

the following inert ingredients to read as follows

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

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(e) * * * *	
Chemical Name	CAS No.
* * *	* *
Citric acid, 2-(acetyloxy)-, tributyl ester	77-90-7
* * *	* *
Citric acid, triethyl ester ..	77-93-0
* * *	* *

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BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0256; FRL-7678-9]

Carfentrazone-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of carfentrazone-ethyl and its metabolite in or on certain raw agricultural commodities. FMC Corporation and Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0256. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm.

119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR

Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of March 31, 2004 (69 FR 16921) (FRL-7348-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F6468 and 3E6746) by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and IR-4, Technology Center, of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by FMC Corporation, the registrant. Comments on the petition were filed by B. Sachau, 15 Elm St., Florham Park, NJ 07932. A response to these comments is provided in Unit V.

In the **Federal Register** of July 28, 2004 (69 FR 45042) (FRL-7365-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F6468, 3E6746, 4E6814, and 3F6584) by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and IR-4, Technology Center, of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by FMC Corporation, the registrant. Comments on the petition were filed by B. Sachau, 15 Elm St., Florham Park, NJ 07932, and Bonita Poulin, R. R. #3, Brockville, Ont. A response to these comments is provided in Section V.

The petitions requested that 40 CFR 180.515(a) be amended by establishing proposed tolerances for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate and the metabolite carfentrazone-ethyl chloropropionic acid (alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid), in or on: Acerola at 0.1 parts per million (ppm); almond hulls at 0.20 ppm and grass, forage, fodder and hay, group 17 at 12 ppm; hops at 0.05 ppm; avocado at 0.1 ppm; atemoya at 0.1 ppm; banana at 0.1 ppm; berry group 13 at 0.1 ppm; birida at 0.1 ppm; borage, seed at 0.1 ppm; cacao at 0.1 ppm; cactus at 0.1 ppm; canistel at 0.1 ppm; cherimoya at 0.1 ppm; citrus, crop group 10 at 0.1 ppm; citrus cultivars and/or hybrids of grapefruit and pummelo, including unqi fruit at 0.1 ppm; coconut at 0.1 ppm; coffee at 0.1 ppm; crambe, seed at 0.1 ppm; custard apple at 0.1 ppm; date at

