stabilizer for formulations used before crop emerges from soil
Trimethylolpropane (CAS Reg. No. 77–99–6)	Not to exceed 15% by weight of the film.	Component in water-soluble film
α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxy poly(oxyethylene), the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Surfactant.
α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxy poly(oxyethylene); mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Do.
α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxy poly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles.	Not more than 15% of the pesticide formulation.	Do.
Tryptophan (CAS Reg. No. 73–22–3)	Maximum of 0.5% of formulation.	Synergist
Valeric acid, normal	Not more than 2% in pesticide formulations.	Stenching agent or odorant

Inert ingredients	Limits	Uses
Xylene		Solvent, cosolvent
Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
Yucca extract from Yucca schidigera		Wetting agent
Ytterbium chloride	10 ppm in formulation	Tagging agent
Yttrium chloride	10 ppm in formulation	Tagging agent
Zinc orthophosphate		Plant nutrient and safener
Zinc stearate, conforming to 21 CFR 182.5994 and 582.5994.		Flow control agent

[69 FR 23124, Apr. 28, 2004, as amended at 70 FR 7900, Feb. 16, 2005; 70 FR 31369, June 1, 2005; 70 FR 41619, July 20, 2005; 70 FR 54280, Sept. 14, 2005; 70 FR 55296, Sept. 21, 2005; 70 FR 55733, Sept. 23, 2005; 71 FR 14415, Mar. 22, 2006; 71 FR 18642, Apr. 12, 2006; 71 FR 30811, May 31, 2006; 71 FR 43667, Aug. 2, 2006; 71 FR 45408, 45411, 45421, Aug. 9, 2006; 72 FR 45656, Aug. 15, 2007; 73 FR 67400, Nov. 14, 2008; 74 FR 12620, Mar. 25, 2009; 74 FR 20887, May 6, 2009; 74 FR 28623, June 17, 2009]

EFFECTIVE DATE NOTE: At 71 FR 45421, Aug. 9, 2006, in §180.920, the table was amended by removing the following entries, effective Aug. 9, 2008. At 73 FR 45312 and 45316, Aug. 4, 2008, the effective date was delayed until Aug. 9, 2009:

a. α-Alkyl (C_{12}-C_{18})-ω-hydroxypoly(oxyethylene) copolymers with poly(oxypropylene); polyoxyethylene content averages 3-12 moles and polyoxypropylene content 2-9 moles.

b. α-Alkyl (C_{10}-C_{16})-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles.

e. α-Alkyl(C_{12}-C_{18})-ω-hydroxypoly (oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content averages 13-17 moles and the oxypropylene content averages 2-6 moles.

f. α-Alkyl (C_{10}-C_{16})-ω-hydroxypoly(oxyethylene)poly(oxypropylene) mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the combined poly(oxyethylene) poly(oxypropylene) content averages 3-20 moles.

g. α-Alkyl (C_{12}-C_{18})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-12 moles and the oxypropylene content is 3-7 moles.

h. α-Alkyl (C_{12}-C_{15})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.

i. α-Alkyl (C_{21}-C_{71})-ω-hydroxypoly (oxyethylene) in which the poly(oxyethylene) content is 2 to 91 moles and molecular weight range from 390 to 5,000.

j. *n*-Alkyl(C_8-C_{18})amine acetate.

k. Amine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (butylamine, dimethylaminopropylamine, mono- and diisopropylamine, mono- , di- , and triethanolamine).

m. *N*,*N*-Bis[α-ethyl-ω-hydroxypoly(oxyethylene) alkylamine; the poly(oxyethylene) content averages 3 moles; the alkyl groups (C_{14}-C_{18}) are derived from tallow, or from soybean or cottonseed oil acids.

n. *N*,*N*-Bis(2-hydroxyethyl)alkylamine, where the alkyl groups (C_8-C_{18}) are derived from coconut, cottonseed, soya, or tallow acids.

o. *N*,*N*-Bis 2-(ω-hydroxypolyoxyethylene) ethyl) alkylamine; the reaction product of 1 mole *N*,*N*-bis(2-hydroxyethyl)alkylamine and 3-60 moles of ethylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

p. *N*,*N*-Bis-2-(ω-hydroxypolyoxyethylene/polyoxypropylene) ethyl alkylamine; the reaction product of 1 mole of *N*,*N*-bis(2-hydroxyethyl alkylamine) and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

s. α-(Di-*sec*-butyl)phenylpoly(oxypropylene) block polymer with poly(oxyethylene); the poly(oxypropylene) content averages 4 moles, the poly(oxyethylene) content averages 5 to 12 moles, the molecular.

y. Linoleic diethanolamide (CAS Reg. No. 56863–02–6).

z. Methyl bis(2-hydroxyethyl)alkyl ammonium chloride, where the carbon chain (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

bb. Methylnaphthalenesulfonic acid—formaldehyde condensate, sodium salt.

cc. Methyl poly(oxyethylene) alkyl ammonium chloride, where the poly(oxyethylene) content is 3-15 moles and the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

ff. Naphthalenesulfonic acid-formaldehyde condensate, ammonium and sodium salts.

gg. Partial sodium salt of *N*-lauryl-α-iminodipropionic acid.

ii. Primary *n*-alkylamines, where the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

ll. Sodium 1,4-dihexyl sulfosuccinate.

mm. Sodium 1,4-diisobutyl sulfosuccinate.

nn. Sodium 1,4-dipentyl sulfosuccinate.

ss. *N,N,N′,N″*-Tetrakis-(2-hydroxypropyl) ethylenediamine.

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

The following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals:

Inert ingredients	Limits	Uses
Acetic acid (CAS Reg. No. 64–19–7)	Not more than 0.5% of pesticide formulation.	Catalyst
Acetic anhydride		Solvent, cosolvent, stabilizer
Alkanoic and alkenoic acids, mono- and diesters of α-hydro-ω-hydroxypoly(oxyethylene) with molecular weight (in amu) range of 200 to 6,000.		Emulsifiers
Alkyl (C_8-C_{24}) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, emulsifier, related adjuvants of surfactants
α-Alkyl (C_{12}- C_{15})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α-Alkyl (C_8-C_{10}) hydroxypoly(oxypropylene) block polymer with polyoxyethylene; polyoxypropylene content averages 3 moles and polyoxyethylene content averages 5-12 moles.		Do.
α-Alkyl (C_6-C_{14})-ω-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 7-9 moles; average molecular weight (in amu) approximately 635.		Surfactants, related adjuvants of surfactants
α-alkyl (C_{12}-C_{15})-ω-hydroxypoly (oxypropylene)poly (oxyethylene)copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles), the resulting ethoxylated propoxylated (C_{12}-C_{15}) alcohols having a minimum molecular weight (in amu) of 1,500, CAS Reg. No. 68551–13–3.	Not to exceed 20% of pesticide formulations.	Surfactant
Alkyl (C_8-C_{18}) sulfate and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactant
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 10213–78–2, 25307–17–9, 26635–92–7, 26635–93–8, 288259–52–9, 58253–49–9, 61790–82–7, 61791–14–8, 61791–24–0, 61791–26–2, 61791–31–9, 61791–44–4, 68155–33–9, 68155–39–5, 68155–40–8,70955–14–5, 73246–96–5).	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations.	Surfactants, related adjuvants of surfactants
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 68213–26–3, 68153–97–9, 75601–76–2).	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations.	Surfactants, related adjuvants of surfactants
Amine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (butylamine; dimethylamino propylamine; mono- and diisopropyl- amine; and mono-, di-, and triethanolamine).		Surfactant
Ascorbyl palmitate		Preservative
Attapulgite-type clay		Solid diluent, carrier

Inert ingredients	Limits	Uses
Barium sulfate (CAS Reg. No. 7727–43–7)		Carrier, density control agent
Benzoic acid		Preservative for formulations
2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7).	0.04% or less by weight of the total pesticide formulation.	In-can preservative
Butane		Propellant
n-Butanol (CAS Reg. No. 71–36–3)		Solvent for blended emulsifiers
Butylated hydroxyanisole		Antioxidant
Butylated hydroxytoluene		Do.
Calcium carbonate		Solid diluent, carrier
Calcium chloride		Stabilizer
Calcium silicate, hydrated calcium silicate		Anticaking agent, solid diluent, carrier
Calcium stearate (CAS Reg. No. 1592–23–0)		Stabilizer, component of plastic animal tag
Calcium sulfate		Solid diluent, carrier
Carbon black (CAS Reg. No. 1333–86–4)		Colorant/pigment in animal tag
Carrageenan, conforming to 21 CFR 172.620	Minimum molecular weight (in amu): 100,000.	Thickener
Cyclohexanone		Solvent, cosolvent
D&C Green No. 6		Dye, coloring agent
D&C Red No. 17		Do.
D&C Violet No. 2		Do.
Dialkyl (C_8-C_{18}) dimethylammonium chloride	Not more than 0.2% in silica hydrated silica.	Flocculating agent in the manufacture of silica hydrated silica for use as a solid diluent, carrier
Diatomite (diatomaceous earth)		Solid diluent, carrier
Diethylphthalate		Solvent, cosolvent
1,1-Difluoroethane (CAS Reg. No. 75–37–6)	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.	Aerosol propellant
Dimethyl ether (CAS Reg. No. 115–10–6)		Propellant
3,6-Dimethyl-4-octyne-3,6-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Dimethylpolysiloxane (CAS Reg. No. 9016–00–6).		Defoaming agent
Dipropylene glycol monomethyl ether		Surfactants, related adjuvants of surfactants
Epoxidized soybean oil (CAS Reg. No. 8013–07–8).		Stabilizer, plasticizer, component animal tag
Ethyl alcohol		Solvent, cosolvent
Ethyl maltol (CAS Reg. No.4940–11–8)	Not more than 0.2 % of the pesticide formulation.	Odor masking agent
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.		Surfactants, related adjuvants of surfactants
2-Ethyl-1-hexanol	Not more than 2.5% of pesticide formulation.	Solvent, adjuvant of surfactants
FD&C Blue No. 1		Dye, coloring agent
FD&C Yellow No. 6 Aluminum Lake (CAS Reg. No. 15790–07–5).	Not more than 2% by weight of pesticide formulation.	Pigment in animal tag and similar slow-release devices
D-glucopyranose, oligomeric, C_{10-16}-alkyl glycosides (CAS Reg. No. 110615–47–9).		Surfactant
Glycerol monooleate		Surfactants, related adjuvants of surfactants
Glyceryl monostearate		Emulsifier
Glyceryl tris-12-hydroxystearate		Flow control agent
Graphite		Solid diluent, carrier
n-Hexyl alcohol (CAS Reg. No. 111–27–3)		Solvent, cosolvent
2-(2′-Hydroxy-5′-methylphenyl)benzotriazole (CAS Reg. No. 2440–22–4).	Not more than 0.5% by weight of pesticide formulation.	Ultraviolet light absorber/stabilizer in animal tag and similar slow-release devices
Iron oxide (CAS Reg. No. 1309–37–1)		Colorant in pesticide formulations for animal tags
Isopropyl myristate, CAS Reg. No. 110–27–0		Solvent
Kaolinite-type clay		Solid diluent, carrier
Kerosene, U.S.P. reagent		Solvent, cosolvent
Lactic acid		Solvent
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).		Solvent
Lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1).		Solvent
Lactic acid, n-propyl ester, (S); (CAS Reg. No. 53651–69–7).		Solvent

Inert ingredients	Limits	Uses
α-Lauryl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.	.....	Emulsifier
α-Lauryl-ω-hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.	.....	Surfactants, related adjuvants of surfactants
Lignin (CAS Reg. No. 9005–53–2)	.....	Surfactant, related adjuvants of surfactants
Lignin, alkali (CAS Reg. No. 8068–05–1)	.....	Do.
Lignin, alkali, oxidized, sodium salt (CAS Reg. No. 68201–23–0).	.....	Do.
Lignin alkali reaction products with disodium sulfite and formaldehyde (CAS Reg. No. 105859–97–0).	.....	Do.
Lignin alkali reaction products with formaldehyde and sodium bisulfite (CAS Reg. No. 68512–35–6).	.....	Do.
Lignosulfonic acid (CAS Reg. No. 8062–15–5) ..	.....	Do.
Lignosulfonic acid, ammonium calcium salt (CAS Reg. No. 12710–04–2).	.....	Do.
Lignosulfonic acid, ammonium magnesium salt (CAS Reg. No. 123175–37–1).	.....	Do.
Lignosulfonic acid, ammonium salt (CAS Reg. No. 8061–53–8).	.....	Do.
Lignosulfonic acid, ammonium sodium salt (CAS Reg. No. 166798–73–8).	.....	Do.
Lignosulfonic acid, calcium magnesium salt (CAS Reg. No. 55598–86–2).	.....	Do.
Lignosulfonic acid, calcium salt (CAS Reg. No. 8061–52–7).	.....	Do.
Lignosulfonic acid, calcium sodium salt (CAS Reg. No. 37325–33–0).	.....	Do.
Lignosulfonic acid, ethoxylated, sodium salt (CAS Reg. No. 68611–14–3).	.....	Do.
Lignosulfonic acid, magnesium salt (CAS Reg. No. 8061–54–9).	.....	Do.
Lignosulfonic acid, potassium salt (CAS Reg. No. 37314–65–1).	.....	Do.
Lignosulfonic acid, sodium salt (CAS Reg. No. 8061–51–6).	.....	Do.
Lignosulfonic acid, sodium salt, oxidized (CAS Reg. No. 68855–41–4).	.....	Do.
Lignosulfonic acid, sodium salt, polymer with formaldehyde and phenol (CAS Reg. No. 37207–89–9).	.....	Do.
Lignosulfonic acid, sodium salt, sulfomethylated (CAS Reg. No. 68512–34–5).	.....	Do.
Lignosulfonic acid, zinc salt (CAS Reg. No. 57866–49–6).	.....	Do.
d-Limonene (CAS Reg. No. 5989–27–5)	.....	Solvent, fragrance
Magnesium carbonate	.....	Solid diluent, carrier
Magnesium silicate, hydrated magnesium silicate.	.....	Do.
Methyl alcohol	.....	Solvent, cosolvent
Methyl *n*-amyl ketone (CAS Reg. No. 110–43–0)	.....	Solvent, cosolvent
Methyl esters of higher fatty acids conforming to 21 CFR 573.640.	.....	Antidusting agent
Methyl-*p*-hydroxybenzoate (Methyl paraben)	Meets specifications of Food Chemicals Codex; not to exceed 0.1% in formulations.	Preservative
Methyl isobutyl ketone	.....	Solvent, cosolvent
Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a), (b).	.....	Solvent, diluent
Montmorillonite-type clay	.....	Solid diluent, carrier
Naphthalenesulfonic acid and its sodium salt	.....	Surfactants, related adjuvants of surfactants
Nonyl, decyl, and undecyl glycoside mixture with a mixture of nonyl, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65% solids) from the reaction of primary alcohols (containing 15 to 20% secondary alcohol isomers) in a ratio of 20% C_9, 40% C_{10}, and 40% C_{11} with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).	.....	Surfactant

Inert ingredients	Limits	Uses
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.	.....	Surfactants, related adjuvants of surfactants
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-15 or 30-90 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-15 or 30-90 moles.	.....	Surfactants, emulsifier, related adjuvants of surfactants.
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.	.....	Surfactants, related adjuvants of surfactants
α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30-90 moles of ethyiene oxide.	.....	Surfactants, related adjuvants of surfactants
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydro cinnamate (CAS Reg. No. 2082–79–3).	Not more than 0.5% by weight of pesticide formulation.	Thermal stabilizer/antioxidant in animal tag and similar slow-release devices
1-Octanal (CAS Reg. No. 124–13–0)	Not more than 0.2% of the pesticide formulation.	Odor masking agent
Octyl and decyl glucosides mixture with a mixture of octyl and decyl oligosaccharides and related reaction products (primarily *n*-decanol) produced as an aqueous-based liquid (68-72% solids) from the reaction of straight chain alcohols (C_8(45%), C_{10}) with anhydrous glucose.	.....	Thermal stabilizer/antioxidant in animal tag and similar slow-release devices
Octyl epoxytallate (CAS Reg. No. 61788–72–5)	.....	Plasticizer, component animal tag
Oleic acid, conforming to 21 CFR 172.862 (CAS Reg. No. 112–80–1).	.....	Defoaming agent
α-Oleoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.	.....	Emulsifier
α-Oleoyl-ω-(oleyloxy)poly(oxyethylene) derived from α-hydro-ω-hydroxypoly(oxyethylene), molecular weight (in amu) 600.	.....	Emulsifier, defoaming agent
Petroleum hydrocarbons, light, odorless, conforming to 21 CFR 172.884 or 178.3650.	.....	Solvent, diluent
Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882 or 178.3530.	.....	Do.
Phenol	.....	Solvent, cosolvent
α-Pinene	Not more than 2% of formulation by weight.	Stabilizer
Polyethylene (CAS Reg. No. 9002–88–4) conforming to 21 CFR 172.615.	.....	Component of plastic slow release tag
Polyethylene glycol [α-hydro-ω-hydroxypoly(oxyethylene)]; mean molecular weight (in amu) 194 to 9,500 conforms to 21 CFR 178.3750.	.....	Surfactants, related adjuvants of surfactants
Polyglyceryl phthalate esters of coconut oil fatty acids.	.....	Do.
Potassium hydroxide	Meeting Food Chemicals, Codex specifications.	Neutralizer
Propane	.....	Propellant
n-Propanol	.....	Solvent, for blended emulsifiers

