

a. "Commercial Base Price," "Commercial Base Pricing," or "ComBasPrice."

b. "Commercial Plus Price," "Commercial Plus Pricing," or "ComPlsPrice."

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420 Priority Mail

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425 Mail Preparation

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2.0 Marking

[Reorganize and revise section 2.0 as follows:]

2.1 Product Marking

The marking "Priority Mail" must be placed prominently on the address side of each piece of Priority Mail.

2.2 Price Marking

Except for pieces paid using permit imprint, Priority Mail pieces claiming the commercial base or commercial plus price must bear the appropriate price marking, printed on the piece or produced as part of the meter imprint or PC Postage indicia. Place the marking directly above, directly below, or to the left of the postage. Markings are as follows:

a. "Commercial Base Price," "Commercial Base Pricing," or "ComBasPrice."

b. "Commercial Plus Price," "Commercial Plus Pricing," or "ComPlsPrice."

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Stanley F. Mires,

Attorney, Legislative.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0458; FRL-8423-8]

Fenamidone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone in or on cilantro, leaves; grape; okra; turnip, greens; and vegetable, root, except sugar beet, subgroup 1B, except radish; and combined residues of fenamidone and its metabolite RPA 717879 in or on corn, field, forage; corn, field, grain; corn, field, stover; corn,

sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; soybean, forage; soybean, hay; and soybean, seed. It also removes existing permanent and time-limited tolerances on carrot that are superseded by the new tolerance on vegetable, root, except sugar beet, subgroup 1B, except radish. The new tolerance on grape will be a tolerance with regional registration (East of the Rocky Mountains) and will replace the current tolerance which is restricted to imported grapes. Interregional Research Project Number 4 (IR-4) and Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 15, 2009. Objections and requests for hearings must be received on or before September 14, 2009, 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-2008-0458. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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-2008-0458 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 14, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0458, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line 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. Petition for Tolerance

In the **Federal Registers** of June 13, 2008 (73 FR 33814) (FRL-8367-3) and December 3, 2008 (73 FR 73644) (FRL 8386-9), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7350) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540; and a pesticide petition (PP 8F7410) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. PP 8E7350 requested that 40 CFR 180.579 be amended by establishing tolerances for residues of the fungicide fenamidone, 4*H*-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-, in or on vegetables, root, except sugar beet, subgroup 1B, except radish at 0.2 parts per million (ppm); turnip, leaves at 55 ppm; coriander, leaves at 60 ppm; okra at 3.5 ppm; and a tolerance with regional registration for residues of fenamidone on grape at 1.0 ppm. The grape tolerance would replace an existing grape tolerance that was established only to address the importation of grapes containing fenamidone residues. PP 8F7410 requested that 40 CFR 180.579 be amended by establishing tolerances for indirect or inadvertent residues of fenamidone and its metabolite RPA 717879, 2,4-imidazolidinedione, 5-methyl-5-phenyl, in or on corn, field, forage at 0.50 ppm; corn, field grain at 0.02 ppm; corn, stover at 0.35 ppm; corn, sweet, forage at 0.15 ppm; corn, sweet, kernel plus cob with husks removed at 0.02 ppm; soybean, forage at

0.20 ppm; soybean, hay at 0.20 ppm; and soybean, seed at 0.02 ppm (all in PP 8F7410). The notices referenced summaries of the petitions prepared by Bayer CropScience, the registrant, which are available to the public in docket ID numbers EPA-HQ-OPP-2008-0458 (PP 8E7350) and EPA-HQ-OPP-2006-0848 (PP 8F7410) at <http://www.regulations.gov>. There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA has revised the commodity terms, and/or tolerance levels for several commodities. EPA also determined that separate tolerances should be established on stover from field and sweet corn. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of fenamidone on cilantro, leaves at 60 ppm; okra at 3.5 ppm; turnip, greens at 55 ppm; and vegetable, root, except sugar beet, subgroup 1B, except radish at 0.15 ppm; a tolerance with regional registration in or on grape at 1.0 ppm; and tolerances for combined residues of fenamidone and its metabolite RPA 717879 in or on corn, field, forage at 0.25 ppm; corn, field, grain at 0.02 ppm; corn, field,

