EPA APPROVED GEORGIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	* *	*	*	* *
391-3-1–.02(2)(a)	General Provisions	8/1/2013	7/28/2017, [Insert citation of publication].	Except for paragraph 391–3–1–.02(2)(a)1 (as approved on 3/16/06).
*	* *	*	*	* *
391-3-1–.02(2)(e)	Particulate Emission from Manufacturing Processes.	8/1/2013	7/28/2017, [Insert citation of publication].	
*	* *	*	*	* *
391-3-1–.02(2)(p)	Particulate Emissions from Kaolin and Fuller's. Earth Processes	8/1/2013	7/28/2017, [Insert citation of publication].	
391-3-1–.02(2)(q)	Particulate Emissions from Cotton Gins.	8/1/2013	7/28/2017, [Insert citation of publication].	
*	* *	*	*	* *
391-3-1–.02(2)(gg)	Kraft Pulp Mills	8/1/2013	7/28/2017, [Insert citation of publication].	
*	* *	*	*	* *
391-3-1–.02(2)(ss)	Gasoline Transport Systems and Vapor Collection Systems.	10/6/2010	7/28/2017, [Insert citation of publication].	
*	* *	*	*	* *
391-3-1–.02(6)	Source Monitoring	8/1/2013	7/28/2017, [Insert citation of publication].	
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[FR Doc. 2017–15737 Filed 7–27–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0064; FRL–9962–96]

Fenamidone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone 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 July 28, 2017. Objections and requests for hearings must be received on or before September 26, 2017, 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–2016–0064, 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: Michael Goodis, 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–2016–0064 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 September 26, 2017. 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–2016–0064, 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 19, 2016 (81 FR 31581) (FRL–9946–02), 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 5E8434) by IR–4, Rutgers University, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.579 be amended by establishing tolerances for residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-) in or on the following raw agricultural commodities: Basil, fresh leaves at 30 parts per million (ppm); and basil, dried leaves at 200 ppm. Additionally, tolerances were proposed for the crops in the proposed crop subgroup 4–15A, leafy greens subgroup at 60.0 ppm, including amaranth, Chinese; amaranth, leafy; aster, Indian; blackjack; cat's whiskers; chervil, fresh leaves; cham-chwi; cham-na-mul; chipilin; chrysanthemum, garland; cilantro, fresh leaves; corn salad; cosmos; dandelion; dang-gwi; dillweed; dock; dol-nam-mul; ebolo; endive; escarole; fameflower; feather cockscomb; good king henry; huauzontle; jute, leaves; lettuce, bitter; lettuce, head; lettuce, leaf; orach; parsley, fresh leaves; plantain, buckhorn; primrose, English; purslane, garden; purslane, winter; radicchio; spinach; spinach, malabar; spinach, New Zealand; spinach, tanier; swiss chard; and violet, Chinese; the crops in the proposed crop subgroup 4–15B, *Brassica* leafy greens subgroup at 55 ppm, including arugula; broccoli raab; broccoli, Chinese; cabbage, Abyssinian; cabbage, seakale; Chinese cabbage, bok choy; collards; cress, garden; cress, upland; hanover salad; kale; maca; mizuna; mustard greens; radish, leaves; rape greens; rocket, wild; shepherd's purse; turnip greens; and watercress; the crops in the proposed crop subgroup 22B, leaf petiole vegetable subgroup at 60 ppm, including cardoon; celery; celery, Chinese; fuki; rhubarb; udo; and zuiki; the crops in the proposed crop group 5–15 (*Brassica* head and stem vegetable) at 5.0 ppm, including broccoli; brussels sprouts; cabbage; cabbage, Chinese, napa; and cauliflower; cottonseed subgroup 20C at 0.02 ppm; kohlrabi at 5.0 ppm; celtuce at 60 ppm; and fennel, Florence, fresh leaves and stalk at 60 ppm. That petition also requested that the following existing tolerances be removed after the petitioned-for tolerances are issued since they would be superseded by the new tolerances: *Brassica,* head and stem, subgroup 5A at 5.0 ppm; *Brassica,* leafy greens, subgroup 5B at 55 ppm; cotton, undelinted seed at 0.02 ppm; cilantro, leaves at 60 ppm; and vegetable, leafy, except *Brassica,* group 4 at 60 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* No comments were received on the notice of filing.