Inert ingredients	Limits	Uses
2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Registration No. 55989–05–4), minimum number average molecular weight (in amu), 18,900.		Encapsulating agent,dispensers, resins, fibers and beads
Propylene glycol		Solvent, cosolvent
Propylene glycol monomethyl ether		Deactivator, emmolient
Propyl gallate		Antioxidant
Propyl *p*-hydroxybenzoate (Propyl paraben)	Meets specifications of Food Chemicals Codex; not to exceed 0.1% in formulations.	Preservative
Pyrophylite		Solid diluent, carrier
Silica, hydrated silica		Anticaking agent, solid diluent, carrier
Silica aerogel (finely powdered microcellular silica foam having a minimum silica content of 89.5%).		Component of antifoaming agent
Soapstone		Solid diluent
Sodium diisobutylnaphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium dioctylsulfosuccinate		Do.
Sodium hydroxide		Neutralizer
Sodium isopropylnaphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium monoalkyl and diakyl (C_8-C_{13}) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.		Do.
Sodium mono- and dimethylnaphthalenesulfonate, molecular weight (in amu) 245-260.		Do.
Sodium mono-, di-, and tributylnaphthalenesulfonates.		Solvent, cosolvent stabilizer
Sodium *N*-oleoyl-*N*-methyl taurine	Not more than 1% of pesticide formulations.	Surfactant
Sodium starch glycolate (CAS Reg. No. 9063–38–1).	Granular and tableted products only; not to exceed 8% of the formulated product.	Disintegrant
Sodium sulfate		Solid diluent, carrier
Sorbitan fatty acid esters (fatty acids limited to C_{12}, C_{14}, C_{16}, and C_{18} containing minor amounts of associated fatty acids) and poly(oxyethylene) derivatives of sorbitan fatty acid esters; the poly(oxyethylene) content averages 16-20 moles.		Buffering agent; corrosion inhibition
Sorbitol		Antidusting agent.
Stearic acid (CAS Reg. No. 57–11–4)		Lubricant, component animal tag
α-Stearoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α-Stearoyl-ω-hydroxypoly(oxyethylene); the poly(oxyethylene) content averages 8, 9, or 40 moles; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be 8, 9, or 40.		Surfactants; related adjuvants of surfactants
Sulfite liquors and cooking liquors, spent, oxidized (CAS Reg. No. 68514–09–0).		Surfactant, related adjuvants of surfactants
Sulfur (CAS Reg. No. 7704–34–9)		Stabilizer
Talc		Do.
Tall oil; fatty acids not less than 58%, rosin acids not more than 44%, unsaponifiables not more than 8%.		Surfactants, related adjuvants of surfactants
Tartrazine		Dye, coloring agent
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p* (1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.		Surfactants, related adjuvants of surfactants
2,4,7,9-Tetramethyl-5-decyne-4.7-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
Titanium dioxide (CAS Reg. No. 13463–67–7)		Pigment/colorant in pesticide formulations for animal tag
Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Do.
Triacetin (glyceryl triacetate)		Solvent, cosolvent
Trisodium phosphate		Precipitant, buffer, filler
Xylene		Solvent, cosolvent
Xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
Zinc oxide		Solid diluent, carrier
Zinc stearate, conforming to 21 CFR 182.5994 and 582.5994.		Water repellant, dessicant, and coating agent.
Zinc stearate (CAS Reg. No. 557–05–1)		Water repellant, desiccant, and coating agent; stabilizer, component of plastic animal tag
Zinc sulfate (basic and monohydrate)		Water repellant, dessicant, and coating agent

[69 FR 23130, Apr. 28, 2004, as amended at 69 FR 29894, May 26, 2004; 69 FR 34949, June 23, 2004; 69 FR 58070, Sept. 29, 2004; 69 FR 58304, Sept. 30, 2004; 70 FR 37692, June 30, 2005; 70 FR 43312, July 27, 2005; 70 FR 44496, Aug. 3, 2005; 70 FR 51628, Aug. 31, 2005; 70 FR 54286, Sept. 14, 2005; 70 FR 55296, Sept. 21, 2005; 70 FR 67910, Nov. 9, 2005; 70 FR 55733, Sept. 23, 2005; 71 FR 14415, Mar. 22, 2006; 71 FR 30811, May 31, 2006; 71 FR 45422, Aug. 9, 2006; 74 FR 28623, June 17, 2009]

EFFECTIVE DATE NOTE: At 71 FR 45422, Aug. 9, 2006, in § 180.930, the table was amended by removing the following entries, effective Aug. 9, 2008. At 73 FR 45312 and 45316, Aug. 4, 2008, the effective date was delayed until Aug. 9, 2009:

b. α-Alkyl (C_{12}-C_{15})-ω-hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.

c. α-Alkyl (C_8-C_{10}) hydroxypoly(oxypropylene) block polymer with polyoxyethylene; polyoxypropylene content averages 3 moles and polyoxyethylene content averages 5-12 moles.

d. α-Alkyl (C_6-C_{14})-ω-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 7-9 moles; average molecular weight (in amu) approximately 635.

f. Amine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (butylamine; dimethylamino propylamine; mono- and diisopropyl- amine; and mono- , di-, and triethanolamine).

l. Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.

n. α-Lauryl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.

o. α-Lauryl-ω-hydroxypoly(oxyethylene), sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.

s. Naphthalenesulfonic acid and its sodium salt.

t. α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.

u. α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.

v. α-(*p*-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30-90 moles of ethyiene oxide.

w. Polyglyceryl phthalate esters of coconut oil fatty acids.

cc. Sodium diisobutylnaphthalenesulfonate.

ee. Sodium isopropylnaphthalenesulfonate.

ff. Sodium monoalkyl and diakyl (C_8-C_{13}) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.

gg. Sodium mono- and dimethylnaphthalenesulfonate, molecular weight (in amu) 245-260.

hh. Sodium mono-, di-, and tributylnaphthalenesulfonates.

ii. Sodium *N*-oleoyl-*N*-methyl taurine.

jj. α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p* (1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

Residues of the following chemical substances are exempted from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food.

(a) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64–19–7	When ready for use, the end-use concentration is not to exceed 290 ppm
α-Alkyl(C_{10}-C_{14})-ω-hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α-Alkyl(C_{12}-C_{18})-ω-hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120	None	None
Ammonium chloride	12125–02–9	When ready for use, the end-use concentration is not to exceed 48 ppm
Amylopectin, acid-hydrolyzed, 1-oxtenylbutanedioate	113894–85–2	none
Amylopectin, hydrogen 1-octadecenylbutanedioate	125109–81–1	none
Ethanol	64–17–5	None
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64–02–8	None
Hydrogen peroxide	7722–84–1	When ready for use, the end-use concentration is not to exceed 91 ppm
Hypochlorous acid, sodium salt	7681–52–9	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553–56–2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Magnesium oxide	1309–48–4	None
Methylene blue	61–73–4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
α-(p-Nonylphenyl)-ω-hydroxypoly (oxyethylene) average poly(oxyethylene) content 11 moles)	None	None
Octadecanoic acid, calcium salt	1592–23–0	None
1-Octanesulfonic acid, sodium salt	5324–84–5	When ready for use, the end-use concentration is not to exceed 46 ppm
Octanoic acid	124–07–2	When ready for use, the end-use concentration is not to exceed 52 ppm
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1900	9003–11–6	None
Peroxyacetic acid	79–21–0	When ready for use, the end-use concentration is not to exceed 58 ppm
Peroxyoctanoic acid	33734–57–5	When ready for use, the end-use concentration is not to exceed 52 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809–21–4	When ready for use, the end-use concentration is not to exceed 14 ppm
Phosphoric acid, trisodium salt	7601–54–9	When ready for use, the end-use concentration is not to exceed 5916 ppm
Potassium bromide	7758–02–3	When ready for use, the end-use concentration is not to exceed 46 ppm total available halogen
Potassium iodide	7681–11–0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Quaternary ammonium compounds, alkyl (C_{12}-C_{18}) benzyldimethyl, chlorides	8001–54–5	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound

Pesticide Chemical	CAS Reg. No.	Limits
Quaternary ammonium compounds: n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride	68424–85–1	When ready for use, the end-use concentration of all quaternary chemicals in solution is not to exceed 400 ppm of active quaternary compound.
Quaternary ammonium compounds, n-alkyl (C_{12}-C_{14}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds n-alkyl (C_{12}-C_{18}) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu) 384	None	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, Di-n-Alkyl (C_{8-10}) dimethyl ammonium chloride, average molecular weight (in amu) 332 to 361	None	When ready for use, the end-use concentration of these specific in quaternary ammonium compounds is not to exceed 240 ppm of active quaternary ammonium compound; the end-use concentration of all quaternary chemicals in the solution is not to exceed 400 ppm of active quaternary compound
Quaternary ammonium compounds, didecyl dimethyl ammonium carbonate/didecyl dimethyl ammonium bicarbonate	148788–55–0/148812–654–1	When ready for use, the end-use concentration of these specific ammonium compounds is not to exceed 240 ppm of active quaternary ammonium compound
Silver ions resulting from the use of electrolytically-generated silver ions stabilized in citric acid as silver dihydrogen citrate (does not include metallic silver)	14701–21–4	When ready for use, the end-use concentration of silver ions is not to exceed 50 ppm of active silver
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151–21–3	When ready for use, the end-use concentration is not to exceed 3 ppm
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893–78–9	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine

(b) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Dairy processing equipment, and food-processing equipment and utensils.

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64–19–7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608–66–2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
Benzenesulfonic acid, dodecyl-	27176–87–0	When ready for use, the end-use concentration is not to exceed 5.5 ppm
Butanedioic acid, octenyl-	28805–58–5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2400	None	None
Calcium chloride	10043–52–4	When ready for use, the end-use concentration is not to exceed 17 ppm
n-Carboxylic acids (C_6-C_{12}), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
Decanoic acid	334–48–5	When ready for use, the end-use concentration is not to exceed 90 ppm
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl) amino]-, sodium salt	132–43–4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139–33–3	When ready for use, the end-use concentration is not to exceed 1400 ppm
FD&C Yellow No. 5 (Tartrazine) (conforming to 21 CFR 74.705)	1934–21–0	None
D-Gluconic acid, monosodium salt	527–07–1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034–85–2	When ready for use, the total end-use concentration of all iodide-producing chemicals is not to exceed 25 ppm of titratable iodine

Pesticide Chemical	CAS Reg. No.	Limits
Hydrogen peroxide	7722–84–1	When ready for use, the end-use concentration is not to exceed 465 ppm
Hypochlorous acid	7790–92–3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553–56–2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Lactic acid	50–21–5	When ready for use, the end-use concentration is not to exceed 138 ppm
Nonanoic acid	112–05–0	When ready for use, the end-use concentration is not to exceed 90 ppm
1-Octanamine, N,N-dimethyl-	7378–99–6	When ready for use, the end-use concentration is not to exceed 113 ppm
1,2-Octanedisulfonic acid	113669–58–2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944–72–7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324–84–5	When ready for use, the end-use concentration is not to exceed 297 ppm
1-Octanesulfonic acid, 2-sulfino-	113652–56–5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124–07–2	When ready for use, the end-use concentration is not to exceed 176 ppm
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)
Peroxyacetic acid	79–21–0	When ready for use, the end-use concentration is not to exceed 315 ppm
Peroxyoctanoic acid	33734–57–5	When ready for use, the end-use concentration is not to exceed 122 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809–21–4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664–38–2	None
Phosphoric acid, monosodium salt	7558–80–7	When ready for use, the end-use concentration is not to exceed 350 ppm
Potassium iodide	7681–11–0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Propanoic acid	79–09–4	When ready for use, the end-use concentration is not to exceed 297 ppm
2,6-Pyridinedicarboxylic acid	499–83–2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Sulfuric acid	7664–93–9	When ready for use, the end-use concentration is not to exceed 288 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151–21–3	When ready for use, the end-use concentration is not to exceed 350 ppm

(c) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64–19–7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608–66–2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
α-Alkyl(C_{10}-C_{14})-ω-hydroxypoly (oxyethylene) poly (oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α-Alkyl(C_{11}-C_{15})-ω-hydroxypoly (oxyethylene) with ethylene oxide content 9 to 13 moles	None	None

Pesticide Chemical	CAS Reg. No.	Limits
α-Alkyl(C_{12}-C_{18})-ω-hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120	None	None
Ammonium chloride	12125–02–9	When ready for use, the end-use concentration is not to exceed 48 ppm
Benzenesulfonic acid, dodecyl-	27176–87–0	When ready for use, the end-use concentration is not to exceed 400 ppm
Benzenesulfonic acid, dodecyl-, sodium salt	25155–30–0	When ready for use, the end-use concentration is not to exceed 430 ppm
[1,1′-Biphenyl]-2-ol	90–43–7	When ready for use, the end-use concentration is not to exceed 400 ppm
Boric acid, sodium salt	7775–19–1	None
Butanedioic acid, octenyl-	28805–58–5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butanedioic acid, sulfo-, 1,4-dioctyl ester, sodium salt	1639–66–3	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, cloudpoint of 90 - 100°C in 0.5 aqueous solution, average molecular weight (in amu), 3300	None	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2400	None	None
Calcium chloride	10043–52–4	When ready for use, the end-use concentration is not to exceed 17 ppm
n-Carboxylic acids (C_6-C_{12}), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
3-Cyclohexene-1-methanol,α,α,4-trimethyl-	98–55–5	None
1-Decanaminium, N-decyl-N, N-dimethyl-, chloride	7173–51–5	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Decanoic acid	3347–48–5	When ready for use, the end-use concentration is not to exceed 234 ppm
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl) amino]-, sodium salt	132–43–4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethanol	64–17–5	None
Ethanol, 2 butoxy-	111–76–2	None
Ethanol, 2-(2-ethoxyethoxy)-	111–90–0	None
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139–33–3	When ready for use, the end-use concentration is not to exceed 1400 ppm
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64–02–8	None
Fatty acids, coco, potassium salts	61789–30–8	None
Fatty acids, tall-oil, sulfonated, sodium salts	68309–27–3	When ready for use, the end-use concentration is not to exceed 66 ppm
FD&C Yellow No. 5 (Tartrazine) (conforming to 21 CFR 74.705)	1934–21–0	None
D-Gluconic acid, monosodium salt	527–07–1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034–85–2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Hydrogen peroxide	7722–84–1	When ready for use, the end-use concentration is not to exceed 1100 ppm
Hypochlorous acid	7790–92–3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Hypochlorous acid, calcium salt	7778–54–3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Hypochlorous acid, lithium salt	13840–33–0	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine and 30 ppm lithium
Hypochlorous acid, potassium salt	7778–66–7	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine

Pesticide Chemical	CAS Reg. No.	Limits
Hypochlorous acid, sodium salt	7681–52–9	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553–56–2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Lactic acid	50–21–5	None
Magnesium oxide	1309–48–4	None
Methylene blue	61–73–4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives	None	When ready for use, the end-use concentration of all naphthalene sulfonate chemicals in the solution is not to exceed 332 ppm naphthalene sulfonates
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives alkylated at 3% by weight with C_6-C_9 linear olefins	None	When ready for use, the end-use concentration of naphthalene sulfonate chemicals in the solution is not to exceed 332 ppm naphthalene sulfonates
Neodecanoic acid	26896–20–8	When ready for use, the end-use concentration is not to exceed 174 ppm
Nonanoic acid	112–05–0	When ready for use, the end-use concentration is not to exceed 90 ppm
α-(p-Nonylphenyl)-ω-hydroxypoly (oxyethylene) maximum average molecular weight (in amu), 748	None	None
α-(p-Nonylphenol)-ω-hydroxypoly (oxyethylene) average poly(oxyethylene) content 11 moles	None	None
α-(p-Nonylphenyl)-ω-hydroxypoly (oxyethylene) produced by the condensation of 1 mole p-nonylphenol with 9 to 12 moles ethylene oxide	None	None
α-(p-Nonylphenyl)-ω-hydroxypoly (oxyethylene), 9 to 13 moles ethylene oxide	None	None
Octadecanoic acid, calcium salt	1592–23–0	None
9-Octadecenoic acid (9Z)-, sulfonated	68988–76–1	When ready for use, the end-use concentration is not to exceed 312 ppm
9-Octadecenoic acid (9Z)-sulfonated, sodium salts	68443–05–0	When ready for use, the end-use concentration is not to exceed 200 ppm
1-Octanamine, N,N-dimethyl-	7378–99–6	When ready for use, the end-use concentration is not to exceed 113 ppm
1,2-Octanedisulfonic acid	113669–58–2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944–72–7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324–84–5	When ready for use, the end-use concentration is not to exceed 312 ppm
1-Octanesulfonic acid, 2-sulfino-	113652–56–5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124–07–2	When ready for use, the end-use concentration is not to exceed 234 ppm
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1900	9003–11–6	None
Oxirane, methyl-, polymer with oxirane, block, average molecular weight (in amu), 1900	106392–12–5	None
Oxirane, methyl-, polymer with oxirane, block, minimum average molecular weight (in amu), 2000	None	None
Oxirane, methyl-, polymer with oxirane, block, 27 to 31 moles of polyoxypropylene, average molecular weight (in amu) 2000	None	None
Oxychloro species (predominantly chlorite, chlorate and chlorine dioxide in an equilibrium mixture) generated either (i) by directly metering a concentrated chlorine dioxide solution prepared just prior to use, into potable water, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominately chlorite and chlorate) followed by dilution with potable water	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, ''Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)''

Pesticide Chemical	CAS Reg. No.	Limits
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, ''Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)''
2,4-Pentanediol, 2-methyl-	107–41–5	None
Peroxyacetic acid	79–21–0	When ready for use, the end-use concentration is not to exceed 315 ppm
Peroxyoctanoic acid	33734–57–5	When ready for use, the end-use concentration is not to exceed 122 ppm
Phenol, 4-chloro-2-(phenylmethyl)-	120–32–1	When ready for use, the end-use concentration is not to exceed 320 ppm
Phenol, 4-(1,1-dimethylpropyl)-	80–46–6	When ready for use, the end-use concentration is not to exceed 80 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809–21–4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664–38–2	None
Phosphoric acid, monosodium salt	7558–80–7	When ready for use, the end-use concentration is not to exceed 350 ppm
Phosphoric acid, trisodium salt	7601–54–9	When ready for use, the end-use concentration is not to exceed 5916 ppm
Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl) phenyl]-ω-hydroxy-, produced with one mole of the phenol and 4 to 14 moles ethylene oxide	None	None
Potassium bromide	7758–02–3	When ready for use, the end-use concentration of all bromide-producing chemicals in the solution is not to exceed 200 ppm total available halogen
Potassium iodide	7681–11–0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Propanoic acid	79–09–4	When ready for use, the end-use concentration is not to exceed 297 ppm
2,6-Pyridinedicarboxylic acid	499–83–2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Quaternary ammonium compounds, alkyl (C_{12}-C_{18}) benzyldimethyl, chlorides	8001–54–5	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, n-alkyl (C_{12}-C_{14}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, n-alkyl (C_{12}-C_{18}) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu) 384	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, di-n-Alkyl (C_8-C_{10}) dimethyl ammonium chloride, average molecular weight (in amu), 332 to 361	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 240 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Sodium-α-alkyl(C_{12}-C_{15})-ω-hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole	None	None
Sodium bromide	7647–15–6	When ready for use, the end-use concentration of all bromide-producing chemicals in the solution is not to exceed 200 ppm total available halogen
Sodium iodide	7681–82–5	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Sulfuric acid	7664–93–9	When ready for use, the end-use concentration is not to exceed 228 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151–21–3	None

Pesticide Chemical	CAS Reg. No.	Limits
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-	2782–57–2	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, potassium salt	2244–21–5	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893–78–9	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-trichloro-	87–90–1	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine, N,N′,N″-trichloro-2,4,6-triamino-	7673–09–8	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Xylenesulfonic acid, sodium salt	1300–72–7	When ready for use, the end-use concentration is not to exceed 62 ppm

[69 FR 23136, Apr. 28, 2004, as amended at 71 FR 30811, May 31, 2006; 71 FR 45423, Aug. 9, 2006; 71 FR 46125, Aug. 11, 2006; 72 FR 51186, Sept. 6, 2007; 73 FR 37858, July 2, 2008; 73 FR 49107, Aug. 20, 2008; 73 FR 53725, Sept. 17, 2008; 74 FR 27454, June 10, 2009]

EFFECTIVE DATE NOTE: At 71 FR 45423, Aug. 9, 2006, § 180.940 was amended as follows, effective Aug. 9, 2008. At 73 FR 45312 and 45316, Aug. 4, 2008, the effective date was delayed until Aug. 9, 2009:

1. The table in paragraph (a) is amended by removing the following entries:

i. α-Alkyl(C_{10}-C_{14})-ω- hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837.

ii. α-Alkyl(C_{12}-C_{18})-ω hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120.

