comment in the proposed rulemaking action. This action updating the Maryland SIP provisions to address state board requirements in section 128 of the CAA for all the NAAQS may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 8, 2016,

Shawn M. Garvin,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart V—Maryland

■ 2. In § 52.1070, the table in paragraph (c) is amended by:

■ a. Removing the entries under heading ''State Government Article of the Annotated Code of Maryland'' for Sections 15–102, 15–103, 15–601, 15–602, 15–607, 15–608; and

■ b. Adding entries under heading ''State Government Article Annotated Code of Maryland'' for Sections 5–101, 5–103, 5–208, 5–501, 5–601, 5–602, 5–606, 5–607, and 5–608.

The additions read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP

Annotated Code of Maryland Citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	*
State Government Article of the Annotated Code of Maryland				
Section 5–101 (a),(e),(f), (g)(1)and (2), (h), (i), (j), (m), (n), (p), (s),(t),(bb), (ff),(gg), (ll).	Definitions	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–103(a) through (c)	Designation of Individuals as Public Officials.	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–208(a)	Determination of public official in executive agency.	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–501(a) and (c)	Restrictions on participation	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–601(a)	Individuals required to file statement.	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–602(a)	Financial Disclosure Statement—Filing Requirements.	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–606(a)	Public Records	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–607(a) through (j)	Content of statements	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.
Section 5–608(a) through (c)	Interests attributable to individual filing statement.	10/01/14	05/02/16 [Insert **Federal Register** citation].	Added; addresses CAA section 128.

* * * * *

[FR Doc. 2016–09438 Filed 4–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0030; FRL–9942–47]

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 multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 2, 2016. Objections and requests for hearings must be received on or before July 1, 2016, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0030, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone

number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA 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–2015–0030 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 July 1, 2016. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0030, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL–9927–39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8337) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide carfentrazone-ethyl, (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-,2,4-triazol-1-yl]-4-fluorobenzenepropanoate) and the metabolite carfentrazone-ethyl chloropropionic acid (a, 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 the raw agricultural commodity artichoke at 0.10 parts per million (ppm); asparagus at 0.25 ppm; peppermint, tops at 0.25 ppm; spearmint, tops at 0.25 ppm; teff, grain at 0.25 ppm; teff, forage at 1.00 ppm; teff, hay at 0.30 ppm; teff, straw at 0.10 ppm; vegetable, bulb, group 3–07 at 0.10 ppm; vegetable, fruiting, group 8–10 at 0.10 ppm; fruit, citrus, group 10–10 at 0.10 ppm; fruit, pome, group 11–10 at 0.10 ppm; fruit, stone, group 12–12 at 0.10 ppm; caneberry subgroup 13–07A at 0.10 ppm; bushberry subgroup 13–07B at 0.10 ppm; fruit, small vine climbing, subgroup 13–07F, except fuzzy kiwi fruit at 0.10 ppm; berry, low growing, subgroup 13–07G at 0.10 ppm; nut, tree, group 14–12 at 0.10 ppm; oilseed group 20 at 0.20 ppm; grain, cereal forage group 16 at 1.0 ppm; grain, cereal, hay, group 16 at 0.30 ppm; grain cereal, stover, group 16 at 0.80 ppm; and grain, cereal, straw, group 16 at 3.0 ppm.