0.1 ppm; feijoa at 0.1 ppm; fig at 0.1 ppm; fish at 0.2 ppm; flax, seed at 0.1 ppm; grape at 0.1 ppm; grapefruit at 0.1 ppm; guava at 0.1 ppm; guayule at 0.1 ppm; herbs and spice group 19 at 0.1 ppm; horseradish at 0.1 ppm; ilama at 0.1 ppm; Indian mulberry at 0.1 ppm; jabotica at 0.1 ppm; Juneberry at 0.1 ppm; kava at 0.1 ppm; kiwi fruit at 0.1 ppm; lingonberry at 0.1 ppm; lychee at 0.1 ppm; longan at 0.1 ppm; mango at 0.1 ppm; mustard seed, Indian at 0.1 ppm; mustard seed, field at 0.1 ppm; mustard seed, black at 0.1 ppm; okra at 0.1 ppm; olive at 0.1 ppm; palm heart, leaves at 0.1 ppm; passionfruit at 0.1 ppm; papaya at 0.1 ppm; pawpaw at 0.1 ppm; peanut at 0.1 ppm; persimmon at 0.1 ppm; pistachio at 0.1 ppm; pome fruit, crop group 11 at 0.1 ppm; pomegranate at 0.1 ppm; pulasan at 0.1 ppm; pummelo at 0.1 ppm; rambutan at 0.1 ppm; rapeseed, Indian at 0.1 ppm; rapeseed, seed at 0.1 ppm; safflower, seed at 0.1 ppm; salal at 0.1 ppm; sapodilla at 0.1 ppm; sapote, black at 0.1 ppm; sapote, mamey at 0.1 ppm; shellfish at 0.2 ppm; sorghum, sweet, stalks at 0.1 ppm; sorghum, sweet, syrup at 0.1 ppm; soursop at 0.1 ppm; Spanish lime at 0.1 ppm; star apple at 0.1 ppm; starfruit at 0.1 ppm; stone fruit, crop group 12 at 0.1 ppm; strawberry at 0.1 ppm; strawberrypear at 0.1 ppm; stevia at 0.1 ppm; sugar apple at 0.1 ppm; sugarcane at 0.1 ppm; sunflower, seed at 0.1 ppm; ti, leaves at 0.1 ppm; tea at 0.1 ppm; tree nut, crop group 14 at 0.1 ppm; tuberous and corm vegetables, crop subgroup 1C at 0.1 ppm; vanilla at 0.1 ppm; vegetable, brassica, leafy, group 5 at 0.1 ppm; vegetable, bulb, group 3 at 0.1 ppm; vegetable, cucurbit group 9 at 0.1 ppm; vegetable, foliage of legume, group 7 at 0.1 ppm; vegetables, fruiting, group, crop group 8 at 0.1 ppm; vegetable, leaves of root and tuber, group 2 at 0.1 ppm; vegetable, leafy, except brassica, group 4 at 0.1 ppm; vegetable, legume, group 6 at 0.1 ppm; vegetable, root and tuber, group 1 at 0.1 ppm; wasabi, roots at 0.1 ppm; and wax jambu at 0.1 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of carfentrazone-ethyl and its metabolite, carfentrazone-ethyl chloropropionic acid, on Vegetable, root and tuber, group 01 at 0.10 ppm; vegetable, leaves of root and tuber, group 2 at 0.10 ppm; vegetable, bulb, group 3 at 0.10 ppm; vegetable, leafy, except brassica, group 4 at 0.10 ppm; vegetable, brassica, leafy, group 5 at 0.10 ppm; vegetable, legume, group 6 at 0.10 ppm; vegetable, foliage of legume (except soybean), group 7 at 0.10 ppm; vegetable, fruiting, group 8 at 0.10 ppm; vegetable, cucurbit, group 9 at 0.10 ppm; fruit, citrus, group 10 at 0.10 ppm; fruit, pome, group 14 at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; berry, group 13 at 0.10 ppm; nut, tree, group 14 at 0.10 ppm; herbs and spices, group 19 at 2.0 ppm; almond, hull at 0.20 ppm; grape at 0.10 ppm; grass, forage at 5.0 ppm; grass, hay at 8.0 ppm; canola at 0.10 ppm; hop, dried cones at 0.10 ppm; peanut at 0.10 ppm; peanut, hay at 0.10 ppm; strawberry at 0.10 ppm; sugarcane at 0.10 ppm; sunflower, seed at 0.10 ppm; okra at 0.10 ppm; stevia at 0.10 ppm; pistachio at 0.10 ppm; coconut at 0.10 ppm; strawberrypear at 0.10 ppm; date at 0.10 ppm; fig at 0.10 ppm; papaya at 0.10 ppm; avocado at 0.10 ppm; sapote, black at 0.10 ppm; canistel at 0.10 ppm; sapote, mamey at 0.10 ppm; mango at 0.10 ppm; sapodilla at 0.10 ppm; star apple at 0.10 ppm; pummelo at 0.10 ppm; guava at 0.10 ppm; feijoa at 0.10 ppm; jaboticaba at

0.10 ppm; wax jambu at 0.10 ppm; starfruit at 0.10 ppm; passionfruit at 0.10 ppm; acerola at 0.10 ppm; lychee at 0.10 ppm; longan at 0.10 ppm; Spanish lime at 0.10 ppm; rambutan at 0.10 ppm; pulasan at 0.10 ppm; sugar apple at 0.10 ppm; atemoya at 0.10 ppm; custard apple at 0.10 ppm; cherimoya at 0.10 ppm; ilama at 0.10 ppm; soursop at 0.10 ppm; biriba at 0.10 ppm; lingonberry at 0.10 ppm; Juneberry at 0.10 ppm; salal at 0.10 ppm; kiwifruit at 0.10 ppm; pomegranate at 0.10 at ppm; persimmon at 0.10 ppm; pawpaw at 0.10 ppm; palm heart at 0.10 ppm; palm heart, leaves at 0.10 ppm; kava, kava at 0.10 ppm; ti, leaves at 0.10 ppm; ti, roots at 0.10 ppm; wasabit, roots at 0.10 ppm; cactus at 0.10 ppm; sorghum, sweet at 0.10 ppm; rapeseed, seed at 0.10 ppm; rapeseed, forage at 0.10 ppm; mustard, seed at 0.10 ppm; flax, seed at 0.10 ppm; safflower, seed at 0.10 ppm; crambe, seed at 0.10 ppm; borage at 0.10 ppm; olive at 0.10 ppm; banana at 0.10 ppm; cacao at 0.10 ppm; tea at 0.10 ppm; mulberry, Indian at 0.10 ppm; vanilla at 0.10 ppm; coffee at 0.10 ppm; horseradish at 0.10 ppm; fish at 0.30 ppm; shellfish at 0.30 ppm; meat, byproducts (cattle, goat, horse, and sheep) at 0.10 ppm; meat (cattle, goat, horse, and sheep) at 0.10 ppm; fat (cattle, goat, horse, and sheep) at 0.10 ppm and milk at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by carfentrazone-ethyl are discussed in the Unit III.A. of the final rule on carfentrazone-ethyl published in the **Federal Register** of August 9, 2000 (65 FR 48620) (FRL-6597-7).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is

applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate ($RfD = NOAEL/UF$). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL/exposure$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of

occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure}/\text{exposures}$) is calculated.

A summary of the toxicological endpoints for carfentrazone-ethyl used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of August 9, 2000 (65 FR 48620).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.515(a)) for the combined residues of carfentrazone-ethyl and its metabolite, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from carfentrazone-ethyl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDTM), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: For the acute analyses, conservative estimates of expected residues were assumed for all food commodities with current or proposed carfentrazone-ethyl tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the acute risk assessment.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCIDTM, which

incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, conservative estimates of expected residues were assumed for all food commodities with current or proposed carfentrazone-ethyl tolerances, and it was assumed that all of the crops included in the analysis were treated. PCT and/or anticipated residues were not used in the chronic risk assessment.

iii. *Cancer.* Carfentrazone-ethyl is classified as "not likely" a human carcinogen.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for carfentrazone-ethyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of carfentrazone-ethyl.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk

assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to carfentrazone-ethyl they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of carfentrazone-ethyl for acute exposures are estimated to be 34.3 parts per billion (ppb) for surface water and 13.4 ppb for ground water. The EECs for chronic exposures are estimated to be 19.0 ppb for surface water and 13.4 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Carfentrazone-ethyl is currently registered for use on the following residential non-dietary sites: Ornamental lawns and turf (application by commercial operators only. There is a proposed aquatic use under review. The risk assessment was conducted using the following residential exposure assumptions: Exposures to toddlers in the residential lawn setting would be higher than that encountered by toddlers in an institutional setting, such as in schools and parks. It was anticipated that herbicide application to homeowner lawns is a seasonal event, thus, only short-term post-application residential exposures were conducted. A swimmer exposure assessment was conducted based on the proposed aquatic application. The swimmer assessment estimates exposures from oral (ingestion) and inhalation routes. No systemic toxicity was seen at the limit-dose (1,000 milligrams/kilogram/day (mg/kg/day)) in a 21-day dermal toxicity study in rats, therefore, these risk assessments are not required. Based on the use pattern, long-term exposure is not anticipated.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether

to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to carfentrazone-ethyl and any other substances and carfentrazone-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that carfentrazone-ethyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with carfentrazone-ethyl. There is no evidence of increased susceptibility of rats in the reproduction study with

carfentrazone-ethyl. EPA concluded there are no residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion.* EPA concluded that, based on the absence of residual uncertainties for prenatal and/or postnatal exposure and complete toxicology, environmental fate, residue chemistry data bases, and the conservative assumptions used when generating the dietary and residential exposure estimates, there are reliable data showing that it is safe for infants and children to remove the additional 10X safety factor.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female and youth 13-19, and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a

pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for

acute exposure, the acute dietary exposure from food to carfentrazone-ethyl will occupy less than 1% of the aPAD for the U.S. population and all population subgroups.

In addition, there is potential for acute dietary exposure to carfentrazone-ethyl in drinking water. After calculating DWLOCs and comparing

them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit.