3. The table in paragraph (c) is amended by removing the following entries:

i. α-Alkyl(C_{10}-C_{14})-ω-hydroxypoly (oxyethylene) poly (oxypropylene) average molecular weight (in amu), 768 to 837.

ii. α-Alkyl(C_{11}-C_{15})-ω-hydroxypoly (oxyethylene) with ethylene oxide content 9 to 13 moles.

iv. α-Alkyl(C_{12}-C_{18})-ω-hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120.

vii. Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives.

viii. Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives alkylated at 3% by weight with C_6-C_9 linear olefins.

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

Unless specifically excluded, residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices.

(a) *Commonly consumed food commodities.* Commonly consumed food commodities means foods that are commonly consumed for their nutrient properties. The term commonly consumed food commodities shall only apply to food commodities (whether a raw agricultural commodity or a processed commodity) in the form the commodity is sold or distributed to the public for consumption.

(1) Included within the term commonly consumed food commodities are:

(i) Sugars such as sucrose, lactose, dextrose and fructose, and invert sugar and syrup.

(ii) Spices such as cinnamon, cloves, and red pepper.

(iii) Herbs such as basil, anise, or fenugreek.

(2) Excluded from the term commonly consumed food commodities are:

(i) Any food commodity that is adulterated under 21 U.S.C. 342.

(ii) Both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat.

(iii) Alcoholic beverages.

(iv) Dietary supplements.

(b) *Animal feed items.* Animal feed items means meat meal and all items derived from field crops that are fed to livestock excluding both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat. Meat meal is an animal feed composed of dried animal fat and protein that has been sterilized. Other than meat meal, the term animal feed item does not extend to any item designed to be fed to animals that contains, to any extent, components of animals. Included within the term animal feed items are:

(1) The hulls and shells of the commodities specified in paragraph (a)(2)(ii) of this section, and cocoa bean.

(2) Bird feed such as canary seed.

(3) Any feed component of a medicated feed meeting the definition of an animal feed item.

(c) *Edible fats and oils.* Edible fats and oils means all edible (food or feed) fats and oils, derived from either plants or animals, whether or not commonly consumed, including products derived from hydrogenating (food or feed) oils, or liquefying (food or feed) fats.

(1) Included within the term edible fats and oils are oils (such as soybean oil) that are derived from the commodities specified in paragraph (a)(2)(ii) of this section when such oils are highly refined via a solvent extraction procedure.

(2) Excluded from the term edible fats and oils are plant oils used in the pesticide chemical formulation specifically to impart their characteristic fragrance and/or flavoring.

(d) [Reserved]

(e) *Specific chemical substances.* Residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices.

Chemical	CAS No.
Acetic acid, sodium salt	127–09–3
Alpha-cyclodextrin	10016–20–3
Amylopectin, acid-hydrolyzed, 1-octenylbutanedioate	113894–85–2
Amylopectin, hydrogen 1-octadecenylbutanedioate	125109–81–1
Animal glue	None
Ascorbic acid (vitamin C)	50–81–7
Beeswax	8012–89–3
Benzoic acid, sodium salt	532–32–1
Beta-cyclodextrin	7585–39–9
Carbonic acid, monopotassium salt	298–14–6
Carbonic acid, monosodium salt (sodium bicarbonate)	144–55–8
Carnauba wax	8015–86–9
Carob gum (locust bean gum)	9000–40–2
Castor oil	8001–79–4
Castor oil, hydrogenated	8001–78–3
Cellulose	9004–34–6
Cellulose acetate	9004–35–7
Cellulose, carboxy methyl ether, sodium salt	9004–32–4
Cellulose, 2-hydroxyethyl ether	9004–62–0
Cellulose, 2-hydroxypropyl ether	9004–64–2
Cellulose, 2-hydroxypropyl methyl ether	9004–65–3
Cellulose, methyl ether	9004–67–5
Cellulose, mixture with cellulose carboxymethyl ether, sodium salt	51395–75–6
Cellulose, pulp	65996–61–4
Cellulose, regenerated	68442–85–3
Citric acid	77–92–9
Citric acid, 2-(acetyloxy)-, tributyl ester	77–90–7
Citric acid, calcium salt	7693–13–2
Citric acid, calcium salt (2:3)	813–94–5
Citric acid, dipotassium salt	3609–96–9
Citric acid, disodium salt	144–33–2
Citric acid, monohydrate	5949–29–1
Citric acid, monopotassium salt	866–83–1
Citric acid, monosodium salt	18996–35–5
Citric acid, potassium salt	7778–49–6
Citric acid, triethyl ester	77–93–0
Citric acid, tripotassium salt	866–84–2
Citric acid, tripotassium salt, monohydrate	6100–05–6
Citric acid, sodium salt	994–36–5
Citric acid, trisodium salt	68–04–2
Citric acid, trisodium salt, dihydrate	6132–04–3
Citric acid, trisodium salt, pentahydrate	6858–44–2
Coffee grounds	68916–18–7
Dextrins	9004–53–9
1,3-Dioxolan-2-one, 4-methyl-(propylene carbonate)	108–32–7
Fumaric acid	110–17–8
Gamma-cyclodextrin	17465–86–0
Gellan gum	71010–52–1
D-Glucitol (sorbitol)	50–70–4
Glycerol (glycerin) (1,2,3-propanetriol)	56–81–5
Guar gum	9000–30–0
Humic acid	1413–93–6
Humic acid, potassium salt	68514–28–3
Humic acid, sodium salt	68131–04–4
Lactic acid, n-butyl ester	138–22–7
Lactic acid, n-butyl ester, (S)	34451–19–9
Lactic acid, ethyl ester	97–64–3
Lactic acid, ethyl ester,(S)	687–47–8
Lanolin	8006–54–0
Lecithins	8002–43–5
Lecithins, soya	8030–76–0
Licorice Extract	68916–91–6
Maltodextrin	9050–36–6
Paper	None

Chemical	CAS No.
Potassium chloride	7447–40–7
2-Propanol (isopropyl alcohol)	67–63–0
Red cabbage color, expressed from edible red cabbage heads via a pressing process using only acidified water	None
Silica, amorphous, fumed (crystalline free)	112945–52–5
Silica, amorphous, precipitated and gel	7699–41–4
Silica gel	63231–67–4
Silica gel, precipitated, crystalline-free	112926–00–8
Silica, hydrate	10279–57–9
Silica, vitreous	60676–86–0
Soap (The water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid)	None
Sorbic acid, potassium salt	24634–61–5
Soapbark (Quillaja saponin)	1393–03–9
Sodium alginate	9005–38–3
Sodium chloride	7647–14–5
Syrups, hydrolyzed starch, hydrogenated	68425–17–2
Ultramarine blue (C.I. Pigment Blue 29)	57455–37–5
Urea	57–13–6
Vanillin	121–33–5
Xanthan gum	11138–66–2

[67 FR 36537, May 24, 2002]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.950, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

Residues resulting from the use of the following substances, that meet the definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR 723.250, as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices.

Polymer	CAS No.
Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly (oxy-1,2-ethanediyl) minimum number average molecular weight (in amu), 15,000	137091–12–4
Acetic acid ethenyl ester, polymer with 1-ethenyl-2-pyrrolidinone	25086–89–9
Acetic acid ethenyl ester, polymer with sodium 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonate (1:1), hydrolyzed, minimum number average molecular weight (in amu), 61,000	924892–37–5
Acrylic acid, polymerized, and its ethyl and methyl esters	None
Acrylic acid-sodium acrylate-sodium-2-methylpropanesulfonate copolymer, minimum average molecular weight (in amu), 4,500	97953–25–8
Acrylic acid-stearyl methacrylate copolymer, minimum number average molecular weight (in amu), 2,500	27756–15–6
Acrylic acid, styrene, α-methyl styrene copolymer, ammonium salt, minimum number average molecular weight (in amu), 1,250	89678–90–0
Acrylic acid terpolymer, partial sodium salt, minimum number average molecular weight (in amu), 2,400	151006–66–5
Acrylic polymers composed of one or more of the following monomers: Acrylic acid, methyl acrylate, ethyl acrylate, butyl acrylate, hydroxyethyl acrylate, hydroxypropyl acrylate, hydroxybutyl acrylate, carboxyethyl acrylate, methacrylic acid, methyl methacrylate, ethyl methacrylate, butyl methacrylate, isobutyl methacrylate, hydroxyethyl methacrylate, hydroxypropyl methacrylate, hydroxybutyl methacrylate, lauryl methacrylate, and stearyl methacrylate; with none and/or one or more of the following monomers: Acrylamide, N-methyl acrylamide, N,N-dimethyl acrylamide, N-octylacrylamide, maleic anhydride, maleic acid, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine, and/or triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1,200	None
Acrylonitrile-butadiene copolymer conforming to 21 CFR 180.22, minimum average molecular weight (in amu), 1,000	9003–18–3
Acrylonitrile-styrene-hydroxypropyl methacrylate copolymer, minimum number average molecular weight (in amu), 447,000	None
α-alkyl (C_{12}–C_{15}) - ω-hydroxypol-y(oxypropylene)poly(oxyethylene)copolymers (where the poly(oxypropylene) content is 3–60 moles and the poly(oxyethylene) content is 5–80 moles), the resulting ethoxylated propoxylated (C_{12}–C_{15}) alcohols having a minimum molecular weight (in amu), 1,500	68551–13–3
Alkyl (C_{12}–C_{20}) methacrylate-methacrylic acid copolymer, minimum molecular weight (in amu), 11,900	None
2H-Azepin-2-one, 1-ethenylhexahydro-, homopolymer	25189–83–7
1,3 Benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol, minimum number average molecular weight (in amu), 2,580	212842–88–1

Polymer	CAS No.
3,5-Bis(6-isocyanatohexyl)-2H-1,3,5-oxadiazine-2,4,6-(3H,5H)-trione, polymer with diethylenetriamine, minimum number average molecular weight (in amu), 1,000,000	87823–33–4
Butadiene-styrene copolymer	None
1,4-Butanediol-methylenebis(4-phenylisocyanate)-poly(tetramethylene glycol) copolymer, minimum molecular weight (in amu) 158,000	9018– 04–6
Butene, homopolymer	9003–29–6
2-butenedioic acid (2Z)-, monobutyl ester, polymer with methoxyethene, sodium salt, minimum number average molecular weight (in amu), 18,200	205193–99–3
2-Butenedioic acid (Z)-, polymer with ethenol and ethenyl acetate, sodium salt, minimum number average molecular weight (in amu), 75,000	139871–83–3
Butyl acrylate-vinyl acetate-acrylic acid copolymer, minimum number average molecular weight (in amu), 18,000	65405–40–5
Castor oil, ethoxylated, oleate, minimum number average molecular weight (in amu) 2,000	220037–02–5
Castor oil, polyoxyethylated; the poly(oxyethylene) content averages 5–54 moles	None
Chlorinated polyethylene	64754–90–1
Cross-linked nylon-type polymer formed by the reaction of a mixture of sebacoyl chloride and polymethylene polyphenylisocycanate with a mixture of ethylenediamine and diethylenetriamine	None
Cross-linked polyurea-type encapsulating polymer	None
Dimethylpolysiloxane minimum number average molecular weight (in amu), 6,800	63148–62–9
Dimethyl silicone polymer with silica, minimum number average molecular weight (in amu), 1,100,000	67762–90–7
α-(o,p-Dinonylphenyl)-ω-hydroxypoly(oxyethylene) produced by condensation of 1 mole of dinonylphenol (nonyl group is a propylene trimer isomer) with an average of 140-160 moles of ethylene oxide	9014–93–1
Docosyl methacrylate-acrylic acid copolymer, or docosyl methacrylate-octadecyl methacrylate-acrylic acid copolymer, minimum number average molecular weight (in amu), 3,000	None
1,12-Dodecanediol dimethacrylate polymer, minimum molecular weight (in amu), 100,000	None
α-(p-Dodecylphenyl)-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 30-70 moles of ethylene oxide	9014–92–0 26401–47–8
1, 2-Ethanediamine, polymer with methyl oxirane and oxirane, minimum number average molecular weight (in amu), 1,100	26316–40–5
Ethylene glycol dimethyacrylate-lauryl methacrylate copolymer, minimum molecular weight (in amu), 100,000	None
Ethylene glycol dimethacrylate polymer, minimum molecular weight (in amu), 100,000	None
Formaldehyde, polymer with α-[bis(1-phenylethyl)phenyl]-ω-hydroxypoly(oxy-1,2-ethanediyl), number average molecular weight (in amu), 1,803	157291–93–5
Formaldehyde, polymer with 2-methyloxirane and 4-nonylphenol, minimum number average molecular weight (in amu), 4,000	37523–33–4
Fumaric acid-isophthalic acid-styrene-ethylene/propylene glycol copolymer, minimum average molecular weight (in amu), 1×10^{18}	None
Hexadecyl acrylate-acrylic acid copolymer, hexadecyl acrylate-butyl acrylate-acrylic acid copolymer, or hexadecyl acrylate-dodecyl acrylate-acrylic acid copolymer, minimum number average molecular weight (in amu), 3,000	None
Hexamethyl disilizane, reaction product with silica, minimum number average molecular weight (in amu), 645,000	68909–20–6
1,6-Hexanediol dimethyacrylate polymer, minimum molecular weight (in amu), 100,000	None
α-Hydro-ω-hydroxy-poly(oxyethylene) C8 alkyl ether citrates, poly(oxyethylene) content is 4–12 moles, minimum number average molecular weight (in amu) 1,300.	330977–00–9
α-Hydro-ω-hydroxy-poly(oxyethylene) C10–C16-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles, minimum number average molecular weight (in amu) 1,100.	330985–58–5
α-Hydro-ω-hydroxy-poly(oxyethylene) C16–C18-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles, minimum number average molecular weight (in amu) 1,300.	330985–61–0
α-Hydro-ω-hydroxypoly(oxyethylene), minimum molecular weight (in amu), 100,000	None
α-Hydro-ω-hydroxypoly(oxyethylene)poly (oxypropylene) poly(oxyethylene) block copolymer; the minimum poly(oxypropylene) content is 27 moles and the minimum molecular weight (in amu) is 1,900	None
α-Hydro-ω-hydroxypoly(oxypropylene); minimum molecular weight (in amu) 2,000	None

Polymer	CAS No.
12-Hydroxystearic acid-polyethylene glycol copolymer, minimum number average molecular weight (in amu), 3,690	70142–34–6
Isodecyl alcohol ethoxylated (2–8 moles) polymer with chloromethyl oxirane, minimum number average molecular weight (in amu) 2,500	None
Lauryl methacrylate-1,6-hexanediol dimethacrylate copolymer, minimum molecular weight (in amu), 100,000	None
Maleic acid-butadiene copolymer	None
Maleic acid monobutyl ester-vinyl methyl ether copolymer, minimum average molecular weight (in amu), 52,000	25119–68–0
Maleic acid monoethyl ester-vinyl methyl ether copolymer, minimum average molecular weight (in amu), 46,000	25087–06–3
Maleic acid monoisopropyl ester-vinyl methyl ether copolymer, minimum average molecular weight (in amu), 49,000	31307–95–6
Maleic anhydride-diisobutylene copolymer, sodium salt, minimum number average molecular weight (in amu) 5,0007–18,000	37199–81–8
Maleic anhydride-methylstyrene copolymer sodium salt, minimum number average molecular weight (in amu), 15,000	60092–15–1
Maleic anhydride-methyl vinyl ether, copolymer, average molecular weight (in amu), 250,000	None
Methacrylic acid-methyl methacrylate-polyethylene glycol methyl ether methacrylate copolymer, minimum number averge molecular weight (in amu), 3,700	100934–04–1
Methacrylic copolymer, minimum number average molecular weight (in amu), 15,000	63150–03–8
Methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer,) minimum number average molecular weight (in amu), 2,730	119724–54–8
Methyl methacrylate-2-sulfoethyl methacrylate-dimethylaminoethylmethacrylate-glycidyl methacrylate-styrene-2-ethylhexyl acrylate graft copolymer, minimum average molecular weight (in amu), 9,600	None
Methyl vinyl ether-maleic acid copolymer), minimum number average molecular weight (in amu), 75,000	25153–40–6
Methyl vinyl ether-maleic acid copolymer, calcium sodium salt, minimum number average molecular weight (in amu), 900,000	62386–95–2
Monophosphate ester of the block copolymer α-hydro-ω-hydroxypoly(oxyethylene) poly(oxypropylene) poly(oxyethylene); the poly(oxypropylene) content averages 37–41 moles, average molecular weight (in amu), 8,000	None
α-(p-Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 30 moles	None
α-(p-Nonylphenyl)-ω-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 30-90 moles of ethylene oxide	None
α-(*p*-Nonylphenyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene); polyoxypropylene content of 10–60 moles; polyoxyethylene content of 10–80 moles; molecular weight (in amu), 1,200–7,100.	None
α-(*p*-Nonylphenyl)poly(oxypropylene) block polymer with poly(oxyethylene); poly oxyethylene content 30 to 90 moles; molecular weight (in amu) averages 3,000	None
Octadecanoic acid, 12-hydroxy-, homopolymer, octadecanoate minimum number average molecular weight (in amu), 1,370	58128–22–6),
α-cis-9-Octadecenyl-ω-hydroxypoly(oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages 20 moles	None
Octadecyl acrylate-acrylic acid copolymer, octadecyl acrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-butyl acrylate-acrylic acid copolymer, octadecyl methacrylate-hexyl acrylate-acrylic acid copolymer, octadecyl methacrylate-dodecyl acrylate-acrylic acid copolymer, or octadecyl methacrylate-dodecyl methacrylate-acrylic acid copolymer, minimum number average molecular weight (in amu) 3,000	None
Oleic acid diester of α-hydro-ω-hydroxypoly(oxyethylene); the poly(oxyethylene), average molecular weight (in amu), 2,300	None
2-oxepanone, homopolymer, minimum number average molecular weight (in amu) 52,000	24980–41–4
Oxirane, decyl-, reaction products with polyethylene-polypropylene glycol ether with trimethylolpropane (3:1)	903890–89–1
Oxirane, hexadecyl-, reaction products with polyethylene-polypropylene glycol ether with trimethylolpropane (3:1)	893427–80–0
Oxirane, methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl) – 1,3 - propanediol (3:1), reaction products with tetradecyloxirane	903890–90–4