EPA is establishing tolerances similar to those requested by the petitioner (the leafy greens crop subgroup 4–15A; the *Brassica* leafy greens crop subgroup 4–15B; the leaf petiole vegetable crop subgroup 22B; and the *Brassica* head and stem vegetable crop group 5–15), except that due to the recent establishment of the new crop groups, the Agency is referencing the current crop groups. Additionally, in order to harmonize with Canada, the Agency is establishing a single tolerance for leafy vegetable crop group 4–16 rather than two separate tolerances for each of the crop subgroup 4–16A and 4–16B.

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 fenamidone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenamidone 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 target organs in fenamidone are the liver in mice, rats and dogs, and the thyroid in rats. Liver effects include liver weight increases, liver enlargement, and histopathological observation. Enlarged thyroid, increased thyroid weights with an increase incidence of a slight, diffuse follicular hypertrophy and/or hyperplasia were observed in rats of both sexes in the chronic toxicity study.

In the acute neurotoxicity study in rats, clinical signs included staining of the anogenital region, mucous in the feces, hunched posture, and unsteady gait. In the subchronic neurotoxicity study in rats, marginal decreases in brain weights were observed only in high dose males. Additionally, decreased brain weight occurred in the rat reproduction study. In a developmental neurotoxicity study in Wistar rats, no neurobehavioral effects and no neuropathological changes were observed at any dose in the offspring, but decreased body weight was observed during pre- and post-weaning.

Fenamidone did not demonstrate qualitative or quantitative increased susceptibility in the rat or rabbit developmental toxicity studies or the 2-generation rat reproduction study. There were no developmental effects up to the highest dose tested and in the presence of maternal toxicity in rats and rabbits. In the reproduction study in rats, decreased absolute brain weight in F2 female pups occurred at the same dose levels as decreased absolute brain weight in F1 parental females; there were no effects on fertility or other measured reproductive parameters. Immunosuppression was demonstrated at the highest dose tested in the immunotoxicity study; however, the existing risk assessment points of departure are lower and are protective of this potential effect.

Fenamidone is classified as ''not likely to be a human carcinogen'' by all relevant routes of exposure. All mutagenicity studies were negative for both the parent and plant metabolites (RPA 412636, RPA 412708, and RPA 410193), except the parent induced mutant colonies at the *tk* locus and increased chromosomal aberrations in human peripheral blood.

Specific information on the studies received and the nature of the adverse effects caused by fenamidone 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 the document titled ''Fenamidone: Human Health Risk Assessment to Support the Section (3) Registration on Basil and Crop Group Expansion on *Brassica* Head and Stem Vegetables; Leafy greens; *Brassica* Leafy Greens; and Cottonseed'' on page 33 in docket ID number EPA–HQ–OPP–2016–0064.

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 fenamidone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENAMIDONE 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 (All populations)	NOAEL = 125 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day	Acute Neurotoxicity in Rats: LOAEL = 500 mg/kg/day based on urination, staining/soiling of the anogenital region, mucous in the feces, and unsteady gait in the females.
Chronic dietary (All populations)	NOAEL= 2.83 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0283 mg/kg/day. cPAD = 0.0283 mg/kg/day	2 Year Chronic Toxicity/Carcinogenicity in Rats: LOAEL = 7.07/9.24 mg/kg/day (M/F) based on increase in severity of diffuse thyroid C-cell hyperplasia in both sexes.
Cancer (Oral, dermal, inhalation)	Fenamidone is classified as ''not likely to be a human carcinogen'' by all relevant routes of exposure.		

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 fenamidone, EPA considered exposure under the petitioned-for tolerances as well as all existing fenamidone tolerances in 40 CFR 180.579. EPA assessed dietary

exposures from fenamidone 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.

Such effects were identified for fenamidone. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, ''What We Eat in America'' (NHANES/WWEIA). As to residue levels in food, EPA used field-trial residue values, assumed 100 percent crop treated (PCT) for all commodities, and incorporated Dietary Exposure Evaluation Model (DEEM)™ default processing factors and empirical factors for processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used field-trial residue values, assumed 100 PCT for all commodities, and incorporated Dietary Exposure Evaluation Model (DEEM)™ default processing factors and empirical factors for processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenamidone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue/Percent Crop Treated information.* Although the Agency assumed 100 percent crop treated for all commodities, EPA used anticipated residue information in the assessment for this fenamidone tolerance action. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenamidone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenamidone. 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 II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS)—Index Reservoir model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fenamidone for acute exposures are estimated to be 41.7 parts per billion (ppb) for surface water and 207 ppb for ground water, and for chronic exposures are estimated to be 11.9 ppb for surface water and 207 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both the acute and chronic dietary risk assessments, the ground water concentration value of 207 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).