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CARFENTRAZONE-ETHYL

Population Subgroup	aPAD	%aPAD (Food)	Surface Water EDWC ¹ ppb	Ground Water EDWC ¹ ppb	DWLOC ² ppb
U.S. pop - all seasons	5	< 1	34.3	13.4	1.7e + 05
All Infants (< 1 year old)	5	< 1	34.3	13.4	5.0e + 04
Children (1-2 years old)	5	< 1	34.3	13.4	5.0e + 04
Children (3-5 years old)	5	< 1	34.3	13.4	5.0e + 04
Children (6-12 years old)	5	< 1	34.3	13.4	5.0e + 04
Youth (13-19 years old)	5	< 1	34.3	13.4	1.5e + 05
Adults (20-49 years old)	5	< 1	34.3	13.4	1.7e + 05
Adults (50+ years old)	5	< 1	34.3	13.4	1.7e + 05
Females (13-49 years old)	5	< 1	34.3	13.4	1.5e + 05

¹ EDWCs resulting from maximum registered and proposed application rate (0.4 lbs ai/acre/season - caneberry)

² DWLOC = ((aPAD -food exposure) x (body weight) x (1,000 µg/mg)) ÷ (water consumption)

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to carfentrazone-ethyl from food will utilize ≤75% of the of the cPAD with children 1–2 years old the population subgroup with the highest

exposures. Based the use pattern, chronic residential exposure to residues of carfentrazone-ethyl is not expected. In addition, there is potential for chronic dietary exposure to carfentrazone-ethyl in drinking water. After calculating DWLOCs and

comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CARFENTRAZONE-ETHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EDWC ¹ ppb	Ground Water EDWC ¹ ppb	DWLOC ² ppb
U.S. population - all seasons	0.03	24	19.0	13.4	8.1e + 02
All Infants (<1 year old)	0.03	43	19.0	13.4	1.8e + 02
Children (1-2 years old)	0.03	75	19.0	13.4	8.6e + 01
Children (3-5 years old)	0.03	58	19.0	13.4	1.3e + 02
Children (6-12 years old)	0.0	35	19.0	13.4	2.1e + 02
Youth (13-19 years old)	0.03	21	19.0	13.4	7.3e + 02
Adults (20-49 years old)	0.03	18	19.0	13.4	8.5e + 02
Adults (50+ years old)	0.03	18	19.0	13.4	8.5e + 02
Females (13-49 years old)	0.03	18	19.0	13.4	7.1e + 02

¹ EDWCs resulting from registered and proposed application rate (0.4 lbs ai/acre/season - caneberry); 56-day surface water average + 3

² DWLOC = ((cPAD -food exposure) x (body weight) x (1,000 µg/mg)) ÷ (water consumption)

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic

exposure to food and water (considered to be a background exposure level).

Carfentrazone-ethyl is currently registered for use that could result in short-term residential exposure and the

Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for carfentrazone-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures (including potential aquatic exposure) aggregated

result in aggregate MOEs of 72,875 for the general population and 22,339 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic

exposure of carfentrazone-ethyl in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CARFENTRAZONE-ETHYL

Population Subgroup	Agg. MOE (food and res.) ¹	Aggregate Level of Concern (LOC)	Ground Water EDWC (ppb)	Surface Water EDWC (ppb)	DWLOC ² (ppb)
General U.S. population	72875	100	19.0	13.4	1.7e + 05
All Infants (<1 year old)	37843	100	19.0	13.4	5.0e + 04
Children (1-2 years old)	22339	100	19.0	13.4	5.0e + 04
Children (3-5 years old)	29228	100	19.0	13.4	5.0e + 04
Children (6-12 years old)	51965	100	19.0	13.4	5.0e + 04
Youth (13-19 years old)	85253	100	19.0	13.4	1.5e + 05
Adults (20-49 years old)	87396	100	19.0	13.4	1.7e + 05
Adults (50+ years old)	87457	100	19.0	13.4	1.7e + 05
Females (13-19 years old)	78541	100	19.0	13.4	1.5e + 05

¹ Aggregate MOE = (NOAEL ÷ (Avg Food Exposure + Residential Exposure))

² DWLOC = ((maximum water exposure) × (body weight) × (1,000 µg/mg)) ÷ (water consumption)

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to carfentrazone-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested 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.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits, for residues of carfentrazone-ethyl and F8426-Cl-PAC in/on the proposed crops, livestock, fish, or shellfish. Therefore, harmonization is not an issue.

C. Conditions

Residue chemistry: Successful Agency Validation of Proposed Livestock/Fish/Shellfish Enforcement Method.

V. Comments

Three comments were received in response to the notices of filing. Two comments from B. Sachau objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and are cruel to the test animals. Bonita Poulin commented that she doesn't approve of more chemical contamination of our food when we should be decreasing the residual poisons building up within us, which are already causing health problems. She also indicated that there are safe alternatives available.