Polymer	CAS No.
Oxirane, methyl-, polymer with oxirane, mono[2-(2-butoxyethoxy) ethyl] ether, minimum number average molecular weight (in amu), 2,500	85637–75–8
Oxirane, methyl-, polymer with Oxirane, Monobutyl Ether	9038–95–3
Oxirane, 2-methyl-, polymer with oxirane, minimum number average molecular weight (in amu), 1,100	9003–11–6
Oxirane, 2-methyl-, polymer with oxirane, mono [2-[2-(2-butoxymethylethoxy)methylethoxy]methylethyl] ether, minimum number average molecular weight (in amu), 3,000	926031–36–9
Polyamide polymer derived from sebacic acid, vegetable oil acids with or without dimerization, terephthalic acid and/or ethylenediamine	None
Polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer, minimum number average molecular weight (in amu), 2,960	68650–28–2
Polyethylene, oxidized, minimum number average molecular weight (in amu), 1,200	None
Polymethylene polyphenylisocyanate, polymer with ethylene diamine, diethylene triamine and sebacoyl chloride, cross-linked; minimum number average molecular weight (in amu), 100,000	None
Polyoxyethylated primary amine (C_{14}–C_{18}); the fatty amine is derived from an animal source and contains 3% water; the poly(oxyethylene) content averages 20 moles	None
Polyoxyethylated sorbitol fatty acid esters; the polyoxyethylated sorbitol solution containing 15% water is reacted with fatty acids limited to C_{12}, C_{14}, C_{16}, and C_{18}, containing minor amounts of associated fatty acids; the poly(oxyethylene) content averages 30 moles.	None
Polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanoic and/or alkenoic fatty acids C_8 through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight (in amu), 1,300	None
Poly(oxyethylene/oxypropylene) monoalkyl (C_6–C_{10}) ether sodium fumarate adduct, minimum number average molecular weight (in amu), 1,900	102900–02–7
Polyoxymethylene copolymer, minimum number average molecular weight (in amu), 15,000	None
Poly(oxypropylene) block polymer with poly(oxyethylene), molecular weight (in amu), 1,800–16,000	None
Poly(phenylhexylurea), cross-linked, minimum average molecular weight (in amu), 36,000	None

Polymer	CAS No.
Polypropylene	9003–07–0
Polystyrene, minimum number average molecular weight (in amu), 50,000	9003–53–6
Polytetrafluoroethylene	9002–84–0
Polyvinyl acetate, copolymer with maleic anhydride, partially hydrolyzed, sodium salt, minimum number average molecular weight (in amu), 53,000	None
Polyvinylpyrrolidone butylated polymer, minimum number average molecular weight (in amu), 9,500	26160–96–3
Polyvinyl acetate, minimum molecular weight (in amu), 2,000	None
Polyvinyl acetate—polyvinyl alcohol copolymer, minimum number average molecular weight (in amu), 50,000	25213–24–5
Polyvinyl alcohol	9002–89–5
Polyvinyl chloride	None
Polyvinyl chloride, minimum number average molecular weight (in amu), 29,000	9002–86–2
Poly(vinylpyrrolidone), minimum number average molecular weight (in amu), 4,000	9003–39–8
Poly(vinylpyrrolidone-1-eicosene), minimum average molecular weight (in amu), 3,000	28211–18–9
Poly(vinylpyrrolidone-1-hexadecene), minimum average molecular weight (in amu), 4,700	63231–81–2
1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, monosodium salt, polymer with ethenol and ethenyl acetate, minimum number average molecular weight (in amu) 50,000	107568–12–7
2-Propene-1-sulfonic acid sodium salt, polymer with ethenol and ethenyl acetate, number average molecular weight (in amu) 6,000–12,000	None
2-Propenoic acid, butyl ester, polymer with ethyl 2-propenoate and N-(hydroxymethyl)-2-propenamide, minimum number average molecular weight (in amu), 30,000	33438–19–6
2-Propenoic acid, methyl ester, polymer with ethenyl acetate, hydrolyzed, sodium salts.	886993–11–9
2-Propenoic acid, 2-Methyl-, Polymer with Butyl 2-Propenoate, Methyl 2-Methyl-2-Propenoate, Methyl 2-Propenoate and 2-Propenoic Acid, graft, Compound with 2-Amino-2-Methyl-1-Propanol	153163–36–1
2-Propenoic Acid, 2-Methyl-, Polymer with Ethenylbenzene, 2-Ethylhexyl 2-Propenoate, 2-Hydroxyethyl 2-Propenoate, N-(Hydroxymethyl) -2-Methyl-2-Propenamide and Methyl 2-Methyl-2-Propenoate, Ammonium Salt	146753–99–3

Polymer	CAS No.
2-Propenoic, 2-methyl-, polymers with ethyl acrylate and polyethylene glycol methylacrylate C_{18-22} alkyl ethers	888969–14–0
2-Propenoic acid, 2-hydroxyethyl ester, polymer with α-[4-(ethenyloxy)butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl), minimum number average molecular weight (in amu), 17,000	1007234–89–0
2-Propenoic acid, monoester with 1,2-propanediol, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 2,5-furandione, minimum number average molecular weight (in amu), 25,000	955015–23–3
2-Propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 2,5-furandione, sodium salt, minimum number average molecular weight (in amu), 25,000	251479–97–7
2-Propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1,2-propanediol mono-2-propenoate, potassium sodium salt, minimum number average molecular weight (in amu), 16,000	518026–64–7
2-Propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1, 2-ethanediyl), sodium salt, minimum number average molecular weight (in amu), 24,000	250591–84–5
2-Propenoic acid, polymer with 2-propenamide, sodium salt, minimum number average molecular weight (in amu), 18,000	25085–02–3
2-Propenoic acid, sodium salt, polymer with 2-propenamide, minimum number average molecular weight (in amu), 18,000	25987–30–8
Silane, dichloromethyl- reaction product with silica minimum number average molecular weight (in amu), 3,340,000	68611–44–9
Silane, trimethoxy[3-(oxiranylmethoxy)propyl]-, hydrolysis products with silica, minimum number average molecular weight (in amu), 640,000	68584–82–7
Sodium polyflavinoidsulfonate, consisting chiefly of the copolymer of catechin and leucocyanidin	None
Soybean oil, ethoxylated; the poly(oxyethylene) content averages 10 moles or greater	61791–23–9
Starch, oxidized, polymers with Bu acrylate, tert-Bu acrylate and styrene, minimum number average molecular weight (in amu), 10,000	204142–80–3
Stearyl methacrylate-1,6-hexanediol dimethacrylate copolymer, minimum molecular weight (in amu), 100,000	None
Styrene, copolymers with acrylic acid and/or methacrylic acid, with none and/or one or more of the following monomers: Acrylamidopropyl methyl sulfonic acid, methallyl sulfonic acid, 3-sulfopropyl acrylate, 3-sulfopropyl methacrylate, hydroxypropyl methacrylate, hydroxypropyl acrylate, hydroxyethyl methacrylate, and/or hydroxyethyl acrylate; and its sodium, potassium, ammonium, monoethanolamine, and triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1,200	None
Styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer, minimum number average molecular weight (in amu), 4,200	30795–23–4
Styrene-2-ethylhexyl acrylate-glycidyl methacrylate-2-acrylamido-2-methylpropanesulfonic acid graft copolymer, minimum number average molecular weight (in amu), 12,500	None
Styrene-maleic anhydride copolymer	None
Styrene-maleic anhydride copolymer, ester derivative	None
Tetradecyl acrylate-acrylic acid copolymer, minimum number average molecular weight (in amu), 3,000	None
Tetraethoxysilane, polymer with hexamethyldisiloxane, minimum number average molecular weight (in amu), 6,500	104133–09–7
α-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-(1,1,3,3-tetramethylbutyl)phenol with a range of 30-70 moles of ethylene oxide	9036–19–5 9002–93–1
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl] poly(oxypropylene) block polymer with poly(oxyethylene); the poly(oxypropylene) content averages 25 moles, the poly(oxyethylene) content averages 40 moles, the molecular weight (in amu) averages 3,400	None
α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxy poly(oxyethylene) poly(oxypropylene) copolymer, the poly(oxypropylene) content averages 2–8 moles, the poly(oxyethylene) content averages 16–30moles, average molecular weight (in amu), 1,500	None
Urea-formaldehyde copolymer, minimum average molecular weight (in amu), 30,000	9011–05–6
Vinyl acetate-allyl acetate-monomethyl maleate copolymer, minimum average molecular weight (in amu), 20,000	None
Vinyl acetate-ethylene copolymer, minimum number average molecular weight (in amu), 69,000	24937–78–8

Polymer	CAS No.
Vinyl acetate polymer with none and/or one or more of the following monomers: Ethylene, propylene, N-methyl acrylamide, acrylamide, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate, maleic anhydride, maleic acid, octyl acrylate, butyl acrylate, ethyl acrylate, methyl acrylate, acrylic acid, octyl methacrylate, butyl methacrylate, ethyl methacrylate, methyl methacrylate, methacrylic acid, carboxyethyl acrylate, and diallyl phthalate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine and/or triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1,200	None
Vinyl acetate-vinyl alcohol-alkyl lactone copolymer, minimum number average molecular weight (in amu), 40,000; minimum viscosity of 18 centipoise	None
Vinyl alcohol-disodium itaconate copolymer, minimum average molecular weight (in amu), 50,290	None
Vinyl alcohol-vinyl acetate copolymer, benzaldehyde-o-sodium sulfonate condensate, minimum number average molecular weight (in amu), 20,000	None
Vinyl alcohol-vinyl acetate-monomethyl maleate, sodium salt-maleic acid, disodium salt-γ-butyrolactone acetic acid, sodium salt copolymer, minimum number average molecular weight (in amu), 20,000	None
Vinyl chloride-vinyl acetate copolymers	None
Vinyl pyrrolidone-acrylic acid copolymer, minimum number average molecular weight (in amu), 6,000	28062–44–4
Vinyl pyrrolidone-dimethylaminoethylmethacrylate copolymer, minimum number average molecular weight (in amu), 20,000	30581–59–0
Vinyl pyrrolidone-styrene copolymer	25086–29–7

[67 FR 36528, May 24, 2002]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 180.960, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 180.1011 Viable spores of the microorganism *Bacillus thuringiensis* Berliner; exemption from the requirement of a tolerance.

(a) For the purposes of this section the microbial insecticide for which exemption from the requirement of a tolerance is being established shall have the following specifications:

(1) The microorganism shall be an authentic strain of *Bacillus thuringiensis* Berliner conforming to the morphological and biochemical characteristics of *Bacillus thuringiensis* as described in Bergey's Manual of Determinative Bacteriology, Eighth Edition.

(2) Spore preparations of *Bacillus thuringiensis* Berliner shall be produced by pure culture fermentation procedures with adequate control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.

(3) Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory test mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

(4) Spore preparations shall be free of the *Bacillus thuringiensis* β-exotoxin when tested with the fly larvae toxicity test (''Microbial Control of Insects and Mites,'' R.P.M. Bond et al., p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain which does not produce β-exotoxin under standard manufacturing conditions or by periodically determining that β-exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.

(b) Exemption from the requirement of a tolerance is established for residues of the microbial insecticide *Bacillus thuringiensis* Berliner, as specified in paragraph (a) of this section, in or on honey and honeycomb and all other raw agricultural commodities when it is applied either to growing crops, or when it is applied after harvest in accordance with good agricultural practices.

[36 FR 22540, Nov. 25, 1971, as amended at 38 FR 19045, July 17, 1973; 42 FR 28540, June 3, 1977; 45 FR 43721, June 30, 1980; 45 FR 56347, Aug. 25, 1980; 74 FR 26533, June 3, 2009]

§ 180.1016 Ethylene; exemption from the requirement of a tolerance.

Ethylene is exempted from the requirement of a tolerance for residues when:

(a) For all food commodities, it is used as a plant regulator on plants, seeds, or cuttings and on all food commodities after harvest and when applied in accordance with good agricultural practices.

(b) Injected into the soil to cause premature germination of witchweed in bean (lima and string), cabbage, cantaloupe, collard, corn, cotton, cucumber, eggplant, okra, onion, pasture grass, pea (field and sweet), peanut, pepper, potato, sweet potato, sorghum, soybean, squash, tomato, turnip, and watermelon fields as part of the U.S. Department of Agriculture witchweed control program.

[39 FR 33315, Sept. 17, 1974, as amended at 40 FR 19477, May 5, 1975; 64 FR 31505, June 11, 1999]

§ 180.1017 Diatomaceous earth; exemption from the requirement of a tolerance.

(a) Diatomaceous earth is exempted from the requirement of a tolerance for residues when used in accordance with good agricultural practice in pesticide formulations applied to growing crops, to food commodities after harvest, and to animals.

(b) Diatomaceous earth may be safely used in accordance with the following conditions. Application shall be limited solely to spot and/or crack and crevice treatments in food or feed processing and food or feed storage areas in accordane with the precribed conditions:

(1) It is used or intended for use for control of insects in food or feed processing and food or feed storage areas: *Provided*, That the food or feed is removed or covered prior to such use.

(2) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[65 FR 33716, May 24, 2000]

§ 180.1019 Sulfuric acid; exemption from the requirement of a tolerance.

(a) Residues of sulfuric acid are exempted from the requirement of a tolerance when used in accordance with good agricultural practice when used as a herbicide in the production of garlic and onions, and as a potato vine dessicant in the production of potatoes.

(b) Residues of sulfuric acid are exempted from the requirement of a tolerance in cattle, meat; goat, meat; hog, meat; horse, meat; sheep, meat; poultry, fat; poultry, meat; poultry, meat, byproducts; egg; milk; fish, shellfish, and irrigated crops when it results from the use of sulfuric acid as an inert ingredient in a pesticide product used in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated. The sulfuric acid is not to exceed 10% of the pesticide formulation (non-aerosol formulations only).

[69 FR 40787, July 7, 2004, as amended by 74 FR 26533, June 3, 2009]

§ 180.1020 Sodium chlorate; exemption from the requirement of a tolerance.

(a) Sodium chlorate is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities when used as a defoliant, desiccant, or fungicide in accordance with good agricultural practice.

COMMODITY	
Bean, dry, seed	Guar, seed
Corn, field, forage	Pepper, chili
Corn, field, grain	Potato
Corn, field, stover	Rice, grain
Corn, pop, grain	Rice, straw
Corn, pop, stover	Safflower, seed
Cotton, undelinted seed	Sorghum, forage
Cowpea, forage	Sorghum, grain, grain
Cowpea, hay	Sorghum, grain, stover
Cowpea, seed	Soybean, forage
Flax, seed	Soybean, hay
Flax, straw	Soybean, seed
Grain, aspirated fractions	Sunflower, seed

(b) A time-limited exemption from the requirement of a tolerance is established for residues of the defoliant/desiccant in connection with use of the pesticide under section 18 emergency

exemptions granted by EPA. The exemption will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Wheat, forage	NA	12/31/06
Wheat, grain	NA	12/31/06
Wheat, hay	NA	12/31/06
Wheat, straw	NA	12/31/06

[54 FR 9800, Mar. 8, 1989, as amended at 60 FR 4862, Jan. 25, 1995; 62 FR 63863, Dec. 3, 1997; 63 FR 35846, July 1, 1998; 64 FR 42849, Aug. 6, 1999; 65 FR 48639, Aug. 9, 2000; 68 FR 2247, Jan. 16, 2003; 69 FR 71717, Dec. 10, 2004; 74 FR 26533, June 3, 2009]

§ 180.1021 Copper; exemption from the requirement of a tolerance.

(a) Copper is exempted from the requirement of a tolerance in cattle, meat; goat, meat; hog, meat; horse, meat; sheep, meat; milk, poultry, fat; poultry, meat; poultry, meat byproducts; egg, fish, shellfish, and irrigated crops when it results from the use of:

(1) Copper sulfate as an algicide or herbicide in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated.

(2) Basic copper carbonate (malachite) as an algicide or herbicide in impounded and stagnant bodies of water

(3) Copper triethanolamine and copper monoethanolamine as an algicide or herbicide in fish hatcheries, lakes, ponds, and reservoirs

(4) Cuprous oxide bearing antifouling coatings for control of algae or other coatings for control of algae or other organisms on submerged concrete or other (irrigation) structures.

