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 the FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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: October 10, 2007.

Donald R. Stubbs,

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. 442 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Beet, garden, roots	0.45
Beet, garden, tops	15
* * *	* *
Grain, aspirated fractions	70
* * *	* *
Groundcherry	0.5
* * *	* *
Mayhaw	1.4
* * *	* *
Peanut	0.05
* * *	* *
Pepino	0.5
* * *	* *
Pistachio	0.05
* * *	* *
Radish, tops	4.5
* * *	* *
Soybean, hulls	0.50
Soybean, refined oil	0.30
Soybean, seed	0.2
* * *	* *
Vegetable, root, subgroup 1B except sugar beet and garden beet	0.10
* * *	* *

* * * * *

[FR Doc. E7–20753 Filed 10–23–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0848; FRL–8152–9]

Fenamidone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone in or on carrot; sunflower; Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; vegetable, fruiting, group 8, except nonbell pepper; pepper, nonbell; vegetable, leafy, except Brassica, group 4; cotton, gin byproducts; cotton, undelinted seed; and combined residues of fenamidone and its metabolite RPA 717879 in or on strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 24, 2007. Objections and requests for hearings must be received on or before December 24, 2007, 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–2006–0848. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2006–0848 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 December 24, 2007.

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–2006–0848, 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'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 Register** of November 8, 2006 (71 FR 65506-65507) (FRL–8099–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540, and Bayer Crop Science, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petitions requested that 40 CFR 180.579 be amended by establishing tolerances for residues of the fungicide fenamidone, (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-,(S)-), in or on carrot at 0.15 parts per million (ppm) (PP 6E7109); sunflower at 0.08 ppm (PP 5E6924); brassica, head and stem, subgroup 5A at 4.0 ppm (PP# 5E6925); brassica, leafy greens, subgroup 5B at 35 ppm (PP 5E6925); vegetables, fruiting, group 8, except nonbell peppers at 2.0 ppm (PP 5E6925); vegetable, leafy, except brassica, group 4 at 35 ppm (PP 5E6925); cotton, undelinted seed at 0.02 ppm (PP 5F6898); and cotton, gin byproducts at 0.02 ppm (PP 5F6898), and residues of the fungicide fenamidone (4-H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methlthio)-5-phenyl-3-(phenylamino)-, (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), in or on strawberry at 0.02 ppm (PP 5F6898).

This notice referenced a summary of the petition prepared by Bayer Crop Science, the registrant, which is available to the public in the docket, at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has revised the tolerance levels for some of the proposed petitions. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for residues of fenamidone on carrot at 0.15 ppm; sunflower at 0.02 ppm; Brassica, head and stem, subgroup 5A at 5.0 ppm; Brassica, leafy greens, subgroup 5B at 55 ppm; vegetable, fruiting, group 8, except nonbell pepper at 1.0 ppm; pepper, nonbell at 3.5 ppm; vegetable, leafy, except Brassica, group 4 at 60 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; and strawberry at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the 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. 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 in Human Health Risk Assessment for Fenamidone on pages 31-34. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2006–0848. The docket is electronically available at http://www.regulations.gov.

The existing toxicological database for fenamidone supports the establishment of permanent tolerances for residues of fenamidone in or on the commodities proposed in this action. Fenamidone has low acute toxicity via the oral, dermal, and inhalation routes with all studies being in toxicity category III or IV. It is a moderate eye irritant, but is not a dermal irritant or a dermal sensitizer. The acute oral assay tests indicated that female rats were more sensitive to the parent than male rats.

The target organs in chronic studies in the mouse and dog were the liver, and in the rat were the liver and thyroid. In the chronic toxicity rat study, the systemic NOAEL was based on diffuse C-cell hyperplasia of the thyroid in both sexes as the most sensitive indicator of toxicity. At higher doses, follicular cells and the liver were affected. The similarity in the systemic NOAELs and the type of toxicity observed (primarily liver) for the 90–day rat studies with the parent and plant metabolites (RPA 412636, RPA 412708, and RPA 410193) demonstrated that, on a subchronic basis, the plant metabolites were not more toxic than the parent. The carcinogenic potential was negative for mice dosed up to the limit dose with liver effects seen as the systemic toxicity. In rats, fenamidone did produce a statistically significant increase ($p < 0.01$ for both trend and pair-wise comparison) in benign, endometrial stromal polyps at 5,000 ppm, the highest dose tested (HDT). Consultation with an EPA consulting pathologist resulted in these findings being characterized as benign proliferate lesions that do not progress to malignant carcinomas or sarcomas. Based on these findings, EPA classified fenamidone as ''not likely'' to be a human carcinogen. All mutagenicity studies were negative for both the parent and plant metabolites (RPA 412636, RPA 412708, and RPA 410193).