The petitioner also proposed to amend the tolerance for banana from 0.20 ppm to 0.10 ppm and to remove the following established tolerances: Vegetable, bulb group 3 at 0.10 ppm; vegetable, fruiting, group 8 at 0.10 ppm; fruit, citrus, group 10 at 0.10 ppm; fruit, pome, group 11 at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; berry group 13 at 0.10 ppm; borage at 0.10 ppm; grape at 0.10 ppm; caneberry subgroup 13A at 0.10 ppm; nut, tree group 14 at 0.10 ppm; pistachio at 0.10 ppm; pummelo at 0.10 ppm; kiwi fruit at 0.10 ppm; canola at 0.10 ppm; cotton, undelinted seed at 0.20 ppm; crambe, seed at 0.10 ppm; flax, seed at 0.10 ppm; rapeseed, seed at 0.10 ppm; okra at 0.10 ppm; safflower seed at 0.10 ppm; salal at 0.10 ppm; sunflower seed at 0.10 ppm; strawberry at 0.10 ppm; juneberry at 0.10 ppm; lingonberry at 0.10 ppm; mustard, seed at 0.10 ppm; barley bran at 0.80 ppm; barley, flour at 0.80 ppm; corn, field, forage at 0.20 ppm; corn, sweet, forage at 0.20 ppm, corn, sweet, kernel plus cob with husk removed at 0.10 ppm; grain, cereal, forage, fodder and straw group 16, except corn and sorghum; forage at 1.0 ppm; grain, cereal, forage, fodder and straw, group 16, hay at 0.30 ppm; grain, cereal, forage, fodder and straw, group 16, stover at 0.30 ppm; grain, cereal, forage, fodder and straw, group 16, except rice; straw at 0.10 ppm; grain, cereal, group 15 at 0.10 ppm; grain, cereal, stover at 0.80 ppm; grain, cereal, straw at 3.0 ppm; millet, flour at 0.80 ppm; oat, flour at 0.80 ppm; rice, straw at 1.0 ppm; rye, bran at 0.80 ppm; rye, flour at 0.80 ppm; sorghum, forage at 0.20 ppm; sorghum, sweet at 0.10 ppm; wheat, bran at 0.80 ppm; wheat, flour at 0.80 ppm; wheat, germ at 0.80 ppm; wheat, middlings at 0.80 ppm; and wheat, shorts at 0.80 ppm.

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL–9935–29), EPA amended the initial notice of filing for pesticide petition (PP 4E8337) to include a proposal to also establish a tolerance in or on the raw agricultural commodity quinoa, grain at 0.10 ppm and psyllium, seed at 0.10 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* EPA received two comments on the notice of filing that supported the establishment of these tolerances.

Based upon review of the data supporting the petition, EPA has changed some of the levels proposed.

The reasons for these changes are 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.

In mammals, protoporphyrinogen oxidase, (PPO) is an important enzyme in heme biosynthesis and its inhibition can lead to toxic effects where heme is utilized (*e.g.,* red blood cells). The mammalian toxicity database for carfentrazone-ethyl indicates that effects observed following repeated oral exposures are consistent with those expected from PPO inhibition, toxicity of the hematopoietic system and liver.

Subchronic oral toxicity studies in rats, mice, and dogs demonstrated that the primary effects were on hematopoietic system (decreased mean corpuscular hemoglobin and mean corpuscular volume). There was also increased urinary porphyrin excretion, increased liver weights, and alterations in liver histopathology 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. Chronic studies in rats and mice found liver histopathology (pigment deposits) and fluorescence microscopy of liver sections revealed red fluorescent granules consistent with porphyrin deposits. There were no indicators of targeted effects on the immune system. The results of the acute neurotoxicity study indicated clinical signs (*i.e.,* salivation) and mild decreases in motor activity but only at the limit dose and only on the treatment day. However, there were no other signs of neurotoxicity in the rest of the database.

There was no evidence of increased susceptibility in prenatal developmental toxicity studies (rats and rabbits) or the multigenerational reproductive toxicity study in rats. Fetal effects in the rat developmental study (increase in litter incidence of wavy and thickened ribs) and offspring effects in the rat reproduction toxicity study (decreased pup body weights) were seen at or above doses eliciting blood and liver effects in maternal/parental animals, effects that are consistent with those observed in the hazard database. No developmental effects were seen in the rabbits.

Carfentrazone-ethyl has been classified as ''not likely to be carcinogenic'' based on the lack of evidence for carcinogenicity in mice and rats; therefore, a quantitative cancer risk assessment was not conducted.

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. Human Health Risk Assessment in Support of Application to Globe Artichoke, Asparagus, Mint, Psyllium, Quinoa, and Teff and Updates to Several Crop Group (CG) or Subgroup (CSG) Designations'' on pages 31–35 in docket ID number EPA–HQ–OPP–2015–0030.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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 May 4, 2012 (77 FR 26456) (FRL–9346–5).