(b) The following copper compounds are exempt from the requirement of a tolerance when applied (primarily) as a fungicide to growing crops using good agricultural practices: Bordeaux mixture, basic copper carbonate (malachite) (CAS Reg. No. 1184–64–1), copper ethylenediamine complex, copper hydroxide (CAS Reg. No. 20427–59–2), copper lime mixtures, copper linoleate (CAS Reg. No. 7721–15–5), copper octanoate (CAS Reg. No. 20543–04–8), copper oleate (CAS Reg. No. 10402–16–1), copper oxychloride (CAS Reg. No. 1332–40–7), copper sulfate basic (CAS Reg. No. 1344–73–6), cupric oxide (CAS Reg. No. 1317–38–0), and cuprous oxide (CAS Reg. No. 1317–19–1).

(c) Copper sulfate pentahydrate (CAS Reg. No. 7758–99–8) is exempt from the requirement of a tolerance when applied as a fungicide to growing crops or to raw agricultural commodities after harvest, and as a bactericide/fungicide in or on meat, fat and meat by-products of cattle, sheep, hogs, goats, horses and poultry, milk and eggs when applied as a bactericide/fungicide to animal premises and bedding.

(d) Copper (II) hydroxide (CAS Reg. No. 20427–59–2) is exempt from the requirement of a tolerance when applied to growing crops or to raw agricultural commodities as an inert ingredient (for pH control) in pesticide products.

[65 FR 68912, Nov. 15, 2000, as amended at 69 FR 4069, Jan. 28, 2004; 71 FR 46110, Aug. 11, 2006; 74 FR 26534, June 3, 2009]

§ 180.1022 Iodine-detergent complex; exemption from the requirement of a tolerance.

The aqueous solution of hydriodic acid and elemental iodine, including one or both of the surfactants (a) polyoxypropylene-polyoxyethylene glycol nomionic block polymers (minimum average molecular weight 1,900) and (b) α-(p- nonylphenyl)-*omega*-hydroxypoly (oxyethylene) having a maximum average molecular weight of 748 and in which the nonyl group is a propylene trimer isomer, is exempted from the requirement of a tolerance for residues in egg, and poultry, fat; poultry, meat; poultry, meat byproducts when used as a sanitizer in poultry drinking water.

[74 FR 26534, June 3, 2009]

§ 180.1023 Propanoic acid; exemptions from the requirement of a tolerance.

(a) Postharvest application of propanoic acid or a mixture of methylene bispropionate and oxy(bismethylene) bisproprionate when used as a fungicide is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities: Alfalfa, forage; alfalfa, hay; alfalfa, seed; barley, grain; Bermudagrass, forage; Bermudagrass, hay; bluegrass, forage; bluegrass, hay;

bromegrass, forage; bromegrass, hay; clover, forage; clover, hay; corn, field, grain; corn, pop, grain; cowpea, hay; fescue, forage; fescue, hay; lespedeza, forage; lespedeza, hay; lupin; oat, grain; orchardgrass, forage; orchardgrass, hay; peanut, hay; pea, field, hay; ryegrass, Italian, hay; sorghum, grain, grain; soybean, hay; sudangrass, forage; sudangrass, hay; timothy, forage; timothy, hay; vetch, forage; vetch, hay; and wheat, grain.

(b) Propanoic acid is exempt from the requirement of a tolerance for residues in or on cattle, meat; cattle, meat byproducts; goat, meat; goat, meat byproducts; hog, meat; hog meat byproducts; horse, meat; horse, meat byproducts; sheep, meat; sheep meat byproducts; and, poultry, fat; poultry meat; poultry meat byproducts; milk, and egg when applied as a bactericide/fungicide to livestock drinking water, poultry litter, and storage areas for silage and grain.

(c) Preharvest and postharvest application of propanoic acid (CAS Reg. No. 79–09–4), propanioc acid, calcium salt (CAS Reg. No. 4075–81–4), and propanioc sodium salt (CAS Reg. No. 137–40–6) are exempted from the requirement of a tolerance on all crops when used as either an active or inert ingredient in accordance with good agricultural practice in pesticide formulations applied to growing crops, to raw agricultural commodities before and after harvest and to animals.

[69 FR 47025, Aug. 4, 2004, as amended at 74 FR 26534, June 3, 2009]

§ 180.1025 Xylene; exemption from the requirement of a tolerance.

Xylene is exempted from the requirement of a tolerance when used as an aquatic herbicide applied to irrigation conveyance systems in accordance with the following conditions:

(a) It is to be used only in programs of the Bureau of Reclamation, U.S. Department of Interior, and cooperating water user organizations.

(b) It is to be applied as an emulsion at an initial concentration not to exceed 750 parts per million.

(c) It is not to be applied when there is any likelihood that the irrigation water will be used as a source of raw water for a potable water system or where return flows of such treated irrigation water into receiving rivers and streams would contain residues of xylene in excess of 10 parts per million.

(d) Xylene to be used as an aquatic herbicide shall meet the requirement limiting the presence of a polynuclear aromatic hydrocarbons as listed in 21 CFR 172.250.

[38 FR 16352, June 22, 1973, as amended at 50 FR 2980, Jan. 3, 1985]

§ 180.1027 Nuclear polyhedrosis virus of Heliothis zea; exemption from the requirement of a tolerance.

(a) For the purposes of this section, the viral insecticide must be produced with an unaltered and unadulterated inoculum of the single-embedded *Heliothis zea* nuclear polyhedrosis virus (HzSNPV). The identity of the seed virus must be assured by periodic checks.

(b) Each lot of active ingredient of the viral insecticide shall have the following specifications:

(1) The level of extraneous bacterial contamination of the final unformulated viral insecticide should not exceed 10^7 colonies per gram as determined by an aerobic plate on trypticase soy agar.

(2) Human pathogens, e.g., Salmonella, Shigella, or Vibrio, must be absent.

(3) Safety to mice as determined by an intraperitoneal injection study must be demonstrated.

(4) Identity of the viral product, as determined by the most sensitive and standardized analytical technique, e.g., restriction endonuclease and/or SDS-PAGE analysis, must be demonstrated.

(c) Exemptions from the requirement of a tolerance are established for the residues of the microbial insecticide *Heliothis zea* NPV, as specified in paragraphs (a) and (b) of this section, in or on all agricultural commodities.

[60 FR 42460, Aug. 16, 1995, as amended at 74 FR 26534, June 3, 2009]

§ 180.1033 Methoprene; exemption from the requirement of a tolerance.

Methoprene is exempt from the requirement of a tolerance in or on all

food commodities when used to control insect larvae.

[68 FR 34829, June 11, 2003]

§ 180.1035 Pine oil; exemption from the requirement of a tolerance.

Pine oil is exempted from the requirement of a tolerance for residues in the raw agricultural commodities honey and honeycomb, when present therein as a result of its use as a deodorant at no more than 12 percent in formulation with the bee repellent butanoic anhydride applied in an absorbent pad over the hive.

[74 FR 26534, June 3, 2009]

§ 180.1037 Polybutenes; exemption from the requirement of a tolerance.

(a) Polybutenes are exempt from the requirement of a tolerance for residues in or on the raw agricultural commodity cotton, undelinted seed when used as a sticker agent for formulations of the attractant gossyplure (1:1 mixture of (*Z*,*Z*)- and (*Z*,*E*)-7,11-hexadecadien-1-ol acetate) to disrupt the mating of the pink bollworm.

(b) Polybutenes are exempt from the requirement of a tolerance for residues in or on the raw agricultural commodity artichoke when used as a sticker agent in multi-layered laminted controlled-release dispensers of (Z)-11-hexaadecenal to disrupt the mating of the artichoke plume moth.

[74 FR 26534, June 3, 2009]

§ 180.1040 Ethylene glycol; exemption from the requirement of a tolerance.

Ethylene glycol as a component of pesticide formulations is exempt from the requirement of a tolerance when used in foliar applications to peanut plants.

[43 FR 41393, Sept. 18, 1978]

§ 180.1041 Nosema locustae; exemption from the requirement of a tolerance.

The insecticide *Nosema locustae* is exempted from the requirement of a tolerance for residues in or on all raw agricultural commodities.

[47 FR 21537, May 19, 1982]

§ 180.1043 Gossyplure; exemption from the requirement of a tolerance.

The pheromone gossyplure, a 1:1 mixture of (*Z*,*Z*)- and (*Z*,*E*)-7,11-hexadecadien-1-ol acetate) is exempt from the requirement of a tolerance in or on the raw agricultural commodity cotton, undelinted seed when applied to cotton from capillary fibers.

[74 FR 26534, June 3, 2009]

§ 180.1049 Carbon dioxide; exemption from the requirement of a tolerance.

The insecticide carbon dioxide is exempted from the requirement of a tolerance when used after harvest in modified atmospheres for stored insect control on food commodities.

[65 FR 33716, May 24, 2000]

§ 180.1050 Nitrogen; exemption from the requirements of a tolerance.

The insecticide nitrogen is exempted from the requirements of a tolerance when used after harvest in modified atmospheres for stored product insect control on all food commodities.

[65 FR 33716, May 24, 2000]

§ 180.1052 2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine; exemption from the requirement of a tolerance.

2,2,5-trimethyl-3-dichloroacetyl-1,3-oxazolidine is exempted from the requirement of a tolerance when used as an inert ingredient in formulations of the herbicides *S*-ethyl dipropylthiocarbamate, *S*-propyl dipropylthiocarbamate, and *S*-ethyl diisobutylthiocarbamate applied to corn fields before the corn plants emerge from the soil with a maximum of 0.5 pound of the inert ingredient per acre.

[45 FR 51201, Aug. 1, 1980]

§ 180.1054 Calcium hypochlorite; exemptions from the requirement of a tolerance.

(a) Calcium hypochlorite is exempted from the requirement of a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities.

(b) Calcium hypochlorite is exempted from the requirement of a tolerance in

or on grape when used as a fumigant postharvest by means of a chlorine generator pad.

[59 FR 59165, Nov. 16, 1994, as amended at 74 FR 26534, June 3, 2009]

§ 180.1056 Boiled linseed oil; exemption from requirement of tolerance.

Boiled linseed oil (containing no more than 0.33 percent manganese naphthenate and no more than 0.33 percent cobalt naphthenate) is exempt from the requirement of a tolerance when used as a coating agent for *S*-ethyl hexahydro-1*H*-azepine-1-carbothioate. No more than 15 percent of the pesticide formulation may consist of ''boiled linseed oil.'' This exemption is limited to use on rice before edible parts form.

[46 FR 33270, June 29, 1981]

§ 180.1057 Phytophthora palmivora; exemption from requirement of tolerance.

Phytophthora palmivora is exempted from the requirement of a tolerance in or on the raw agricultural commodity fruit, citrus.

[74 FR 26534, June 3, 2009]

§ 180.1058 Sodium diacetate; exemption from the requirement of a tolerance.

Sodium diacetate, when used postharvest as a fungicide, is exempt from the requirement of a tolerance for residues in or on alfalfa, hay; Bermudagrass, hay; bluegrass, hay; bromegrass, hay; clover,hay; corm, field, grain; corn, pop, grain; oat, grain; orchardgrass, hay; sorghum, grain, grain; sudangrass, hay; ryegrass, Italian, hay; timothy, hay.

[74 FR 26534, June 3, 2009]

§ 180.1064 Tomato pinworm insect pheromone; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for combined residues of both components of the tomato pinworm insect pheromone (*E*)-4-tridecen-1-yl acetate and (*Z*)-4-tridecen-1-yl acetate in or on all raw agricultural commodities (preharvest) in accordance with the following prescribed conditions:

(a) Application shall be limited solely to point source dispensers or point source chopped fibers containing the tomato pinworm insect pheromone.

(b) Cumulative yearly application cannot exceed 200 grams of tomato pinworm pheromone per acre.

[58 FR 34376, June 25, 1993]

§ 180.1065 2-Amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one; exemption from the requirement of a tolerance.

The inert ingredient, 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one is exempted from the requirement of a tolerance when used as an emetic at not more than 0.3 percent in formulations of paraquat dichloride. Further restrictions on this exemption are that this ingredient may not be advertised as an emetic and the paraquat product may not be promoted in any way because of the inclusion of this inert ingredient.

[70 FR 46431, Aug. 10, 2005]

§ 180.1067 Methyl eugenol and malathion combination; exemption from the requirement of a tolerance.

The insect attractant methyl eugenol and the insecticide malathion are exempt from the requirement of tolerances on all raw agricultural commodities when used in combination in Oriental fruit fly eradication programs under the authority of the U.S. Department of Agriculture, in accordance with the following directions and specifications:

(a) The combination shall be at the ratio of three parts methyl eugenol to one part technical malathion (3:1).

(b) This combination is to be impregnated on a carrier (cigarette filter tips (cellulose acetate); cotton strings; fiberboard squares) or mixed with a jel cleared under 40 CFR 180.920 or 180.950.

(c) The maximum actual dosage per application per acre shall be 28.35 grams (one ounce avoirdupois) methyl eugenol and 9.45 grams (one-third (0.33) ounce avoirdupois) technical malathion.

[47 FR 9002, Mar. 3, 1982, as amended at 69 FR 23142, Apr. 28, 2004]

§ 180.1068 C_{12}-C_{18} fatty acid potassium salts; exemption from the requirement of a tolerance.

C_{12}-C_{18} fatty acids (saturated and unsaturated) potassium salts are exempted from the requirement of a tolerance for residues in or on all raw agricultural commodities when used in accordance with good agricultural practice.

[60 FR 34871, July 5, 1995]

§ 180.1069 (*Z*)-11-Hexadecenal; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biological insecticide (pheromone) (*Z*)-11-hexadecenal when used as a sex attractant on artichoke plants to control the artichoke plume moth.

[47 FR 14906, Apr. 7, 1982]

§ 180.1070 Sodium chlorite; exemption from the requirement of a tolerance.

Sodium chlorite is exempted from the requirement of a tolerance for residues when used in accordance with good agricultural practice as a seed-soak treatment in the growing of the raw agricultural commodities vegetable, brassica, leafy, group 5 and radish, roots and radish, tops.

[74 FR 26534, June 3, 2009]

§ 180.1071 Peanuts, Tree Nuts, Milk, Soybeans, Eggs, Fish, Crustacea, and Wheat; exemption from the requirement of a tolerance.

(a) *General.* Residues resulting from the following uses of the food commodity forms of peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, and wheat are exempted from the requirement of a tolerance in or on all food commodities under FFDCA section 408 (when used as either an inert or an active ingredient in a pesticide formulation), if such use is in accordance with good agricultural practices:

(1) Use in pesticide products intended to treat seeds.

(2) Use in nursery and greenhouse operations, as defined in 40 CFR 170.3, which includes seeding, potting and transplanting activities.

(3) Pre-plant and at-transplant applications.

(4) Incorporation into seedling and planting beds.

(5) Applications to cuttings and bare roots.

(6) Applications to the field that occur after the harvested crop has been removed.

(7) Soil-directed applications around and adjacent to all plants.

(8) Applications to rangelands, which is land, mostly grasslands, whose plants can provide food (*i.e.*, forage) for grazing or browsing animals.

(9) Use in chemigation and irrigation systems (via flood, drip, or furrow application with no overhead spray applications).

(10) Application as part of a dry fertilizer on which an active ingredient is impregnated.

(11) Aerial and ground applications that occur when no above-ground harvestable food commodities are present (usually pre-bloom).

(12) Application as part of an animal feed-through product.

(13) Applications as gel and solid (non-liquid/non-spray) crack and crevice treatments that place the gel or bait directly into or on top of the cracks and crevices via a mechanism such as a syringe.

(14) Applications to the same crop from which the food commodity is derived, whether the plant fraction(s) intended for harvest are present or not, e.g., applications of peanut meal when applied to peanut plants.

(b) *Specific chemical substances.* Residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide formulation are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural practices and such use is included in paragraph (a):

Chemical Substance	CAS No.
Caseins	9000–71–9
Caseins, ammonium complexes	9005–42–9
Caseins, hydrolyzates	65072–00–6
Caseins, potassium complexes	68131–54–4
Caseins, sodium complexes	9005–46–3

[70 FR 1360, Jan. 7, 2005]

§ 180.1072 Poly-*D*-glucosamine (chitosan); exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of the biological plant growth regulator poly-*D*-glucosamine when used as a seed treatment in or on barley, beans, oats, peas, rice, and wheat.

(b) An exemption from the requirement of a tolerance is established for residues of the biological plant growth regulator poly-D-glucosamine when used as a pesticide in the production any raw agricultural commodity.

[60 FR 19524, Apr. 19, 1995]

§ 180.1073 Isomate-M; exemption from the requirement of a tolerance.

The oriental fruit moth pheromone (Isomate-M) (Z-8-dodecen-l-yl acetate, E-8-dodecen-l-yl acetate, Z-8-dodecen-l-ol) is exempt from the requirement of a tolerance in or on all the raw agricultural commodities (food and feed) including, peach; quince; nectarine; and nut, macadamia when used in orchards with encapsulated polyethylene tubing to control oriental fruit moth.

[74 FR 26534, June 3, 2009]

§ 180.1074 F.D.&C. Blue No. 1; exemption from the requirement of a tolerance.

F.D.&C. Blue No. 1 is exempted from the requirement of a tolerance when used as an aquatic plant control agent.

[47 FR 25963, June 16, 1982]

§ 180.1075 *Colletotrichum gloeosporioides* f. sp. *aeschynomene;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the mycoherbicide *Colletotrichum gloeosporioides* f. sp. *aeschynomene* in or on the following raw agricultural commodities:

COMMODITY
Aspirated grain fractions
Rice, grain
Soybean, forage
Soybean, hay
Soybean, seed

[47 FR 25742, June 15, 1982, as amended at 74 FR 26534, June 3, 2009]

§ 180.1076 Viable spores of the microorganism *Bacillus popilliae;* exemption from the requirement of a tolerance.

(a) For the purposes of this section the microbial insecticide for which exemption from the requirement of a tolerance is being established shall have the following specifications:

(1) The microorganism shall be an authentic strain of *Bacillus popilliae* conforming to the morphological and biochemical characteristics of *Bacillus popilliae* as described in Bergey's Manual of Determinative Bacteriology, Eighth Edition.