stover at 0.40 ppm; corn, sweet, forage at 0.15 ppm; corn, sweet, kernel plus cob with husks removed at 0.02 ppm; corn, sweet, stover at 0.20 ppm; soybean, forage at 0.15 ppm; soybean, hay at 0.25 ppm; and soybean, seed at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Fenamidone has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is a moderate eye irritant, but is not a dermal irritant or a dermal sensitizer. The liver is the target organ in chronic studies in the rat, mouse and dog. The thyroid is also a target organ in the rat. There is no evidence of immunotoxicity in the available toxicity studies with fenamidone and no indication of carcinogenicity in the carcinogenicity studies conducted in rats and mice. EPA has classified fenamidone as "not likely to be a human carcinogen" by all relevant routes of exposure.

Fenamidone did not demonstrate any qualitative or quantitative increased susceptibility of fetuses or offspring in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In the rat reproduction study (Sprague Dawley rat), decreased absolute brain weight and pup body weight occurred at the same dose levels as decreased absolute brain weight and parental body weight, food consumption and increased liver and spleen weight. Developmental toxicity (decreased fetal weights and incomplete ossification) was observed in the rat only at the limit dose. Fenamidone did not produce developmental toxicity in the rabbit or reproductive toxicity in the rat.

No treatment-related effects were observed on motor activity or in the functional observation battery (FOB) parameters measured in the subchronic neurotoxicity study in rats. In this subchronic neurotoxicity study, marginal decreases in brain weights were observed only in high dose males. In the acute neurotoxicity study in rats, the most commonly observed clinical sign was staining/soiling of the anogenital region. Other day-1 FOB findings included mucous in the feces,

hunched posture and unsteady gait. 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.

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 *Fenamidone. Human Health Risk Assessment to Support Section 3 Proposals to Add New Uses on the Root Vegetable Subgroup 1B (except radish), Okra, Turnip Greens, Cilantro Leaves, Grapes Grown East of the Rock Mountains and Rotational Crop Uses for Field Corn, Sweet Corn and Soybeans*, page 30 in docket ID number EPA-HQ-OPP-2008-0458.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 fenamidone used for human risk assessment can be found at <http://www.regulations.gov> in the document *Fenamidone. Human Health Risk Assessment to Support Section 3 Proposals to Add New Uses on the Root Vegetable Subgroup 1B (except radish), Okra, Turnip Greens, Cilantro Leaves, Grapes Grown East of the Rock Mountains and Rotational Crop Uses for Field Corn, Sweet Corn and Soybeans*, page 12 in docket ID number EPA-HQ-OPP-2008-0458.

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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that 100% of all crops with existing or proposed registrations are treated with fenamidone and that residues are present at maximum field trial levels.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed that 100% of all crops with existing or proposed registrations are treated with fenamidone and that residues are present at maximum field trial levels.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified fenamidone as "not likely to be carcinogenic to humans;" therefore, an exposure assessment for

evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information.* 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.

EPA did not use PCT information in assessing dietary exposure to fenamidone.

2. *Dietary exposure from drinking water.* The fenamidone residues of toxicological concern in drinking water include parent fenamidone and its degradation products, RPA 412636, RPA 412108, RPA 411639, RPA 413255, RPA 409446, and RPA 410995. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenamidone and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenamidone and its degradates. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fenamidone and its degradates for acute exposures are estimated to be 47.88 parts per billion (ppb) for surface water and 176 ppb for ground water. The EDWCs of fenamidone and its degradates for chronic exposures for non-cancer assessments are estimated to be 12.86 ppb for surface water and 176 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 176 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 website at <http://www.epa.gov/pesticides/cumulative>.