All of the toxicological endpoints remain the same except the acute dietary endpoint has been removed. The Agency reevaluated the points of departure and available data. Previously, the acute neurotoxicity study in rats was used to evaluate acute dietary exposures; however, effects (salivation and decreased motor activity) were only seen at the LOAEL of 1000 mg/kg/day which is not considered relevant for human health risk assessment. There were no other effects seen in the database attributable to a single dose. Therefore, the previous acute dietary endpoint is no longer considered valid.

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 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. No such effects were identified in the toxicological studies for carfentrazone-ethyl; therefore, a quantitative acute dietary exposure assessment was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM–FCID). This software incorporates 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). 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 and 100 percent crop treated (PCT). Since adequate processing studies have been submitted which indicate that tolerances in/on apple juice, citrus juice, grape juice, grape raisin, dried potato, dried prune, prune juice, tomato paste, and tomato puree are unnecessary, the DEEM™ (ver 7.81) default processing factors for these commodities were reduced to 1. The DEEM™ (ver 7.81) default processing factors were retained for the remaining relevant commodities.

iii. *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.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for carfentrazone-ethyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of carfentrazone-ethyl for chronic exposures for non-cancer assessments are estimated to be 86 ppb for surface water and 43.9 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 86 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 using the following assumptions: 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. Aquatic applications by homeowners are not permitted by the label directions for use, therefore no residential handler exposure from the aquatic application scenario is anticipated.

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 are also assessed for carfentrazone-ethyl.

The Agency assessed residential handler (adult) exposure for the turf application scenario and adult post-application exposure for the aquatic exposure scenario. The most conservative exposure scenario for adults, the aquatic exposure scenario-swimmer exposure assessment (combined incidental oral and inhalation), was used to estimate post-application risk. Dermal risks assessments were not conducted because no hazard was identified via the dermal route of exposure. For children, the aquatic exposure scenario-swimmer exposure assessment was used. Since the incidental oral and inhalation PODs are based on the same study, the exposures from these routes were combined. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA 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.* There is no evidence of increased pre- and/or postnatal susceptibility following carfentrazone-ethyl exposure.

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. The toxicity database for carfentrazone-ethyl is complete. Since the last risk assessment, an immunotoxicity study has been submitted and the results of the study incorporated into the current assessment.

ii. Although effects were seen in the acute neurotoxicity study (clinical signs and mild decreases in motor activity), concern is low since: (a) The effects are minimal; (b) the effects were seen at the highest doses tested (≥1000 mg/kg); and (c) there is no evidence of neurotoxicity in the rest of the carfentrazone-ethyl database, including the subchronic neurotoxicity study.

iii. There is no evidence that carfentrazone-ethyl results in increased susceptibility in 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 postapplication 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 acute PAD (aPAD) and chronic PAD (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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, carfentrazone-ethyl is not expected to pose an acute risk.

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 78% 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 the combined short-term food, water, and residential exposures result in aggregate MOEs of 7,500 for adults (residential handlers) and 2,100 for children (1–2 years old) (hand-to-mouth exposures). 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). An intermediate-term adverse effect was identified; however carfentrazone-ethyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risks for carfentrazone-ethyl.

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 liquid chromatography/mass spectrometry/gas chromatography/electron capture detection (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.

The Codex has not established a MRL for carfentrazone-ethyl for these crops.

C. Revisions to Petitioned-For Tolerances

The Agency is revising the petitioned-for tolerance requests for asparagus, peppermint, and spearmint from the proposed 0.25 ppm to 0.10 ppm. The residue field trials for these commodities resulted in residues that are less than 0.05 ppm, the limit of quantitation (LOQ). Using the Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedures, the Agency modified the requested tolerance levels from 0.25 ppm to 0.10 ppm. In an effort to not create a potential trade irritant, the Agency also determined that the requested tolerance amendment in or on oilseed subgroup 20 at 0.20 ppm should be established on the separate subgroups for rapeseed subgroup 20A and sunflower subgroup 20B at 0.10 ppm to align with the MRLs for rapeseed and sunflower at 0.10 ppm in Canada and establish a cottonseed subgroup 20C at 0.20 ppm. Coconut will be removed and superseded by nut, tree, group 14–12. EPA also determined that the tolerance for teff straw should be 3.0 ppm based on available residue data.