(2) Spore preparations of *Bacillus popilliae* shall be produced by an extraction process from diseased Japanese beetles, and may contain a small percentage of the naturally occurring milky disease bacterium *Bacillus lentimorbus.*

(3) Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory test mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection of injury in the test animals when observed for 7 days following injection.

(b) Exemption from the requirement of a tolerance is established for residues of the microbial insecticide *Bacillus popilliae,* as specified in paragraph (a) of this section in or on grass, pasture, forage and grass, rangeland, forage when it is applied to growing crops in accordance with good agricultural practices.

[47 FR 38535, Sept. 1, 1982, as amended at 74 FR 26535, June 3, 2009]

§ 180.1080 Plant volatiles and pheromone; exemptions from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant volatiles cyclic decadiene, cyclic decene, cyclic pentadecatriene, and decatriene and the pheromone Z-2-isopropenyl-1-methylcyclobutaneethanol; Z-3,3-dimethyl-Δ1,β-cyclohexaneethanol; Z-3,3-dimethyl-Δ1,α-cyclohexaneethanal; E-3,3-dimethyl-Δ1,α-cyclohexaneethanal

combination when applied to cotton in hollow synthetic fibers.

[48 FR 28442, June 22, 1983]

§ 180.1083 Dimethyl sulfoxide; exemption from the requirement of a tolerance.

Dimethyl sulfoxide (DMSO) [CAS Registry Number 67–68–5] is exempted from the requirement of a tolerance when used as an inert solvent or cosolvent in formulations with the following pesticides when used in accordance with good agricultural practices in or on the following raw agricultural commodities:

(a) Carbaryl (1-naphthyl methyl-carbamate)

Pea, dry, seed
Pea, succulent

(b) *O-O*-Diethyl *O*-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate

Pea, dry, seed
Pea, succulent

[48 FR 54819, Dec. 7, 1983, as amended at 74 FR 26535, June 3, 2009]

§ 180.1084 Monocarbamide dihydrogen sulfate; exemption from the requirement of a tolerance.

Monocarbamide dihydrogen sulfate is exempted from the requirement of a tolerance when used as a herbicide or desiccant in or on all raw agricultural commodities.

[53 FR 12152, Apr. 13, 1988]

§ 180.1086 3,7,11-Trimethyl-1,6,10-dodecatriene-1-ol and 3,7,11-trimethyl-2,6,10-dodecatriene-3-ol; exemption from the requirement of a tolerance.

The insect pheromone containing the active ingredients 3,7,11-trimethyl-1,6,10-dodecatriene-1-ol and 3,7,11-trimethyl-2,6,10-dodecatriene-3-ol is exempted from the requirement of a tolerance in or on all raw agricultural commodities.

[52 FR 12165, Apr. 15, 1987; 52 FR 29014, Aug. 5, 1987]

§ 180.1087 Sesame stalks; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biorational nematicide sesame stalk in or on the following raw agricultural commodities: Almond; almond, hulls; cotton, undelinted seed; cotton, gin byproducts; soybean, seed; soybean, forage; soybean, hay; aspirated grain fractions; potato; beet, sugar, roots; beet, sugar, tops; tomato; pepper, bell; squash; strawberry; eggplant; cucumber; carrot, roots; radish, roots; radish, top; turnip, roots; turnip, tops; onion; pea, dry; pea, succulent; melon; grape; walnut; orange; grapefruit; mulberry; peach; apple; apricot; blackberry; loganberry; pecan; cherry; plum, and cranberry.

[74 FR 26535, June 3, 2009]

§ 180.1089 Poly-*N*-acetyl-*D*-glucosamine; exemption from the requirement of tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical nematicide poly-*N*-acetyl-*D*-glucosamine on a variety of agricultural crops.

[53 FR 10249, Mar. 30, 1988]

§ 180.1090 Lactic acid; exemption from the requirement of a tolerance.

Lactic acid (2-hydroxypropanoic acid) is exempted from the requirement of a tolerance when used as a plant growth regulator in or on all raw agricultural commodities.

[53 FR 15286, May 4, 1988]

§ 180.1091 Aluminum isopropoxide and aluminum secondary butoxide; exemption from the requirement of a tolerance.

Aluminum isopropoxide (CAS Reg. No. 555–31–7) and aluminum secondary butoxide (CAS Reg. No. 2269–22–9) are exempted from the requirement of a tolerance when used in accordance with good agricultural practices as stabilizers in formulations of the insecticide amitraz [*N′*-(2,4-dimethylphenyl)-*N*-[[(2,4-dimethylphenyl)imino]-*N*-

methylmethanimidamide] applied to growing crops or animals.

[53 FR 34509, Sept. 7, 1988; 53 FR 36696, Sept. 21, 1988]

§ 180.1092 Menthol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticidal chemical menthol in or on honey and honeycomb when used in accordance with good agricultural practice in over-wintering bee hives.

[74 FR 26535, June 3, 2009]

§ 180.1095 Chlorine gas; exemptions from the requirement of a tolerance.

Chlorine gas is exempted from the requirement of a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities.

[56 FR 21309, May 8, 1991]

§ 180.1097 GBM-ROPE; exemption from the requirement of a tolerance.

The grape berry moth pheromone (GBM-ROPE) containing the active ingredients (Z)-9-dedecenyl acetate and (Z)-11-tetradecenyl acetate is exempt from the requirement of a tolerance in or on the raw agricultural commodity grape when used in orchards with encapsulated polyethylene tubing to control grape berry moth.

[74 FR 26535, June 3, 2009]

§ 180.1098 Gibberellins [Gibberellic Acids (GA3 and GA4 + GA7), and Sodium or Potassium Gibberellate]; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of gibberellins [gibberellic acids (GA3 and GA4 + GA7), and sodium or potassium gibberellate] in or on all food commodities when used as plant regulators on plants, seeds, or cuttings and on all food commodities after harvest in accordance with good agricultural practices.

[64 FR 31505, June 11, 1999]

§ 180.1100 *Gliocladium virens* isolate GL-21; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Gliocladium virens* GL-21 in or on all raw agricultural commodities when used either as a fungicide for inoculation of plant growth media in greenhouses or on terrestrial food crops grown outdoors in accordance with good agricultural practices.

[60 FR 48659, Sept. 20, 1995; 60 FR 52248, Oct. 5, 1995]

§ 180.1101 Parasitic (parasitoid) and predatory insects; exemption from the requirement of a tolerance.

Parasitic (parasitoid) and predatory insects are exempted from the requirement of a tolerance for residues when they are used in accordance with good agricultural and pest control practices to control insect pests of stored raw whole grains such as corn, small grains, rice, soybeans, peanuts, and other legumes either bulk or warehoused in bags. For the purposes of this rule, the parasites (parasitoids) and predators are considered to be species of Hymenoptera in the genera *Trichogramma,* Trichogrammatidae; *Bracon,* Braconidae; *Venturia, Mesostenus,* Ichneumonidae; *Anisopteromalus, Choetospila, Lariophagus, Dibrachys, Habrocytus, Pteromalus,* Pteromalidae; *Cephalonomia, Holepyris, Laelius,* Bethylidae; and of Hemiptera in the genera *Xylocoris, Lyctocoris,* and *Dufouriellus,* Anthocoridae. Whole insects, fragments, parts, and other residues of these parasites and predators remain subject to 21 U.S.C. 342(a)(3).

[57 FR 14646, Apr. 22, 1992]

§ 180.1102 *Trichoderma harzianum* KRL-AG2 (ATCC #20847) strain T–22; exemption from requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Trichoderma harzianum* KRL-AG2 (ATCC #20847); also known as strain T-22 when applied in/or on all food commodities.

[64 FR 16860, Apr. 7, 1999]

§ 180.1103 Isomate-C; exemption from the requirement of a tolerance.

The codling moth pheromone (Isomate-C) E,E-8,10-dodecenyl alcohol, dodecanol, tetradecanol is exempt from the requirements of a tolerance in or on all raw agricultural commodities when formulated in polyethylene pheromone dispensers for use in orchards with encapsulated polyethylene tubing to control codling moth.

[74 FR 26535, June 3, 2009]

§ 180.1107 Delta endotoxin of *Bacillus thuringiensis* variety *kurstaki* encapsulated into killed *Pseudomonas fluorescens;* exemption from the requirement of a tolerance.

The delta endotoxin of *Bacillus thuringiensis* variety *kurstaki* encapsulated into killed *Pseudomonas fluorescens* is exempt from the requirements of a tolerance in or on all raw agricultural commodities.

[56 FR 28328, June 20, 1991]

§ 180.1108 Delta endotoxin of *Bacillus thuringiensis* variety *San Diego* encapsulated into killed *Pseudomonas fluorescens;* exemption from the requirement of a tolerance.

The delta endotoxin of *Bacillus thuringiensis* variety *San Diego* encapsulated into killed *Pseudomonas fluorescens* is exempt from the requirements of a tolerance in or on all raw agricultural commodities.

[56 FR 28326, June 20, 1991]

§ 180.1110 3-Carbamyl-2,4,5-trichlorobenzoic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of chlorothalonil to crops in § 180.275 (a) and (b) and/or as an inadvertent residue resulting from the soil metabolism of chlorothalonil when applied to crops in § 180.275 (a) and (b), and subsequent uptake by rotated crops when used according to approved agricultural practices.

[57 FR 24552, June 10, 1992]

§ 180.1111 Bacillus subtilis GB03; exemption from the requirement of a tolerance.

The biofungicide *Bacillus subtilis* GB03 is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used in accordance with good agricultural practices.

[73 FR 50556, Aug. 27, 2008]

§ 180.1113 Lagenidium giganteum; exemption from the requirement of a tolerance.

Lagenidium giganteum (a fungal organism) is exempt from the requirement of a tolerance in or on the raw agricultural commodities aspirated grain fractions; grass, forage; grass, hay; rice, grain; rice, straw; soybean, seed; soybean, forage; soybean, hay; rice, wild, grain.

[74 FR 26535, June 3, 2009]

§ 180.1114 *Pseudomonas fluorescens* A506, *Pseudomonas fluorescens* 1629RS, and *Pseudomonas syringae* 742RS; exemptions from the requirement of a tolerance.

The biological pesticides *Pseudomonas fluorescens* A506, *Pseudomonas fluorescens* 1629RS, and *Pseudomonas syringae* 742RS are exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a frost protection agent or biological control agent to growing agricultural crops in accordance with good agricultural practices.

[57 FR 42700, Sept. 16, 1992]

§ 180.1118 *Spodoptera exigua* nuclear polyhedrosis virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the microbial pest control agent *Spodoptera exigua* nuclear polyhedrosis virus when used as a pesticide control agent on all raw agricultural commodities.

[58 FR 25784, Apr. 28, 1993]

§ 180.1119 Azadirachtin; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the biochemical azadirachtin, which is isolated from the berries of the Neem tree (*Azadirachta indica*), when used as a pesticide at 20 grams or less per acre on all raw agricultural commodities.

[58 FR 8696, Feb. 17, 1993]

§ 180.1120 *Streptomyces* sp. strain K61; exemption from the requirement of a tolerance.

The biological pesticide *Streptomyces* sp. strain K61 is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used as a fungicide for the treatment of seeds, cuttings, transplants, and plants of agricultural crops in accordance with good agricultural practices.

[58 FR 21403, Apr. 21, 1993]

§ 180.1121 Boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate; exemptions from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticidal chemical boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate, in or on raw agricultural commodities when used as an active ingredient in insecticides, herbicides, or fungicides preharvest or postharvest in accordance with good agricultural practices.

[58 FR 44283, Aug. 20, 1993]

§ 180.1122 Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.

(a) All inert ingredients of semiochemical dispenser products formulated with, and/or contained in, dispensers made of polymeric matrix materials (including the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers, and other inert ingredients) are exempted from the requirement of a tolerance when used as carriers in pesticide formulations for application to growing crops only. These dispensers shall conform to the following specifications:

(1) Exposure must be limited to inadvertent physical contact only. The design of the dispenser must be such as to preclude any contamination by its components of the raw agricultural commodity (RAC) or processed foods/feeds derived from the commodity by virtue of its proximity to the RAC or as a result of its physical size.

(2) The dispensers must be applied discretely. This exemption does not apply to components of semiochemical formulations applied in a broadcast manner either to a crop field plot or to individual plants.

(b) A semiochemical dispenser is a single enclosed or semi-enclosed unit that releases semiochemical(s) into the surrounding atmosphere via volatilization and is applied in a manner to provide discrete application of the semiochemical(s) into the environment.

(c) Semiochemicals are chemicals that are emitted by plants or animals and modify the behavior of receiving organisms. These chemicals must be naturally occurring or substantially identical to naturally occurring semiochemicals.

[58 FR 64494, Dec. 8, 1993]

§ 180.1124 Arthropod pheromones; exemption from the requirement of a tolerance.

Arthropod pheromones, as described in § 152.25(b) of this chapter, when used in retrievably sized polymeric matrix dispensers are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops only at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices.

[59 FR 14759, Mar. 30, 1994]

§ 180.1126 Codlure, (E,E)-8,10-Dodecadien-1-ol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the insect pheromone codlure, (E,E)-8,10-

dodecadien-1-ol, on all raw agricultural commodities in accordance with the following prescribed conditions:

(a) Application shall be limited solely to codlure dispensers that conform to the following specifications:

(1) Commodity exposure must be limited to inadvertent physical contact. The design of the dispenser must be such as to preclude any exposure of its components to the raw agricultural commodity (RAC) or processed foods/feeds derived from the commodity due to its proximity to the RAC or as a result of its physical size. Dispensers must be of such size and construction that they are readily recognized post-application.

(2) The dispensers must be applied discretely, *i.e.*, placed in the field in easily perceived distinct locations in a manner that does not prevent later retrieval. This exemption does not apply to codlure applied in a broadcast manner either to a crop field plot or to individual plants.

(b) A codlure dispenser is a single enclosed or semi-enclosed unit that releases codlure into the surrounding atmosphere via volatilization and is applied in a manner to provide discrete application (*i.e.*, in easily perceived distinct locations in a manner that does not prevent later retrieval) of the codlure into the environment.

[59 FR 9931, Mar. 2, 1994]

§ 180.1127 Biochemical pesticide plant floral volatile attractant compounds: cinnamaldehyde, cinnamyl alcohol, 4-methoxy cinnamaldehyde, 3-phenyl propanol, 4-methoxy phenethyl alcohol, indole, and 1,2,4-trimethoxybenzene; exemptions from the requirement of a tolerance.

Residues of the biochemical pesticide plant floral volatile attractant compounds: cinnamaldehyde, cinnamyl alcohol, 4-methoxy cinnamaldehyde, 3-phenyl propanol, 4-methoxy phenethyl alcohol, indole, and 1,2,4-trimethoxybenzene are exempt from the requirement of a tolerance in or on the following raw agricultural commodities: the following field crops—alfalfa, clover, cotton, dandelion, peanuts (including hay), rice, sorghum (milo), soybeans, sunflower, sweet potatoes, and wheat; the following vegetable crops—asparagus, beans (including forage hay), beets, carrots, celery, cole crops (cabbage, broccoli, brussels sprouts, cauliflower), collards (kale, mustard greens, turnip greens, kohlrabi), corn, fresh (field, sweet, pop, seed), corn fodder and forage, chinese cabbage, cowpeas, cucurbitis (cucumbers, squash, pumpkin), egg plant, endive (escarole), horseradish (radish, rutabagas, turnip roots), leafy greens (spinach, swiss chard), lettuce (head leaf), okra, parsley, parsnip, peas, peas with pods, peppers, potatoes, sugar beets, tomatoes; the following tree fruit, berry and nut crops—almonds, apples, apricots, berries (blackberry, boysenberry, dewberry, loganberry, raspberry), blueberry, cherry, citrus (grapefruit, kumquat, lemon, lime, orange, tangelo, and tangerine) cranberry, grapes, melons, (watermelon, honeydew, crenshaw, cantaloupe, casaba, persian), nectarines, pears, pecans, peaches, and strawberry as dispersed from the end-use product Corn Rootworm Bait®, a pesticidal bait, in accordance with the prescribed conditions in paragraph (a) of this section.

(a) Cumulative yearly application cannot exceed 20 grams of each floral attractant/acre/application.

(b) [Reserved]

[59 FR 15857, Apr. 5, 1994]

§ 180.1128 *Bacillus subtilis* MBI 600; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices.

[74 FR 15869, Apr. 8, 2009]

§ 180.1130 *N*-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.

N-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone are exempt from the requirement of a tolerance when

used as solvents in cotton defoliant formulations containing thidiazuron and diuron as active ingredients.

[59 FR 32084, June 22, 1994]

§ 180.1131 *Ampelomyces quisqualis* isolate M10; exemption from the requirement of a tolerance.

The biological fungicide *Ampelomyces quisqualis* isolate M10 is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used as a fungicide on agricultural crops in accordance with good agricultural practices.

[59 FR 33437, June 29, 1994]

§ 180.1135 *Pasteuria penetrans;* exemption from the requirement of a tolerance.

The biological nematicide *Pasteuria penetrans* is exempted from the requirement of a tolerance in or on all raw agricultural commodities, except roots and tubers, when used as a nematicide in the production of fruits and vegetables in greenhouses.

[59 FR 66741, Dec. 28, 1994]

§ 180.1139 Sodium 5-nitroguaiacolate; exemption from the requirement of a tolerance.

The biochemical sodium 5-nitroguiacolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use products at a concentration of 0.1% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

[65 FR 66181, Nov. 3, 2000]

§ 180.1140 Sodium *o*-nitrophenolate; exemption from the requirement of a tolerance.

The biochemical sodium *o*-nitrophenolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use products at a concentration of 0.2% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

[65 FR 66181, Nov. 3, 2000]

§ 180.1141 Sodium *p*-nitrophenolate; exemption from the requirement of a tolerance.

The biochemical sodium *p*-nitrophenolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use product at a concentration of 0.3% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

[65 FR 66181, Nov. 3, 2000]

§ 180.1142 1,4-Dimethylnaphthalene; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant growth regulator 1,4-dimethylnaphthalene when applied post harvest to potatoes in accordance with good agricultural practices.