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.* The pre- and postnatal toxicity database for fenamidone includes rat and rabbit developmental toxicity studies, a rat developmental neurotoxicity study (DNT) and a 2-generation reproduction toxicity study in rats. No evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure was observed in the developmental toxicity studies. There was no developmental toxicity in rabbit fetuses up to 100 milligrams/kilogram/

day (mg/kg/day), the highest dose tested (HDT); whereas an increase in absolute liver weight was observed in the does at 30 and 100 mg/kg/day. Since the liver was identified as one of the principal target organs in rodents and dogs, the occurrence of this finding in rabbits at 30 and 100 mg/kg/day was considered strong evidence of maternal toxicity. In the rat developmental study, developmental toxicity manifested as decreased fetal body weight and incomplete fetal ossification in the presence of maternal toxicity in the form of decreased body weight and food consumption at the limit dose (1,000 mg/kg/day). The effects at the limit dose were comparable between fetuses and dams. No quantitative or qualitative evidence of increased susceptibility was observed in the 2-generation reproduction study in rats. In that study, both the parental and offspring LOELs were based on decreased absolute brain weight in female F₁ adults and female F₂ offspring at 89.2 mg/kg/day. At 438.3 mg/kg/day, parental effects consisted of decreased body weight and food consumption, and increased liver and spleen weight. Decreased pup body weight was also observed at the same dose level of 438.3 mg/kg/day. There were no effects on reproductive performance up to 438.3 mg/kg/day (HDT).

The results of the DNT study indicated an increased susceptibility of offspring. There was no maternal toxicity at the HDT (429 mg/kg/day). Effects in the offspring included decreased body weight (9–11%) and body weight gain (8–20%) during pre-weaning and decreased body weight (4–6%) during post-weaning at 429 mg/kg/day (LOAEL). There were no neurobehavioral effects and no neuropathological changes at any dose in the offspring. The concern for the increased susceptibility observed in the DNT is low because:

- i. Of the lack of neurobehavioral or neuropathological changes in the offspring at any dose;
- ii. A clear NOAEL for the adverse effects in the study was identified;
- iii. 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); and
- iv. The NOAELs of 10.4, 5.4 and 2.83 mg/kg/day used for short-term, intermediate-term and long-term risk assessments, respectively, are considerably (9–45 fold) lower than the offspring NOAEL of 92.3 mg/kg/day in the DNT.

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 adequate to assess the pre- and postnatal toxicity of fenamidone. In accordance with the revised 40 CFR part 158 Data Requirements for Pesticides, an immunotoxicity study (870.7800) is required for fenamidone. In the absence of specific immunotoxicity studies, EPA has evaluated the available fenamidone toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system in any study with fenamidone, and fenamidone does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on these considerations, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for fenamidone; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

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, mucus 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. There is no evidence that fenamidone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in offspring in the 2-generation reproduction study. Although there is evidence of increased quantitative susceptibility in the DNT study, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity

endpoints and traditional UFs to be used in the risk assessment of fenamidone.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on reliable data from residue field trials and assuming 100 PCT. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenamidone in drinking water. Residential exposure is not expected from the existing and new uses of fenamidone. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenamidone will occupy 5% of the aPAD for children, 1 to 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 88% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for fenamidone.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure take into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenamidone is not registered for any use patterns that would result in residential exposure. Therefore, the short-term or

intermediate-term aggregate risk is the sum of the risk from exposure to fenamidone through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* Fenamidone is classified as “not likely to be carcinogenic to humans” and is, therefore, not expected to pose a cancer risk.

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)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no Codex, Canadian or Mexican MRLs (maximum residue levels) for residues of fenamidone in or on any of the commodities requested in these petitions.

C. Revisions to Petitioned-for Tolerances

EPA has revised the commodity terms and/or tolerance levels for several commodities. EPA revised the commodity terms proposed by IR–4 as “vegetables, root, except sugar beet, subgroup 1B, except radish”; “coriander, leaves”; and “turnip, leaves” to read “vegetable, root, except sugar beet, subgroup 1B, except radish”; “cilantro, leaves”; and “turnip, greens”; and determined that separate tolerances were needed for stover from field and sweet corn (i.e., “corn, field, stover” and “corn, sweet, stover”) to agree with the Food and Feed Vocabulary. EPA revised the tolerance level for “vegetable, root, except sugar beet, subgroup 1B, except radish” from 0.2 ppm to 0.15 ppm to agree with the existing tolerance on carrot, the representative commodity on which the proposed tolerance was based. EPA revised the tolerances for “corn, field, forage” from 0.50 ppm to 0.25 ppm”; “corn, field, stover” from 0.35 ppm to 0.40 ppm; “corn, sweet, stover” from 0.35 ppm to 0.20 ppm; “soybean, forage” from 0.20 ppm to 0.15 ppm; and “soybean, hay” from 0.20

ppm to 0.25 based on analyses of field trial data using the Agency’s Tolerance Spreadsheet in accordance with the Agency’s *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