Further, on November 20, 2015, the **Federal Register** published a final rule (80 FR 72599) that removed the entries in paragraph (a) in 180.515, for caneberry subgroup 13A; cotton, hulls; cotton, meal; cotton, refined oil and rice, straw, effective on May 18, 2016. Therefore, these commodities will not be removed under this action.

V. Conclusion

Therefore, tolerances are established for residues of 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 (a, 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 the raw agricultural commodity artichoke, globe 0.10 ppm; asparagus at 0.10 ppm; banana at 0.10 ppm; berry, low growing, subgroup 13–07G at 0.10 ppm; bushberry, subgroup 13–07B at 0.10 ppm; caneberry subgroup 13–07A at 0.10 ppm; cottonseed subgroup 20C at 0.20 ppm; fruit, citrus, group 10–10 at 0.10 ppm; fruit, pome, group 11–10 at 0.10 ppm; fruit, small, vine climbing, subgroup 13–07F, except Fuzzy kiwifruit at 0.10 ppm; fruit, stone, group 12–12 at 0.10 ppm; grain, cereal, group 16, forage at 1.0 ppm; grain, cereal, group 16, hay at 0.30 ppm; grain, cereal, group 16, stover at 0.80 ppm; grain, cereal, group 16, straw at 3.0 ppm; nut, tree, group 14–12 at 0.10 ppm; peppermint, tops at 0.10 ppm; psyllium, seed at 0.10 ppm; quinoa, grain at 0.10 ppm; rapeseed subgroup 20A at 0.10 ppm; spearmint, tops at 0.10 ppm; sunflower subgroup 20B at 0.10 ppm; teff, forage at 1.0 ppm; teff, grain at 0.25 ppm; teff, hay at 0.30 ppm; teff, straw at 3.0 ppm; vegetable, bulb, group 3–07 at 0.10 ppm; and vegetable, fruiting, group 8–10 at 0.10 ppm.

Additionally, tolerances are removed, for barley, bran at .80 ppm; barley, flour at 0.80 ppm; berry group 13 at 0.10 ppm; borage at 0.10 ppm; canola at 0.10 ppm; coconut at 0.10 ppm; corn, field, forage at 0.20 ppm; corn, sweet, forage at 0.20 ppm; corn, sweet, kernel plus cob with husk removed at 0.10 ppm; cotton, undelinted seed at 0.20 ppm; crambe, seed at 0.10 ppm; flax, seed at 0.10 ppm; fruit, citrus, group 10 at 0.10 ppm; fruit, pome, group 11 at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; grain, cereal, forage, fodder and straw group 16, except corn and sorghum, forage at 1.0 ppm; grain, cereal, forage, fodder and straw group 16, hay at 0.30 ppm; grain, cereal, forage, fodder and straw group 16, stover at 0.30 ppm; grain, cereal, forage, fodder and straw, group 16 except rice, straw at 0.10 ppm; grain, cereal, group 15 at 0.10 ppm; grain, cereal, stover at 0.80 ppm; grain, cereal, straw at 3.0 ppm; grape at 0.10 ppm; juneberry at 0.10 ppm; lingonberry at 0.10 ppm; millet, flour at .80 ppm; mustard, seed at 0.10 ppm; nut, tree, group 14 at 0.10 ppm; oat, flour at 0.80 ppm; okra at 0.10; pistachio at 0.10 ppm; pummelo at 0.10 ppm; rapeseed, seed at 0.10 ppm; rice, hulls at 3.5 ppm; rye, bran at 0.80 ppm; rye, flour at 0.80 ppm; safflower, seed at 0.10 ppm; salal at 0.10 ppm; sorghum, forage at 0.20 ppm; sorghum, sweet at 0.10 ppm; strawberry at 0.10 ppm; sunflower, seed at 0.10 ppm; vegetable, bulb, group 3 at 0.10 ppm; vegetable, fruiting, group 8 at 0.10 ppm; wheat, bran at 0.80 ppm; wheat, flour at 0.80 ppm; wheat, germ at 0.80 ppm; wheat middlings at 0.80 ppm; and wheat, shorts at 0.80 ppm.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: April 25, 2016.

Susan Lewis,

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. In § 180.515, the table in paragraph (a) is revised to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerance for residues.