[60 FR 7457, Feb. 8, 1995]

§ 180.1143 Methyl anthranilate; exemption from the requirement of a tolerance.

Residues of methyl anthranilate, a biochemical pesticide, are exempt from the requirement of a tolerance in or on all food commodities, when used in accordance with good agricultural practices.

[67 FR 51088, Aug. 7, 2002]

§ 180.1144 *Candida oleophila* isolate I-182; exemption from the requirement of a tolerance.

Candida oleophila isolate I-182, when used as a post-harvest biological fungicide, is exempted from the requirement of a tolerance in or on all raw agricultural commodities.

[60 FR 11033, Mar. 1, 1995]

§ 180.1145 *Pseudomonas syringae;* exemption from the requirement of a tolerance.

Pseudomonas syringae is exempted from the requirement of a tolerance on all raw agricultural commodities when applied postharvest according to good agricultural practices.

[60 FR 12703, Mar. 8, 1995]

§ 180.1146 *Beauveria bassiana* Strain GHA; exemption from the requirement of a tolerance.

Beauveria bassiana Strain GHA is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops according to good agricultural practices.

[60 FR 18547, Apr. 12, 1995]

§ 180.1148 Occlusion Bodies of the Granulosis Virus of *Cydia pomenella;* tolerance exemption.

An exemption from the requirement of a tolerance is established for residues of the microbial pest control agent Occlusion Bodies of the Granulosis Virus of *Cydia pomonella* (codling moth) in or on all raw agricultural commodities.

[60 FR 42450, Aug. 16, 1995]

§ 180.1149 Inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera;* exemption from the requirement of a tolerance.

The microbial pest control agent inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera* is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used to control certain lepidopteran pest species.

[60 FR 37020, July 19, 1995]

§ 180.1150 6-Benzyladenine; exemption from the requirement of a tolerance.

The biochemical plant regulator 6-benzyladenine (6–BA) is exempt from the requirement of a tolerance in or on apple and pear when applied at a rate of ≤182 grams of active ingredient per acre per season, and in or on pistachio when applied at a rate of ≤60 grams of active ingredient per acre per season.

[72 FR 13179, Mar. 21, 2007]

§ 180.1153 Lepidopteran pheromones; exemption from the requirement of a tolerance.

Lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone, are exempt from the requirement of a tolerance in or on all raw agricultural commodities. This exemption only pertains to those situations when the pheromone is: Applied to growing crops at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices; and applied as a post-harvest treatment to stored food commodities at a rate not to exceed 3.5 grams active ingredient/1,000 ft^2/year (equivalent to 150 grams active ingredient/acre/year) in accordance with good agricultural practices.

[71 FR 45399, Aug. 9, 2006]

§ 180.1154 CryIA(c) and CryIC derived delta-endotoxins of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens,* and the expression plasmid and cloning vector genetic constructs.

CryIA(c) and CryIC derived delta-endotoxins of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens* and the expression plasmid and cloning vector genetic constructs are exempt from the requirement of a tolerance when used in or on all raw agricultural commodities.

[60 FR 47489, Sept. 13, 1995]

§ 180.1156 Cinnamaldehyde; exemption from the requirement of a tolerance.

Cinnamaldehyde (3-phenyl-2-propenal) is exempted from the requirement of a tolerance in or on all food commodities, when used as a fungicide, insecticide, and algaecide in accordance with good agricultual practices.

[64 FR 7804, Feb. 17, 1999; 64 FR 14099, Mar. 24, 1999]

§ 180.1157 Cytokinins; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of cytokinins (specifically: aqueous extract of seaweed meal and kinetin) in or on all food commodities

when used as plant regulators on plants, seeds, or cuttings and on all food commodities after harvest in accordance with good agricultural practices.

[64 FR 31505, June 11, 1999]

§ 180.1158 Auxins; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of auxins (specifically: indole-3-acetic acid and indole-3-butyric acid) in or on all food commodities when used as plant regulators on plants, seeds, or cuttings and on all food commodities after harvest in accordance with good agricultural practices.

[64 FR 31505, June 11, 1999]

§ 180.1159 Pelargonic acid; exemption from the requirement of tolerances.

(a) An exemption from the requirement of a tolerance is established for residues of pelargonic acid in or on all food commodities when used as a plant regulator on plants, seeds, or cuttings and on all food commodities after harvest in accordance with good agricultural practices.

(b) Pelargonic acid when used as an herbicide is exempt from the requirement of a tolerance on all plant food commodities provided that:

(1) Applications are not made directly to the food commodity except when used as a harvest aid or desiccant to: any root and tuber vegetable, bulb vegetable or cotton.

(2) When pelargonic acid is used as a harvest aid or desiccant, applications must be made no later than 24 hours prior to harvest.

(c) An exemption from the requirement of a tolerance is established for residues of pelargonic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of pelargonic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of pelargonic acid up to 170 ppm per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

[62 FR 28364, May 23, 1997, as amended at 64 FR 31505, June 11, 1999; 68 FR 7935, Feb. 19, 2003]

§ 180.1160 Jojoba oil; exemption from the requirement of a tolerance.

The insecticide and spray tank adjuvant jojoba oil is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied at the rate of 1.0% or less of the final spray in accordance with good agricultural practices, provided the jojoba oil does not contain simmondsin, simmondsin-2-ferulate, and related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin.

[61 FR 2121, Jan. 25, 1996]

§ 180.1161 Clarified hydrophobic extract of neem oil; exemption from the requirement of a tolerance.

Clarified hydrophobic extract of neem oil is exempt from the requirement of a tolerance on all food commodities when used as a botanical fungicide/insecticide/miticide.

[67 FR 43552, June 28, 2002]

§ 180.1162 Acrylate polymers and copolymers; exemption from the requirement of a tolerance.

(a) Acrylate polymers and copolymers are exempt from the requirement of a tolerance when used as inert ingredients in pesticidal formulations applied to growing, raw agricultural commodities. This tolerance exemption covers the acrylate polymers/copolymers that are intrinsically safe and already listed in TSCA inventory or will meet the polymer tolerance exemption from requirements of premanufacturing notification under 40 CFR 723.250. Polymers exempted can be used as dispensers, resins, fibers, and beads, as long as the fibers, beads and resins particle sizes are greater than 10 microns and insoluble in water. This exemption pertains to the acrylate polymers/copolymers used as inert ingredients for sprayable and dispenser pesticide formulations that are applied on food crops. Any acrylate polymers/

copolymers used for encapsulating material must be cleared as an inert ingredient when used in pesticide formulation applied on food crops.

(b) For the purposes of this exemption, acrylate polymers/copolymers used as inert ingredients in an end-use formulation must meet the definition for a polymer as given in 40 CFR 723.250(b), are not automatically excluded by 40 723.250(d), and meet the tolerance exemption criteria in 40 CFR 723.250(e)(1), 40 CFR 723.250 (e)(2) or 40 CFR 723.250(e)(3). Therefore, acrylate polymers and copolymers that are already listed in the TSCA inventory or will meet the polymer tolerance exemption under 40 CFR 723.250 as amended on March 29, 1995 are covered by this exemption.

[61 FR 6551, Feb. 21, 1996]

§ 180.1163 Killed *Myrothecium verrucaria;* exemption from the requirement of a tolerance.

Killed *Myrothecium verrucaria* is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a preseed or pre- or post-planting soil treatment alone or mixed with water and the mixed suspension be applied through drip or border irrigation systems and the indicator mycotoxin levels do not exceed 15 ppm.

[61 FR 11315, Mar. 20, 1996, as amended at 61 FR 58332, Nov. 14, 1996]

§ 180.1165 Capsaicin; exemption from the requirement of a tolerance.

Capsaicin is exempt from the requirement of a tolerance in or on all food commodities when used in accordance with approved label rates and good agricultural practice.

[63 FR 39521, July 23, 1998]

§ 180.1167 Allyl isothiocyanate as a component of food grade oil of mustard; exemption from the requirement of a tolerance.

The insecticide and repellent Allyl isothiocyanate is exempt from the requirement of a tolerance for residues when used as a component of food grade oil of mustard, in or on all raw agricultural commodities, when applied according to approved labeling.

[61 FR 24894, May 17, 1996]

§ 180.1176 Sodium bicarbonate; exemption from the requirement of a tolerance.

The biochemical pesticide sodium bicarbonate is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a fungicide or post-harvest fungicide in accordance with good agricultural practices.

[61 FR 67473, Dec. 23, 1996]

§ 180.1177 Potassium bicarbonate; exemption from the requirement of a tolerance.

The biochemical pesticide potassium bicarbonate is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a fungicide or post-harvest fungicide in accordance with good agricultural practices.

[61 FR 67473, Dec. 23, 1996]

§ 180.1178 Formic acid; exemption from the requirement of a tolerance.

The pesticide formic acid is exempted from the requirement of a tolerance in or on honey and honeycomb when used to control tracheal mites and suppress varroa mites in bee colonies, and applied in accordance with label use directions.

[74 FR 26535, June 3, 2009]

§ 180.1179 Plant extract derived from *Opuntia lindheimeri, Quercus falcata, Rhus aromatica,* and *Rhizophoria mangle;* exemption from the requirement of a tolerance.

The biochemical pesticide plant extract derived from *Opuntia lindheimeri, Quercus falcata, Rhus aromatica,* and *Rhizophoria mangle* is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a nematicide/plant regulator in accordance with good agricultural practices.

[62 FR 24842, May 7, 1997]

§ 180.1180 Kaolin; exemption from the requirement of a tolerance.

(a) The biochemical pesticide kaolin is temporarily exempted from the requirement of a tolerance for residues of the insecticide Kaolin, when used on crops (apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cranberries, cucurbits, grapes, melons, nuts, ornamentals, peaches, peanuts, pears, peppers, plums, potatoes, seed crops, small grains, soybeans, strawberries, sugar beets, and tomatoes) to control certain insect, fungus, and bacterial damage to plants. This temporary exemption from the requirement of a tolerance will permit the marketing of the food commodities in this paragraph when treated in accordance with the provisions of experimental use permit 70060–EUP–1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked December 31, 1999. This temporary exemption from the requirement of a tolerance may be revoked at any time if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

(b) Kaolin is exempted from the requirement of a tolerance for residues when used on or in food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

[62 FR 19685, Apr. 23, 1997, as amended at 63 FR 9430, Feb. 25, 1998]

§ 180.1181 *Bacillus cereus* strain BPO1; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the *Bacillus cereus* strain BPO1 in or on all raw agricultural commodities when applied/used in accordance with label directions.

[67 FR 70017, Nov. 20, 2002]

§ 180.1187 L-glutamic acid; exemption from the requirement of a tolerance.

L-glutamic acid is exempt from the requirement of a tolerance on all food commodities when used in accordance with good agricultural practices.

[66 FR 33198, June 21, 2001]

§ 180.1188 Gamma aminobutyric acid; exemption from the requirement of a tolerance.

Gamma aminobutyric acid is exempt from the requirement of a tolerance on all food commodities when used in accordance with good agricultural practices.

[66 FR 33198, June 21, 2001]

§ 180.1189 Methyl salicylate; exemption from the requirement of a tolerance.

The biochemical pesticide methyl salicylate is exempt from the requirement of a tolerance for residues in or on food or feed when used as an insect repellant in food packaging and animal feed packaging at an application rate that does not exceed 0.2 mg of methyl salicylate per square inch of packaging materials.

[62 FR 61639, Nov. 19, 1997]

§ 180.1191 Ferric phosphate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, ferric phosphate ($FePO_4$, CAS No. 11045–86–0) in or on all food commodities.

[62 FR 56105, Oct. 29, 1997]

§ 180.1193 Potassium dihydrogen phosphate; exemption from the requirement of a tolerance.

Potassium dihydrogen phosphate is exempted from the requirement of a tolerance in or on all food commodities when applied as a fungicide in accordance with good agricultural practices.

[63 FR 43085, Aug. 12, 1998]

§ 180.1195 Titanium dioxide.

Titanium dioxide is exempted from the requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambdacyhalothrin at

no more than 3.0% by weight of the formulation.

[63 FR 14363, Mar. 25, 1998]

§ 180.1196 Peroxyacetic acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid in or on all food commodities, when such residues result from the use of peroxyacetic acid as an antimicrobial treatment in solutions containing a diluted end use concentration of peroxyacetic acid up to 100 ppm per application on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

(b) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid, in or on all food commodities when used in sanitizing solutions containing a diluted end-use concentration of peroxyacetic acid up to 500 ppm, and applied to tableware, utensils, dishes, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, milking equipment, and other food processing equipment in food handling establishments including, but not limited to dairies, dairy barns, restaurants, food service operations, breweries, wineries, and beverage and food processing plants.

[74 FR 26535, June 3, 2009]

§ 180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of ≤ 1% hydrogen peroxide per application on growing and postharvest crops.

[67 FR 41844, June 20, 2002]

§ 180.1198 *Gliocladium catenulatum* strain J1446; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide, *Gliocladium catenulatum* strain J1446 when used in or on all food commodities.

[63 FR 37288, July 10, 1998]

§ 180.1199 Lysophosphatidylethanolamine (LPE); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide lysophosphatidylethanolamine in or on all food commodities.

[67 FR 17636, Apr. 11, 2002]

§ 180.1200 *Pseudomonas fluorescens* strain PRA–25; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide, *pseudomonas fluorescens* strain PRA–25 when used on peas, snap beans and sweet corn and will expire July 31, 2001.

[63 FR 38498, July 17, 1998]

§ 180.1201 *Trichoderma harzianum* strain T-39; exemption from the requirement of a tolerance.

Trichoderma harzianum strain T-39 is exempt from the requirement of a tolerance on all food commodities.

[65 FR 38757, June 22, 2000]

§ 180.1202 *Bacillus sphaericus;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticides, *Bacillus sphaericus* when used in or on all food crops.

[63 FR 48597, Sept. 11, 1998]

§ 180.1204 Harpin protein; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of individual harpin proteins that meet specified physiochemical and toxicological criteria when used as biochemical pesticides on all food commodities to enhance plant growth, quality and yield, to improve overall plant health, and to aid in pest management. The physiochemical and toxicological criteria identifying harpin proteins are as follows:

(a) Consists of a protein less than 100 kD in size, that is acidic (pI<7.0), glycine rich (>10%), and contains no more than one cystine residue.

(b) The source(s) of genetic material encoding the protein are bacterial plant pathogens not known to be mammalian pathogens.

(c) Elicits the hypersensitive response (HR) which is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves.

(d) Possesses a common secondary structure consisting of α and β units that form an HR domain.

(e) Is heat stable (retains HR activity when heated to 65 °C for 20 minutes).

(f) Is readily degraded by a proteinase representative of environmental conditions (no protein fragments >3.5 kD after 15 minutes degradation with Subtilisin A).

(g) Exhibits a rat acute oral toxicity (LD_{50}) of greater than 5,000 mg product/kg body weight.

[69 FR 24996, May 5, 2004]

§ 180.1205 *Beauveria bassiana* ATCC #74040; exemption from the requirements of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the insecticide *Beauveria bassiana* (ATCC #74040) in or on all food commodities when applied or used as ground and aerial foliar sprays for use only on terrestrial crops.

[64 FR 22796, Apr. 28, 1999]

§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* AF36 in or on cotton, gin byproducts; cotton, hulls; cotton, meal; cotton, refined oil; cotton, undelinted seed.

(b) *Aspergillus flavus* AF36 is temporarily exempt from the requirement of a tolerance on pistachio when used in accordance with the Experimental Use Permit, EPA File Symbol 71693–EUP–1. This temporary exemption from tolerance expires on December 31, 2011.

(c) *Aspergillus flavis* AF 36 is temporarily exempt from the requirement of a tolerance on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover when used in accordance with the Experimental Use Permit 71693–EUP–2. This temporary exemption from the tolerance will expire December 31, 2011.

[68 FR 41541, July 14, 2003, as amended at 72 FR 28871, May 23, 2007; 72 FR 72965, Dec. 26, 2007; 74 FR 26535, 26546, June 3, 2009]

§ 180.1207 N-acyl sarcosines and sodium N-acyl sarcosinates; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the following substances when used as inert ingredients (surfactants) at levels not to exceed 10% in pesticide formulations containing glyphosate:

Name	CAS Reg. No.
N-acyl sarcosines.	
N-cocoyl sarcosine mixture	68411-97-2
N-lauroyl sarcosine	97-78-9
N-myristoyl sarcosine	52558-73-3
N-oleoyl sarcosine	110-25-8
N-stearoyl sarcosine	142-48-3
Sodium N-acyl sarcosinates.	
N-cocoyl sarcosine sodium salt mixture	61791-59-1
N-methyl-N-(1-oxo-9-octodecenyl) glycine	3624-77-9
N-methyl-N-(1-oxododecyl) glycine	137-16-6
N-methyl-N-(1-oxooctadecyl) glycine	5136-55-0
N-methyl-N-(1-oxotetradecyl glycine	30364-51-3

[64 FR 68046, Dec. 6, 1999]

§ 180.1209 *Bacillus subtilis* strain QST 713; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus subtilis* strain QST 713 when used in or on all food commodities.

[65 FR 41369, July 5, 2000]

§ 180.1210 Phosphorous acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium, and potassium salts in or on all food commodities when used as an agricultural fungicide and in or on potatoes when applied as a post-

harvest treatment at 35,600 ppm or less phosphorous acid.

[71 FR 49373, Aug. 23, 2006]

§ 180.1212 *Pseudomonas chlororaphis* Strain 63–28; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Pseudomonas chlororaphis* Strain 63–28 in or on all food commodities.

[66 FR 53346, Oct. 22, 2001]

§ 180.1213 *Coniothyrium minitans* strain CON/M/91–08; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Coniothyrium minitans* strain CON/M/91–08 when used in or on all food commodities.

[66 FR 16874, Mar. 28, 2001]

§ 180.1218 Indian Meal Moth Granulosis Virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide Indian Meal Moth Granulosis Virus when used in or on all food commodities.

[68 FR 55875, Sept. 29, 2003]

§ 180.1219 Foramsulfuron; exemption from the requirement of a tolerance.

The pesticide foramsulfuron is exempted from the requirement of a tolerance in corn, field, grain/corn, field, forage/ corn, field, stover/corn, pop, grain/corn, pop, forage/corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover when applied as a herbicide in accordance with good agricultural practices.

