



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0428; FRL-9346-5]

### Carfentrazone-ethyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of carfentrazone-ethyl in or on crop group 18, non-grass animal feed (forage, hay, and seed). FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0428. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: [benbow.bethany@epa.gov](mailto:benbow.bethany@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0428 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the Federal Register*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0428, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of July 6, 2011(76 FR 39360) (FRL-8875-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7839) by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. The petition requested that 40 CFR 180.515 be amended by establishing tolerances for residues of the herbicide, carfentrazone-ethyl and its

metabolite, carfentrazone-ethyl chloropropionic acid, in or on alfalfa, forage at 5 parts per million (ppm); alfalfa, hay at 18 ppm; alfalfa, seed at 10 ppm; clover, forage at 5 ppm; clover, hay at 18 ppm; and clover, seed at 10 ppm. That notice referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed individual alfalfa and clover tolerances to crop group 18 tolerances. The reason for this change is explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

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....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 for carfentrazone-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with carfentrazone-ethyl 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.

Carfentrazone-ethyl was ranked low in acute oral toxicity in rats via the oral, dermal, and inhalation routes of exposure. It was minimally irritating to eyes, non-irritating to skin, and not a skin sensitizer.

The proposed mode of action of carfentrazone-ethyl in target plants is through inhibition of the enzyme protoporphyrinogen oxidase (PPO) which is involved in chlorophyll biosynthesis. In mammals, PPO is also an important enzyme in heme biosynthesis and its inhibition can lead toxic effects where heme is utilized (e.g., red blood cells). Some of the toxicities reported for carfentrazone-ethyl are consistent with this mode of action. The target tissues/organs identified are the blood and liver and the most sensitive species was the rat. Subchronic toxicity studies in rats, mice, and dogs demonstrated that the primary effects were on hematological parameters (decreased mean

corpuscular hemoglobin (MCH) and mean corpuscular volume (MCV)). There was also increased urinary porphyrin excretion, increased liver weights, and liver histopathology findings consisting of hepatic pigment deposition, hepatocytomegaly, single cell necrosis, and cell mitosis. Similarly, chronic toxicity studies in rats and dogs demonstrated increased urinary porphyrin excretion and liver histopathology findings in rats and mice consisting of liver pigmentation and increases in red fluorescence. Fluorescence microscopy on liver sections also revealed red fluorescent granules consistent with porphyrin deposits in rats and mice.

There was no evidence of increased susceptibility in prenatal developmental toxicity studies (rats and rabbits) or the multigenerational reproductive toxicity study in rats. Carfentrazone-ethyl induced a significant increase in litter incidences of wavy and thickened ribs in rats at a dose (1,250 mg/kg/day) much higher than the dose (600 mg/kg/day) that caused maternal toxicity consistent with interference with porphyrin metabolism (i.e., staining of the abdominogenital area and of the cage pan liner). The rabbit prenatal developmental toxicity study did not yield any evidence of treatment-related prenatal developmental toxicity even at the highest dose tested (HDT) (300 mg/kg/day). The offspring effects from the 2-generation reproduction study consisted of decreased pup body weight in both sexes of the F<sub>2</sub> generation at the HDT (343 mg/kg/day) and at which maternal toxicity was observed in the form of decreased body-weight gains, increased liver weights, liver and bile duct histopathology, and reductions in the mean cell volume (F<sub>0</sub> and F<sub>1</sub> males, F<sub>1</sub> females), mean cell hemoglobin (F<sub>0</sub> and F<sub>1</sub> males, F<sub>1</sub> females), hematocrit (F<sub>1</sub> males), and hemoglobin (F<sub>1</sub> males).

There is no concern for neurotoxicity. The results of the acute neurotoxicity study indicate clinical signs (i.e., salivation) and mild decreases in motor activity only on the treatment day and the subchronic neurotoxicity showed no signs of neurotoxicity up to the limit dose (1,178 mg/kg/day for males and 1,434 mg/kg/day for females).