(a) * * *

Commodity	Parts per million
Acerola	0.10
Almond, hulls	0.20
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
Artichoke, globe	0.10
Asparagus	0.10
Atemoya	0.10
Avocado	0.10
Banana	0.10
Berry, low growing, subgroup 13–07G	0.10
Birida	0.10
Bushberry subgroup 13–07B	0.10
Cacao bean, bean	0.10
Cactus	0.10
Caneberry subgroup 13A [1]	0.1
Caneberry subgroup 13–07A	0.10
Canistel	0.10
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.10
Cherimoya	0.10
Coffee, bean, green	0.10
Cotton, gin byproducts	10
Cotton, hulls [1]	0.60
Cotton, meal [1]	0.35
Cotton, refined oil [1]	1.0
Cottonseed subgroup 20C	0.20
Custard apple	0.10
Date, dried fruit	0.10
Feijoa	0.10
Fig	0.10
Fish	0.30
Fruit, citrus, group 10–10	0.10
Fruit, pome, group 11–10	0.10
Fruit, small vine climbing, subgroup 13–07F, except Fuzzy kiwifruit	0.10
Fruit, stone, group 12–12	0.10
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.10
Grain, aspirated grain fractions	1.8
Grain, cereal, group 15 (except rice grain and sorghum grain)	0.10
Grain, cereal, group 16, forage	1.0
Grain, cereal, group 16, hay	0.30
Grain, cereal, group 16, stover	0.80
Grain, cereal, group 16, straw	3.0
Grass, forage	5.0
Grass, hay	8.0
Guava	0.10
Herbs and spices group 19	2.0
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.10
Hop, dried cones	0.10
Horse, fat	0.10
Horse, meat	0.10
Horse, meat byproducts	0.10
Horseradish	0.10
Ilama	0.10
Jaboticaba	0.10
Kava, roots	0.10
Kiwifruit	0.10
Longan	0.10
Lychee	0.10
Mango	0.10
Milk	0.05
Noni	0.10
Nut, tree, group 14–12	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
Peppermint, tops	0.10
Persimmon	0.10
Pomegranate	0.10
Poultry, meat byproducts	0.10
Psyllium, seed	0.10
Pulasan	0.10
Quinoa, grain	0.10
Rambutan	0.10
Rapeseed, forage	0.10
Rapeseed subgroup 20A	0.10
Rice, grain	1.3
Rice, straw [1]	1.0
Sapodilla	0.10
Sapote, black	0.10
Sapote, mamey	0.10
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.10
Shellfish	0.30
Sorghum, grain	0.25
Soursop	0.10
Soybean, seed	0.10
Spanish lime	0.10
Spearmint, tops	0.10
Star apple	0.10
Starfruit	0.10
Stevia	0.10
Strawberrypear	0.10
Sugar apple	0.10
Sugarcane	0.15
Sunflower, subgroup 20B	0.10
Tea, dried	0.10
Teff, forage	1.0
Teff, grain	0.25
Teff, hay	0.30
Teff, straw	3.0
Ti, leaves	0.10
Ti, roots	0.10
Vanilla	0.10
Vegetable, brassica, leafy, group 5	0.10
Vegetable, bulb, group 3–07	0.10
Vegetable, cucurbit, group 9	0.10
Vegetable, foliage of legume, except soybean, subgroup 7A	0.10
Vegetable, fruiting, group 8–10	0.10
Vegetable, leafy, except brassica, group 4	0.10
Vegetable, leaves of root and tuber, group 2	0.10
Vegetable, legume, group 6	0.10
Vegetable, root and tuber, group 1	0.10
Wasaba, roots	0.10
Wax jambu	0.10

[1] Effective Date to be removed: May 18, 2016.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0524; FRL–9944–10]

Propanamide, 2-hydroxy-N, N-dimethyl- ; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of propanamide, 2-hydroxy-*N, N*-dimethyl- (CAS Reg. No. 35123–06–9) when used as an inert ingredient (solvent/co-solvent) in pesticides applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 or in pesticides applied to animals under 40 CFR 180.930 limited to maximum concentration of 20% by weight in the pesticide formulation. Spring Trading Company, LLC on behalf of BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the