[74 FR 26535, June 3, 2009]

§ 180.1220 1-Methylcyclopropene; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the 1-Methylcyclopropene in or on fruits and vegetables when:

(a) Used as a post harvest plant growth regulator, *i.e.*, for the purpose of inhibiting the effects of ethylene.

(b) Applied or used outdoors for preharvest treatments.

[73 FR 19150, Apr. 9, 2008]

§ 180.1221 *Pseudozyma flocculosa* strain PF-A22 UL; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

[67 FR 60966, Sept. 27, 2002]

§ 180.1222 Sucrose octanoate esters; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] in or on all food commodities when used in accordance with good agricultural practices.

[67 FR 60152, Sept. 25, 2002]

§ 180.1223 Imazamox; exemption from the requirement of a tolerance.

The herbicide imazamox, (±) 2, -[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid, is exempt from the requirement of a tolerance on all food commodities when applied as a herbicide in accordance with good agricultural practices.

[68 FR 7433, Feb. 14, 2003]

§ 180.1224 *Bacillus pumilus* GB34; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities. An exemption is also granted for such residues on treated but unplanted soybean seeds.

[69 FR 76625, Dec. 22, 2004]

§ 180.1225 Decanoic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of decanoic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid (up to 170 ppm per application) on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

[68 FR 7939, Feb. 19, 2003; 68 FR 17308, Apr. 9, 2003]

§ 180.1226 *Bacillus pumilus* strain QST2808; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[68 FR 36480, June 18, 2003]

§ 180.1228 Diallyl sulfides; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of diallyl sulfides when used in/on garlic, leeks, onions, and shallots.

[68 FR 40808, July 9, 2003]

§ 180.1230 Ferrous sulfate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of ferrous sulfate.

[70 FR 33363, June 8, 2005]

§ 180.1231 Lime; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of lime.

[70 FR 33363, June 8, 2005]

§ 180.1232 Lime-sulfur; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of lime-sulfur.

[70 FR 33363, June 8, 2005]

§ 180.1233 Potassium sorbate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of potassium sorbate.

[70 FR 33363, June 8, 2005]

§ 180.1234 Sodium carbonate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sodium carbonate.

[70 FR 33363, June 8, 2005]

§ 180.1235 Sodium hypochlorite; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sodium hypochlorite.

[70 FR 33363, June 8, 2005]

§ 180.1236 Sulfur; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sulfur.

[70 FR 33363, June 8, 2005]

§ 180.1237 Sodium metasilicate; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of sodium metasilicate in or on all food commodities when used in accordance with approved label rates and good agricultural practices as a plant desiccant, so long as the sodium metasilicate does not exceed 4% by weight in aqueous solution.

(b) An exemption from the requirement of a tolerance is established for residues of sodium metasilicate in or on all food commodities when used in accordance with approved label rates and good agricultural practices as an insecticide and fungicide, so long as the sodium metasilicate does not exceed 2.41% by weight in aqueous solution.

[71 FR 19441, Apr. 14, 2006]

§ 180.1240 Thymol; exemption from the requirement of a tolerance.

(a) Time-limited exemptions from the requirement of a tolerance are established for residues of thymol on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of thymol will expire and are revoked on June 30, 2007.

(b) An exemption from the requirement of a tolerance for residues of the thymol (as present in thyme oil) in or on food commodities when applied/used in/on public eating places, dairy processing equipment, and/or food processing equipment and utensils.

[70 FR 37696, June 30, 2005, as amended at 71 FR 2895, Jan. 18, 2006; 74 FR 12617, Mar. 25, 2009]

§ 180.1241 Eucalyptus oil; exemption from the requirement of a tolerance.

Time-limited exemptions from the requirement of a tolerance are established for residues of eucalyptus oil on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of eucalyptus oil will expire and are revoked on June 30, 2007.

[70 FR 37696, June 30, 2005]

§ 180.1243 *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 in or on all agricultural commodities when applied/used in accordance with label directions.

[68 FR 44640, July 30, 2003]

§ 180.1244 Ammonium bicarbonate; exemption from the requirement of a tolerance.

An exemption from the requirement of tolerance is established for residues of ammonium bicarbonate used in or on all food commodities when used in accordance with good agricultural practices.

[69 FR 13745, Mar. 24, 2004]

§ 180.1245 Rhamnolipid biosurfactant; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of rhamnolipid biosurfactant when used in accordance with good agricultural practices as a fungicide in or on all food commodities.

[69 FR 16800, Mar. 31, 2004]

§ 180.1246 Yeast Extract Hydrolysate from *Saccharomyces cerevisiae:* exemption from the requirement of a tolerance.

This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* on all food commodities when applied/used for the management of plant diseases.

[69 FR 9958, Mar. 3, 2004]

§ 180.1248 Exemption of citronellol from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide citronellol in or on all food commodities.

[69 FR 23146, Apr. 28, 2004]

§ 180.1250 C8, C10, and C12 fatty acid monoesters of glycerol and propylene glycol; exemption from the requirement of a tolerance.

The C8, C10, and C12 straight-chain fatty acid monoesters of glycerol (glycerol monocaprylate, glycerol monocaprate, and glycerol monolaurate) and propylene glycol

(propylene glycol monocaprylate, propylene glycol monocaprate, and propylene glycol monolaurate) are exempt from the requirement of a tolerance in or on all food commodities when used in accordance with approved label rates and good agricultural practice.

[69 FR 34944, June 23, 2004]

§ 180.1251 Geraniol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide geraniol in or on all food commodities.

[69 FR 23151, Apr. 28, 2004]

§ 180.1253 *Streptomyces lydicus* WYEC 108; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Streptomyces lydicus* WYEC 108 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[69 FR 31301, June 3, 2004]

§ 180.1254 Aspergillus flavus NRRL 21882 on peanut; exemption from requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 in or on peanut; peanut hay; peanut, meal; peanut, refined oil.

[74 FR 26535, June 3, 2009]

§ 180.1255 *Bacillus pumilus* strain QST 2808; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST 2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[69 FR 63954, Nov. 3, 2004]

§ 180.1256 *Alternaria destruens* strain 059; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Alternaria destruens* Strain 059 when used in or on all raw agricultural commodities when applied/used in accordance with label directions.

[70 FR 28459, May 18, 2005]

§ 180.1257 *Paecilomyces lilacinus* strain 251; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Paecilomyces lilacinus* strain 251 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[70 FR 19283, Apr. 13, 2005]

§ 180.1258 Acetic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide acetic acid when used as a preservative on post-harvest agricultural commodities intended for animal feed, including Alfalfa, seed; alfalfa, hay; barley, grain; bermudagrass, hay; bluegrass, hay; bromegrass, hay; clover, hay; corn, field, grain; corn, pop, grain; cowpea, hay; fescue, hay; lespedeza, hay; lupin; oat, grain; orchardgrass, hay; peanut, hay; timothy, hay; vetch, hay; and wheat, grain, or commodities described as grain or hay.

[74 FR 26536, June 3, 2009]

§ 180.1259 *Reynoutria sachalinensis* extract; exemption from the requirement of a tolerance.

Residues of the biochemical pesticide *Reynoutria sachalinensis* extract, when derived from the whole plant extract, are exempt from the requirement of a tolerance in or on all food commodities.

[70 FR 55277, Sept. 21, 2005]

§ 180.1260 *Muscodor albus* QST 20799 and the volatiles produced on rehydration; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established on all food/feed commodities, for residues of *Muscodor albus* QST 20799, and the volatiles produced on its rehydration,

when the pesticide is used for all agricultural applications, including seed, propagule and post harvest treatments.

[70 FR 56576, Sept. 28, 2005]

§ 180.1261 Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato specific Bacteriophages.

An exemption from the requirement of a tolerance is established for residues of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages in or on pepper and tomato.

[74 FR 26536, June 3, 2009]

§ 180.1262 Sorbitol octanoate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sorbitol octanoate in or on all food commodities when used in accordance with label directions.

[71 FR 4518, Jan. 27, 2006]

§ 180.1263 Tetrahydrofurfuryl alcohol; exemption from the requirement of a tolerance.

Tetrahydrofurfuryl alcohol (THFA, CAS Reg. No. 97–99–4) is exempt from the requirement of a tolerance in or on all raw agricultural commodities when used in accordance with good agricultural practices as an inert ingredient applied only:

(a) For use as a seed treatment.

(b) For applications prior to planting and at the time of planting.

(c) For use on cotton.

(d) For use in herbicides with one application to wheat and barley prior to the pre-boot stage, and two applications to canola and soybeans prebloom.

(e) For use in herbicides with two applications to field corn up to 24 inches tall (V 5 stage).

[71 FR 45415, Aug. 9, 2006]

§ 180.1267 Pantoea agglomerans strain C9–1; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pantoea agglomerans* strain C9–1 when used on apples and pears.

[71 FR 24596, Apr. 26, 2006]

§ 180.1268 Potassium silicate; exemption from the requirement of a tolerance.

Potassium silicate is exempt from the requirement of a tolerance in or on all food commodities so long as the potassium silicate is not applied at rates exceeding 1% by weight in aqueous solution and when used in accordance with good agricultural practices.

[71 FR 34272, June 14, 2006]

§ 180.1269 Bacillus mycoides Isolate J: exemption from the requirement of a tolerance.

Bacillus mycoides isolate J is temporarily exempt from the requirement of a tolerance when used as a fungicide on pecans, potatoes, sugar beets, tomatoes, and peppers in accordance with the Experimental Use Permit 82761–EUP–2. This temporary exemption from the requirement of a tolerance expires and is revoked on March 31, 2011.

[74 FR 10498, Mar. 11, 2009]

§ 180.1270 Isophorone; exemption from the requirement of a tolerance.

Isophorone (CAS Reg. No. 78–59–1) is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to beets, ginseng, rice, spinach, sugar beets, and Swiss chard.

[71 FR 45408, Aug. 9, 2006]

§ 180.1271 Eucalyptus oil; exemption from the requirement of a tolerance.

An exemption from the requirement of tolerance is established for residues of eucalyptus oil in or on honey, honeycomb, and honeycomb with honey when used at 2g or less eucalyptus oil per hive, where the eucalyptus oil contains 80% or more eucalyptol.

[71 FR 53979, Sept. 13, 2006]

§ 180.1272 Pantoea agglomerans strain E325; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pantoea agglomerans* strain E325 when used on apples and pears.

[71 FR 54933, Sept. 20, 2006]

§ 180.1273 Beauveria bassiana HF23; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established on all food/feed commodities, for residues of *Beauveria bassiana* HF23 when the pesticide is used for chicken manure treatment.

[72 FR 1183, Jan. 10, 2007]

§ 180.1274 Tris (2-ethylhexyl) phosphate; exemption from the requirement of a tolerance.

Tris (2-ethylhexyl) phosphate (TEHP, CAS Reg. No. 78–42–2) is exempt from the requirement of a tolerance for residues in grain, aspirated fractions; barley, grain, barley, hay, barley, straw; wheat, grain; wheat, forage; wheat, hay; wheat, straw when used under the following conditions:

(a) The use is in accordance with good agricultural practices;

(b) Tris (2-ethylhexyl) phosphate is used as an inert ingredient in pesticide formulations with the active ingredients pinoxaden, clodinafop-propargyl, and tralkoxydium;

(c) Tris (2-ethylhexyl) phosphate is applied no more than twice per season; and

(d) The applications occur no later than the pre-boot stage (prior to formation of edible grain).

[72 FR 5624, Feb. 7, 2007, as amended at 74 FR 26536, June 3, 2009]

§ 180.1275 Pythium; exception from the requirement of a tolerance.

An exemption from the requirement of tolerance is established on all food/feed commodities, for residues of *pythium oligandrum* DV 74 when the pesticide is used on food crops.

[72 FR 27452, May 16, 2007]

§ 180.1276 Tobacco mild green mosaic tobamovirus (TMGMV); temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of tobacco mild green mosaic tobamovirus in or on all grass, forage and grass, hay.

[74 FR 26536, June 3, 2009]

§ 180.1277 Dibasic esters; exemption from the requirement of a tolerance.

Dibasic esters (CAS Reg. No. 95481–62–2) is exempted from the requirement of a tolerance for residues when used as an inert ingredient (solvent and/or anti-freeze) at 10% W/W or less in microencapsulated pesticide formulations with the active ingredient cyfluthrin.

[73 FR 10398, Feb. 27, 2008]

§ 180.1278 Quillaja saponaria extract (saponins); exemption from the requirement of a tolerance.

Residues of the biochemical pesticide *Quillaja saponaria* extract (saponins) are exempt from the requirement of a tolerance in or on all food commodities.

[72 FR 41935, Aug. 1, 2007]

§ 180.1279 Zucchini yellow mosaic virus—weak strain; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the ZYMV–WK strain in or on all raw cucurbit when applied/used in accordance with label directions.

[74 FR 26536, June 3, 2009]

§ 180.1280 Poly(hexamethylenebiguanide) hydrochloride (PHMB); exemption from the requirement of a tolerance.

Poly(hexamethylenebiguanide) hydrochloride (PHMB)(CAS Reg. No. 32289–58–0) is exempt from the requirement of a tolerance for residues of the antimicrobial in or on all food commodities when the residues are the result of the lawful application of a food

contact surface sanitizer containing PHMB at 550 parts per million (ppm).

[73 FR 1517, Jan. 9, 2008]

§ 180.1281 S-Abscisic Acid; exemption from the requirement of a tolerance.

S-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2Z,4E)-dienoic Acid, is temporarily exempt from the requirement of a tolerance when used as a plant regulator in or on grape in accordance with the Experimental Use Permit 73049–EUP–4. This temporary exemption from tolerance will expire October 1, 2010.

[73 FR 16562, Mar. 28, 2008]

§ 180.1282 Bacillus firmus I-1582; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established in/on all food/feed commodities, for residues of *Bacillus firmus* I-1582 when used as a soil application or seed treatment.

[73 FR 25528, May 7, 2008]

§ 180.1283 (Z)-7,8-epoxy-2-methyloctadecane (Disparlure); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of (Z)-7,8-epoxy-2-methyloctadecane on all food and feed crops that occur when it is used to treat trees, shrubs, and pastures and such use results in unintentional spray and drift to non-target vegetation including non-food, food, and feed crops. This active ingredient is also known as Disparlure.

[73 FR 33714, June 13, 2008]

§ 180.1284 Ammonium salts of higher fatty acids (C_8–C_{18} saturated; C_8–C_{12} unsaturated); exemption from the requirement of a tolerance.

This regulation establishes an exemption from the requirement of a tolerance for residues of the ammonium salts of higher fatty acids C_8–C_{18} saturated; C_8–C_{12} unsaturated on in or on all food commodities when applied for the suppression and control of a wide variety of grasses and weeds.

[73 FR 39268, July 9, 2008]

§ 180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the biochemical pesticide polyoxin D zinc when used as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

[73 FR 69564, Nov. 19, 2008]

§ 180.1287 Extract of Chenopodium ambrosioides near ambrosioides; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of Extract of *Chenopodium ambrosioides* near *ambrosioides* when used as an insecticide/acaricide on all food commodities.

[74 FR 634, Jan. 7, 2009]

§ 180.1288 Tristyrylphenol ethoxylates; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 70559–25–0) and poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5) on citrus crops, group 10, when used as inert ingredients under the following conditions:

(a) They are applied post-harvest;

(b) They are used as inert ingredients in pesticide formulations with azoxystrobin and fludioxonil; and

(c) They constitute no more than 10.0% of the formulated pesticide product.

[74 FR 12625, Mar. 25, 2009]

§ 180.1289 *Candida oleophila* Strain O; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the microbial pesticide, *Candida oleophila* Strain O, on apples

and pears when applied/used as a post-harvest biofungicide.

[74 FR 22464, May 13, 2009]

Subpart E—Pesticide Chemicals Not Requiring a Tolerance or an Exemption From a Tolerance

SOURCE: 66 FR 66772, Dec. 27, 2001, unless otherwise noted.

§ 180.2000 Scope.

This subpart sets forth the pesticide chemicals for use in agricultural or other food-related settings for which neither a tolerance nor an exemption is deemed to be needed by EPA.

§ 180.2003 Definitions.

(a) Food uses are the uses of a pesticide chemical that are likely to yield residues in food or feed crops, meat, milk, poultry or egg.

(b) Non-food uses are those uses that are not likely to yield residues in food or feed crops, meat, milk, poultry or egg.

[66 FR 66772, Dec. 27, 2001, as amended at 73 FR 60158, Oct. 10, 2008]

§ 180.2010 Threshold of regulation determinations.

The following pesticide chemical uses on food or feed, or food or feed crops, do not need a tolerance or exemption from the requirement of a tolerance, and may be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, without obtaining such tolerance or exemption, based on EPA's determination that the uses are below the threshold of regulation.

Pesticide Chemical	CAS Reg. No.	Use/Limits	Analytical Method
Thiabendazole	148–79–8	As a seed treatment for dry pea (including field pea, pigeon pea, chickpea or lentil), using a maximum application rate of 0.075 pounds of active ingredient per 100 pounds of seed. Vines or hay grown from treated seed may not be fed to livestock..	High Performance Liquid Chromatography/Florescence Detector method [1]; Modification of *Ion-Pairing Liquid Chromatographic Determination of Benzimidazole Fungicides in Foods*, Gilvydis and Walters, JAOAC, vol. 73, no. 5, 1990.

[1]Available from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*

[73 FR 1978, Jan. 11, 2008]

§ 180.2020 Non-food determinations.

The following pesticide chemical uses do not need a tolerance or exemption from the requirement of a tolerance based on EPA's determination that they are not likely to result in residues in or on food.

Pesticide Chemical	CAS Reg. No.	Limits	Uses
Methyl bromide	74–83–9	When applied as a pre-plant soil fumigant	All pre-plant soil uses
Potassium triiodide (KI_3)	12298–68–9	When applied to growing crops in foreign countries	Bananas, grapes, and melons
Rhodamine B	81–88–9	Not to exceed 2% by weight of the formulated product and 60 ppm on the treated seed	Dye for seed treatment

[66 FR 66772, Dec. 27, 2001, as amended at 70 FR 40201, July 13, 2005; 71 FR 45402, Aug. 9, 2006]

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