In a 21-day dermal toxicity study, carfentrazone-ethyl did not induce any type of dermal or systemic toxicity up to the limit dose of 1,000 mg/kg/day. There are no toxicity studies based on repeated inhalation exposures to carfentrazone-ethyl. A waiver of a 28-day inhalation toxicity study was previously accepted based on its relatively low volatility, low acute inhalation lethality, and the large inhalation MOEs associated with the requested applications.

The mutagenic test battery demonstrated that carfentrazone-ethyl is not mutagenic. In accordance with the Draft Proposed Guidelines for Carcinogen Risk Assessment (April, 1999), carfentrazone-ethyl is classified as a “not likely human carcinogen,” based on the lack of evidence for carcinogenicity in the mouse and rat.

Specific information on the studies received and the nature of the adverse effects caused by carfentrazone-ethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Carfentrazone-ethyl. Section 3 Registration for Application to the Non-grass Animal Feed Crop Group 18. Human-Health Risk Assessment” pp. 30-32 in docket ID number EPA-HQ-OPP-2011-0428.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk

posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for carfentrazone-ethyl used for human risk assessment is shown in the Table of this unit.

**Table —Summary of Toxicological Doses and Endpoints for Carfentrazone-ethyl for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL =500 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 5 mg/kg/day  aPAD = 5 mg/kg/day	Acute neurotoxicity-rat LOAEL = 1000 mg/kg/day based on clinical observations (salivation) and decreased motor activity.
Chronic dietary	NOAEL=3	Chronic RfD	Chronic toxicity-rat

(All populations)	mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	= 0.03 mg/kg/day  cPAD = 0.03 mg/kg/day	LOAEL = 12 mg/kg/day based on liver histopathology (increases in microscopic red fluorescence and pigmentation) and increased urinary porphyrin levels in both sexes.
Incidental oral short-term (1 to 30 days) and intermediate term (1 to 6 months)	NOAEL= 50 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE $\leq 100$	Subchronic toxicity-dog LOAEL = 150 mg/kg/day based on decreased body weight gain and increased urinary excretion of porphyrins
Dermal short-term (1 to 30 days) and intermediate-term(1 to 6 months)	Dermal risk assessment is not required - No toxicity seen at the limit-dose (1,000 mg/kg/day) in a 21-day rat dermal toxicity study and low level of concern for developmental effects.		
Inhalation short-term (1 to 30 days) and intermediate term (1 to 6 months)	Oral NOAEL= 50 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE $\leq 100$	Subchronic toxicity-dog LOAEL = 150 mg/kg/day based on decreased body weight gain and increased urinary excretion of porphyrins
Cancer (Oral, dermal, inhalation)	Classification: "not likely to be carcinogen;" therefore, a quantitative cancer risk assessment is not necessary.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL =lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day= milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level.PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF= uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to carfentrazone-ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing carfentrazone-ethyl tolerances in 40 CFR 180.515. EPA assessed dietary exposures from carfentrazone-ethyl in food as follows:

i. *Acute and chronic exposure.* Quantitative acute dietary exposure and 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. Since such effects were identified for carfentrazone-ethyl, both acute and chronic dietary risk assessments were conducted. In estimating acute and chronic dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues or, if necessary, tolerance-level residues adjusted to account for the residues of concern for risk assessment, 100 PCT.

ii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that carfentrazone-ethyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for carfentrazone-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of carfentrazone-ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of carfentrazone-ethyl for acute exposures are estimated to be 126 parts per billion (ppb) for

surface water and 13 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 48 ppb for surface water and 13 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 126 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48 ppb was used to assess the contribution to drinking 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 the following uses that could result in residential exposures: Golf courses, residential lawns, and aquatic areas. EPA assessed residential exposure with the assumption that homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for residential lawn applications are considered to be short-term only, due to the infrequent use patterns associated with homeowner products. Therefore, short-term inhalation risk was assessed for residential handlers; however, since no hazard was identified via the dermal route of exposure, a dermal risk assessment was not conducted for residential handlers.