Fenamidone is not registered for any specific use patterns that would result in residential exposure.

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 fenamidone to share a common mechanism of toxicity with any other substances, and fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenamidone 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.* Fenamidone did not demonstrate any qualitative or quantitative increased susceptibility in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In rabbits and rats, there were no developmental effects up to the highest dose tested and in the presence of maternal toxicity. In the reproduction study in rats, decreased absolute brain weight in F2 female pups occurred at the same dose levels as decreased absolute brain weight in F1 parental females.

In the developmental neurotoxicity (DNT) study in rats, no maternal toxicity was observed at doses up to 4,700 ppm (429 mg/kg/day), although offspring systemic toxicity, manifested as decreased body weight (9–11%) and body weight gain (8–20%) during pre-weaning and decreased body weight (4–6%) during post-weaning, occurred at the highest dose tested (429 mg/kg/day). The offspring NOAEL of 1,000 ppm (92.3 mg/kg/day) indicates an increased susceptibility of offspring. Nevertheless, the concern for the increased susceptibility observed in the DNT is low because: (1) Of the lack of neurobehavioral or neuropathological changes in the offspring at any dose; and (2) the endpoints used for the various risk assessment scenarios are much more sensitive than that of the decreased bodyweight of the offspring occurring at almost half the limit-dose (429 mg/kg/day).

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 fenamidone is complete.

ii. There was no evidence of neurotoxicity in the subchronic neurotoxicity study submitted for fenamidone. There was evidence of neurotoxicity (urination, staining/soiling of the anogenital region, mucous in the feces and unsteady gait in females) in the acute neurotoxicity study, and EPA used the NOAEL from this study to assess acute dietary exposure. There was also evidence of neurotoxicity (decreased absolute brain weights) in the 2-generation rat reproduction study; however, there was no indication of increased susceptibility of offspring with regard to these effects. Finally, there was no evidence of neurotoxicity at any dose in the submitted DNT study. Based on the results of these studies, EPA concluded that there is no need for additional UFs to account for neurotoxicity.

iii. No qualitative or quantitative increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental toxicity studies was observed. There was no qualitative or quantitative increased susceptibility in the two generation reproduction study (rat). There is low concern for increased susceptibility observed in the DNT study for the reasons noted in Unit III.D.2.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and maximum or average field trial residue values. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenamidone in drinking water. These assessments will not underestimate the exposure and risks posed by fenamidone.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenamidone will occupy 4.9% of the aPAD for children 1–2 years 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 fenamidone from food and water will utilize 56% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for fenamidone.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, fenamidone is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fenamidone.

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

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, or to infants and children from aggregate exposure to fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatographic method coupled with tandem mass spectrum detection (LC/MS/MS), Method RPA 407213) 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; 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 Codex MRLs for flowerhead brassicas including broccoli, Chinese broccoli, and cauliflower at 4 ppm; cabbage at 0.9 ppm; lettuce at 20 ppm; and celery at 40 ppm which are all lower than the proposed U.S. tolerances. The U.S. tolerances cannot be harmonized (lowered) because following the label use directions could result in residues above the Codex MRLs.

C. Revisions to Petitioned-For Tolerances

The petitioner sought separate tolerances on the subgroups 4–16A at 60 ppm and 4–15B at 55 ppm. The Agency is establishing the whole group tolerance at 60 ppm for group 4–16, in order to harmonize with Canada.

V. Conclusion

Therefore, tolerances are established for residues of fenamidone in or on basil, dried leaves at 200 ppm; basil, fresh leaves at 30 ppm; celtuce at 60 ppm; cottonseed subgroup 20C at 0.02 ppm; fennel, Florence, fresh leaves and stalk at 60 ppm; kohlrabi at 5.0 ppm; leaf petiole vegetable subgroup 22B at 60 ppm; leafy vegetable group 4–16 at 60 ppm; and the vegetable, *Brassica,* head and stem, group 5–16 at 5.0 ppm.