V. Conclusion

Therefore, tolerances are established for residues of fenamidone, 4*H*-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-, on cilantro, leaves at 60 ppm; okra at 3.5 ppm; turnip, greens at 55 ppm; and vegetable, root, except sugar beet, subgroup 1B, except radish at 0.15 ppm; a tolerance with regional registration is established for residues of fenamidone in or on grape at 1.0 ppm; and tolerances are established for combined residues of fenamidone and its metabolite RPA 717879 in or on corn, field, forage at 0.25 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 0.40 ppm; corn, sweet, forage at 0.15 ppm; corn, sweet, kernel plus cob with husks removed at 0.02 ppm; corn, sweet, stover at 0.20 ppm; soybean, forage at 0.15 ppm; soybean, hay at 0.25 ppm; and soybean, seed at 0.02 ppm. The existing permanent and time-limited tolerances on carrot are removed, since residues on carrots will be covered by the new tolerance on vegetable, root, except sugar beet, subgroup 1B, except radish.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of FFCA, 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 section 408(n)(4) of FFCA. 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 recordkeeping requirements.

Dated: July 1, 2009.

G. Jeffery Herndon,

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 180.579 paragraph (a)(1) table is amended by removing the commodities “carrot” and “grape (imported)” and adding the following commodities; by removing and reserving paragraph (b); by revising paragraph (c); and by adding the following commodities to the table in paragraph (d) to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * *	* *
Cilantro, leaves	60
Okra	3.5
Turnip, greens	55
Vegetable, root, except sugar beet, subgroup 1B, except radish	0.15
* * *	* *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* A tolerance with regional registration as defined in §180.1(m) is established for residues of fenamidone, 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-, in or on the following commodity:

Commodity	Parts per million
Grape ¹	1.0

¹Applicable to grapes grown East of the Rocky Mountains.

(d) *Indirect or inadvertent residues.* * * *

Commodity	Parts per million
Corn, field, forage	0.25
Corn, field, grain	0.02
Corn, field, stover	0.40
Corn, sweet, forage	0.15

Commodity	Parts per million
Corn, sweet, kernel plus cob with husks removed	0.02
Corn, sweet, stover	0.20
Soybean, forage	0.15
Soybean, hay	0.25
Soybean, seed	0.02
* * *	* *

[FR Doc. E9-16817 Filed 7-14-09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[EPA-HQ-OPPT-2005-0049; FRL-8422-7]

RIN 2070-AJ48

Lead; Minor Amendments to the Renovation, Repair, and Painting Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a final rule making two minor revisions to the final Lead Renovation, Repair, and Painting Program (RRP) rule that published in the **Federal Register** on April 22, 2008. First, this final rule requires accredited providers of renovator or dust sampling technician training to submit post-course notifications, including digital photographs of each successful trainee, to EPA. The 2008 rule establishes accreditation, training, certification, and recordkeeping requirements as well as work practice standards on persons performing renovations for compensation in most pre-1978 housing and child-occupied facilities. The post-course notification requirement, designed to supply important information for EPA’s compliance monitoring efforts, was inadvertently omitted from the final RRP rule’s regulatory text. In addition, this final rule removes the requirement for accredited lead-based paint activities training providers—those who provide inspector, risk assessor, project designer, and abatement supervisor and worker training—to submit to EPA a digital photograph of each successful trainee along with their post-course notifications. That requirement, inadvertently imposed as part of the final RRP rule, is unnecessary because EPA already receives photographs of these individuals through other means.

DATES: This final rule is effective July 15, 2009.