EPA uses the term “post-application” to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Carfentrazone-ethyl can be used in many areas that can be frequented by the

general population including home lawns, golf courses and aquatic recreational areas such as ponds and lakes that have been treated for removal of aquatic vegetation. As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-term post-application exposure and risk were also assessed for carfentrazone-ethyl. The most conservative exposure scenario for adults, the aquatic exposure scenario (combined incidental oral and inhalation), was used to estimate post-application risk. For children, the most conservative exposure scenario, the hand-to-mouth exposure in residential turf scenario (incidental oral), was used to estimate post-application risk. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

*<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.*

*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.” EPA has not found carfentrazone-ethyl to share a common mechanism of toxicity with 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 assumed that carfentrazone-ethyl does not have 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 EPA's website at

*<http://www.epa.gov/pesticides/cumulative>.*

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* As discussed in Unit III.A., based on the results of the rat/rabbit prenatal developmental toxicity studies and the rat 2-generation reproductive toxicity study, there is no evidence of increased pre- and/or postnatal sensitivity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. Although an immunotoxicity study is currently lacking in the toxicity database for carfentrazone-ethyl, there is no evidence in the current database that the immune system organs are directly affected following carfentrazone-ethyl exposure.

ii. There is no indication that carfentrazone-ethyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that carfentrazone-ethyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to carfentrazone-ethyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by carfentrazone-ethyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to carfentrazone-ethyl will occupy 1% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to carfentrazone-ethyl from food and

water will utilize 69% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of carfentrazone-ethyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Carfentrazone-ethyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to carfentrazone-ethyl. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that children (1-2 years old) provide the most conservative short-term exposure scenario. Chronic dietary estimates (food + water) for this age group, combined with incidental oral exposure from turf use (hand-to-mouth) results in aggregate MOEs of 2,300. Because EPA's level of concern for carfentrazone-ethyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Although intermediate-term residential exposures are not anticipated, the relevant short-/intermediate-term PODs are the same and, therefore, the short-term risk assessment is protective of intermediate-term exposure.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, carfentrazone-ethyl is not expected to pose a cancer risk to humans.

6. *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 or to infants and children from aggregate exposure to carfentrazone-ethyl residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology is available to enforce the tolerance expression. This analytical enforcement method involves separate analyses for parent and the metabolite. The parent is analyzed by evaporation and reconstitution of the sample prior to analysis by LC/MS/MS GC/ECD. The metabolite is refluxed in the presence of acid and cleaned up with solid phase extraction prior to analysis by LC/MS/MS.

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; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex, Canadian, or Mexican MRLs established for carfentrazone-ethyl in or on the requested crops.

### *C. Revisions to Petitioned-For Tolerances*

Based on the proposed uses and the submitted data, the Agency concludes that crop group 18 tolerances are appropriate for carfentrazone-ethyl, as opposed to individual tolerances on alfalfa and clover as proposed. These crop group tolerances are based on the submitted field trial data, which were conducted on the representative commodities for crop group 18, and the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedure.

## **V. Conclusion**

Therefore, tolerances are established for residues of carfentrazone-ethyl, including its metabolites and degradates, as set forth in the regulatory text. Compliance with the tolerance levels is to be determined by measuring only the sum of 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), calculated as the stoichiometric equivalent of carfentrazone-ethyl.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCa section 408(d) 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

## **VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 record keeping requirements.

Dated: April 25, 2012.

**Daniel J. Rosenblatt,**

*Acting 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 is amended in paragraph (a) by revising the introductory text and by alphabetically adding the following entries to the table to read as follows:

**§ 180.515 Carfentrazone-ethyl; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the herbicide carfentrazone-ethyl, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the following tolerance levels is to be determined by measuring only the sum of 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), calculated as the stoichiometric equivalent of carfentrazone-ethyl, in or on the following commodities:

Commodity	Parts per million
* * * *	* * *
Animal feed, nongrass, crop group 18, forage	2.0
Animal feed, nongrass, crop group 18, hay	5.0
Animal feed, nongrass, crop group 18, seed	15.0
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