Additionally, the following existing crop group tolerances are being removed since the commodities covered by those crop groups are covered by the newly established crop group tolerances: *Brassica,* head and stem subgroup 5A; *Brassica* leafy greens, subgroup 5B; cotton, undelinted seed; and vegetable,

leafy, except *Brassica,* group 4. The majority of the commodities in subgroups 5A and 5B and group 4 are explicitly included in the new group tolerances, but some commodity entries from the existing subgroup and group tolerances are not repeated in the new group tolerances. To clarify how those commodities remain covered, EPA provides the following explanation. First, subgroup 5A includes two commodities that are not explicitly covered by other group tolerances: ''cabbage, Chinese mustard'' and ''cavalo broccolo''. As EPA discussed in its preamble to the proposed rule amending crop groups, 79 FR 68153 (Nov. 14, 2014), ''cabbage, Chinese mustard'' is not a distinct crop, just a general reference to leafy, non-heading *Brassica* greens, which are covered in group 4–16, and ''cavalo broccolo'' is the same species as cauliflower, which is covered in group 5–16. Second, subgroup 5B includes ''mustard spinach''. In the same preamble document, EPA noted that ''mustard spinach'' is one of several names for mustard greens, which are covered by the new group 5–16. Third, group 4 includes ''tampala amaranth'', ''chrysanthemum, edible-leaved'', and ''Indian spinach''. Each of these commodity entries are alternative names for other commodities still contained in the new group 4–16 and so no longer necessary: ''edible-leaved chrysanthemum'' is another name for ''chrysanthemum garland''; the preferred name for ''tampala amaranth'' is ''Chinese amaranth''; and the preferred name for ''Indian spinach'' is ''Malabar spinach''. Therefore, residues on commodities listed in the existing group tolerances are still covered by the establishment of the new group tolerances.

Lastly, the existing entry for cilantro, leaves is being modified to read ''Cilantro, fresh leaves'' in accordance with Agency nomenclature.

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: June 12, 2017.

Michael L. Goodis,

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 § 180.579;

■ i. Add alphabetically the entries ''Basil, dried leaves''; ''Basil, fresh leaves''; ''Celtuce''; ''Cottonseed subgroup 20C''; ''Fennel, Florence, fresh leaves and stalk''; ''Kohlrabi''; ''Leaf petiole vegetable subgroup 22B''; Leafy vegetable group 4–16''; and Vegetable, *Brassica,* head and stem, group 5–16'' to the table in paragraph (a)(1):

■ ii. Remove the entries for ''*Brassica,* head and stem subgroup 5A''; ''*Brassica* leafy greens, subgroup 5B''; ''Cotton, undelinted seed''; and ''Vegetable, leafy, except *Brassica,* group 4'' from the table in paragraph (a)(1).

■ iii. Remove the entry ''Cilantro, leaves'' and add in its place ''Cilantro, fresh leaves''.

The additions and revisions read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Basil, dried leaves	200
Basil, fresh leaves	30
* * * * *	
Celtuce	60
Cilantro, fresh leaves	60
* * * * *	
Cottonseed subgroup 20C	0.02
Fennel, Florence, fresh leaves and stalk	60
* * * * *	
Kohlrabi	5.0
Leaf petiole vegetable subgroup 22B	60
Leafy vegetable group 4–16	60

Commodity	Parts per million
* * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	5.0
* * * * *	

* * * * *

[FR Doc. 2017–15743 Filed 7–27–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0825; FRL–9960–37]

Topramezone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of topramezone in or on sugarcane, cane. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 28, 2017. Objections and requests for hearings must be received on or before September 26, 2017, 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–2015–0825, 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: Michael Goodis, 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–2015–0825 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 September 26, 2017. 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–2015–0825, 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 June 22, 2016 (81 FR 40594) (FRL–9947–32), 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 5F8421) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.612 be amended by establishing a tolerance for residues of the herbicide topramezone, [3-(4,5-dihydro-isoxazol-3-yl)-4-methylsulfonyl-2-methylphenyl](5-hydroxyl-1-methyl-1*H*-pyrazol-4-yl)methanone, in or on sugarcane, cane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed 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