Ms. Sachau's and Ms. Poulin's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to carfentrazone ethyl, including all anticipated dietary exposures and all other exposures for which there is reliable information.

VI. Conclusion

Therefore, the tolerance is established for combined residues of carfentrazone-ethyl (ethyl- α ,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate and the metabolite carfentrazone-ethyl chloropropionic acid (alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid), all expressed as carfentrazone-ethyl, in or on vegetable, root and tuber, group 01 at 0.10 ppm; vegetable, leaves of root and tuber, group 2 at 0.10 ppm; vegetable, bulb, group 3 at 0.10 ppm; vegetable, leafy, except brassica, group 4 at 0.10 ppm; vegetable, brassica, leafy, group 5 at 0.10 ppm; vegetable, legume, group 6 at 0.10 ppm; vegetable, foliage of legume (except soybean), group 7 at 0.10 ppm; vegetable, fruiting, group 8 at 0.10 ppm; vegetable, cucurbit, group 9 at 0.10 ppm; fruit, citrus, group 10 at 0.10 ppm; fruit, pome, group 14 at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; berry, group 13 at 0.10 ppm; nut, tree, group 14 at 0.10 ppm; herbs and spices, group 19 at 2.0 ppm; almond, hull at 0.20 ppm; grape at 0.10 ppm; grass, forage at 5.0 ppm; grass, hay at 8.0 ppm; canola at 0.10 ppm, hop, dried cones at

0.10 ppm; peanut at 0.10 ppm; peanut, hay at 0.10 ppm; strawberry at 0.10 ppm; sugarcane at 0.10 ppm; sunflower, seed at 0.10 ppm; okra at 0.10 ppm; stevia at 0.10 ppm; pistachio at 0.10 ppm; coconut at 0.10 ppm; strawberrypear at 0.10 ppm; date at 0.10 ppm; fig at 0.10 ppm; papaya at 0.10 ppm; avocado at 0.10 ppm; sapote, black at 0.10 ppm; canistel at 0.10 ppm; sapote, mamey at 0.10 ppm; mango at 0.10 ppm; sapodilla at 0.10 ppm; star apple at 0.10 ppm; pummelo at 0.10 ppm; guava at 0.10 ppm; feijoa at 0.10 ppm; jaboticaba at 0.10 ppm; wax jambu at 0.10 ppm; starfruit at 0.10 ppm; passionfruit at 0.10 ppm; acerola at 0.10 ppm; lychee at 0.10 ppm; longan at 0.10 ppm; Spanish lime at 0.10 ppm; rambutan at 0.10 ppm; pulasan at 0.10 ppm; sugar apple at 0.10 ppm; atemoya at 0.10 ppm; custard apple at 0.10 ppm; cherimoya at 0.10 ppm; ilama at 0.10 ppm; soursoy at 0.10 ppm; biriba at 0.10 ppm; lingonberry at 0.10 ppm; Juneberry at 0.10 ppm; salal at 0.10 ppm; kiwifruit at 0.10 ppm; pomegranate at 0.10 ppm; persimmon at 0.10 ppm; pawpaw at 0.10 ppm; palm heart at 0.10 ppm; palm heart, leaves at 0.10 ppm; kava, kava at 0.10 ppm; ti, leaves at 0.10 ppm; ti, roots at 0.10 ppm; wasabit, roots at 0.10 ppm; cactus at 0.10 ppm; sorghum, sweet at 0.10 ppm; rapeseed, seed at 0.10 ppm; rapeseed, forage at 0.10 ppm; mustard, seed at 0.10 ppm; flax, seed at 0.10 ppm; safflower, seed at 0.10 ppm; crambe, seed at 0.10 ppm; borage at 0.10 ppm; olive at 0.10 ppm; banana at 0.10 ppm; cacao at 0.10 ppm; tea at 0.10 ppm; mulberry, Indian at 0.10 ppm; vanilla at 0.10 ppm; coffee at 0.10 ppm; horseradish at 0.10 ppm; fish at 0.30 ppm; shellfish at 0.30 ppm; meat, byproducts (cattle, goat, horse, and sheep) at 0.10 ppm; meat (cattle, goat, horse, and sheep) at 0.10 ppm; fat (cattle, goat, horse, and sheep) at 0.10 ppm and milk at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons

to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0256 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 29, 2004.

Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; 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; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801*et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a

report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.515(a) is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
Acerola	0.10
Almond, hull	0.20
Atemoya	0.10
Avocado	0.10
Banana	0.20
Berry, group 13	0.10
Birida	0.10
Borage	0.10
Cacao	0.10
Cactus	0.10
* * *	* * *
Canistel	0.10
Canola	0.10
Cherimoya	0.10
Coffee	0.10
Coconut	0.10
* * *	* * *
Crambe, seed	0.10
Custard apple	0.10
Date	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
* * *	* * *
Grape	0.10
Grass, forage	5.0
Grass, hay	8.0
Guava	0.10

Commodity	Parts per million
Herb and Spices, group 19	2.0
Hops, dried cones	0.10
Horseradish	0.10
llama	0.10
Jaboticaba	0.10
Juneberry	0.10
Kava, Kava	0.10
Kiwi fruit	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
Mulberry, Indian	0.10
Mustard, seed	0.10
Nut, tree, group 14	0.10
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
Pummelo	0.10
Pusalan	0.10
Rambutan	0.10
Rapeseed, forage	0.10
Rapeseed, seed	0.10
* * *	* * *
Safflower, seed	0.10
Salal	0.10
Sapodilla	0.10
Sapote, black	0.10
Sapote, mamey	0.10
Shellfish	0.30
Sorghum, sweet	0.10
Soursop, group	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	0.10
Sunflower, seed	0.10
Tea	0.10
Ti, leaves	0.10
Ti, roots	0.10
Vanilla	0.10
Vegetable, bulb, group 03	0.10
Vegetable, brassica, leafy, group 05	0.10
Vegetable, cucurbit, group 09	0.10
Vegetable, foliage of legume (except soybean), group 07	0.10
Vegetable, fruiting, group 8	0.10

Commodity	Parts per million
Vegetable, legume, group 06	0.10
Vegetable, leafy, except brassica, group 04	0.10
Vegetable, leaves of root and tuber, group 02	0.10
Vegetable, root and tuber, group 01	0.10
Wasabia, roots	0.10
Wax, Jambu	0.10

* * * * *

[FR Doc. 04-21586 Filed 9-28-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0260; FRL-7679-7]

Allethrin, Bendiocarb, Burkholderia cepacia, Fenridazon potassium, and Molinate; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking all tolerances for residues of the insecticides allethrin and bendiocarb, plant growth regulator fenridazon potassium, herbicide molinate, and biological pesticide *Burkholderia cepacia* because EPA canceled food registrations or deleted food uses from registrations following requests for voluntary cancellation or use deletion by the registrants. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006, to reassess the tolerances in existence on August 2, 1996. The regulatory actions in this document pertain to the revocation of 110 tolerances and tolerance exemptions of which 106 count as tolerance reassessments toward the August 2006 review deadline.

DATES: This regulation is effective September 29, 2004. However, certain regulatory actions will not occur until the date specified in the regulatory text. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION**. EPA has established a

docket for this action under docket identification (ID) number OPP-2004-0260. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET, <http://www.epa.gov/edocket/>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** of July 7, 2004 (69 FR 40831) (FRL-7362-2), EPA issued a proposed rule to revoke certain tolerances and tolerance exemptions for residues of the insecticides allethrin and bendiocarb, plant growth regulator fenridazon potassium, herbicide molinate, and biological pesticide *Burkholderia cepacia*. Also, the July 7, 2004 proposal provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under the Federal Food, Drug, and Cosmetic Act (FFDCA) standards.

In this final rule, EPA is revoking certain tolerances and tolerance exemptions for residues of the insecticides allethrin and bendiocarb, plant growth regulator fenridazon potassium, herbicide molinate, and the biological pesticide *Burkholderia cepacia* because these specific tolerances and exemptions correspond to uses no longer current or registered under FIFRA in the United States. The tolerances revoked by this final rule are no longer necessary to cover residues of the relevant pesticides in or on domestically treated commodities or commodities treated outside but imported into the United States. It is EPA's general practice to revoke those tolerances and tolerance exemptions for residues of pesticide active ingredients on crop uses for which there are no active registrations under FIFRA, unless any person in comments on the proposal indicates a need for the tolerance or tolerance exemption to cover residues in or on imported commodities or domestic commodities legally treated.

EPA has historically expressed a concern that retention of tolerances that