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, there were no developmental effects up to the HDT and in the presence of maternal toxicity. In rats, developmental findings and maternal findings both occurred at the limit dose. In the 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. There were no effects on fertility and other measured reproductive parameters. In the acute neurotoxicity study in rats, the most commonly observed clinical sign was staining/soiling of the anogenital region at 500 and 2,000 milligrams/kilogram (mg/kg). These findings were observed at low incidences and were consistent with those observed on day 1 of the functional observational battery (FOB). Other day-1 FOB findings included mucous in the feces of the 500 and 2,000 mg/kg males and females; hunched posture when walking or sitting in the 2,000 mg/kg females; and unsteady gait in the 500 and 2,000 mg/kg females. In the subchronic neurotoxicity study (Sprague Dawley rat), marginal decrease in brain weights was observed only in high dose males. Additionally, fenamidone displayed decreased brain weight in F_1 female adults and F_2 female offspring in the rat reproduction study. Other evidence of neurotoxicity (clinical signs such as lethargy, prostration, tremors, eye closure, unsteady gait) was observed in a mouse bone marrow micronucleus assay with plant metabolites (RPA 412636 and RPA 412708).

Based on the evidence of neurotoxicity summarized above, EPA requested a developmental neurotoxicity (DNT) study conducted with Sprague Dawley rats. The petitioner submitted a DNT study conducted with Wistar rats. In this study, no maternal toxicity was observed at doses up to 4,700 ppm (429 mg/kg/day). The offspring systemic toxicity manifested as decreased body weight (9 to 11%) and body weight gain (8 to 20%) during pre-weaning and decreased body weight (4 to 6%) during post-weaning. The offspring NOAEL was 1,000 ppm (92.3 mg/kg/day). The results of this DNT study suggest increased susceptibility of offspring to fenamidone; however, the concern for increased susceptibility is low since there is a well established NOAEL protecting the offspring and the NOAEL used for establishing the chronic reference dose (cRfD) is approximately 45X below the NOAEL observed for the offspring toxicity in the DNT study. EPA reviewed these data and determined that the 10X database uncertainty factor due to lack of DNT should be removed. However, since this study was conducted using Wistar rats rather than Sprague Dawley rat as requested, EPA requested a modified DNT in the Sprague Dawley rat with measurement of the following endpoint: brain weights (samples should be retained for possible morphometric measurements); this study is necessary to confirm the lack of brain weight changes in the Wistar rat DNT.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for fenamidone used for human risk assessment can be found at *www.regulations.gov* in the document entitled ''Fenamidone Human Health Risk Assessment'' on page 12 in Docket ID EPA–HQ–OPP–2006–0848.

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. The Agency generated dietary exposure estimates for exposure to fenamidone and its residues of concern. The following paragraphs are summaries of these analyses. EPA assessed dietary exposures from fenamidone 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 one-day or single exposure.

In estimating acute dietary exposure to fenamidone, EPA used food consumption information from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed maximum field trial residues for the residues of concern for risk assessment and 100% crop treated. The Dietary Exposure Evaluation Model (DEEM™) (ver. 7.81) default processing factors were maintained for all commodities excluding grape juice, dried potato, tomato paste, and tomato puree; for these commodities; the DEEM™ (ver. 7.81) default processing factors were reduced to 1 based on processing data (grape), or empirical processing factors were applied to the RAC residue (tomato paste, tomato puree, and dried potato).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment for fenamidone, EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed maximum field trial residues for the residues of concern for risk assessment and 100% crop treated. DEEM™ (ver. 7.81) default processing factors were maintained for all commodities excluding grape juice, dried potato, tomato paste, and tomato puree; for these commodities, the DEEM™ (ver. 7.81) default processing factors were reduced to 1 based on processing data (grape), or empirical processing factors were applied to the RAC residue (tomato paste, tomato puree, and dried potato).

iii. *Cancer*. EPA has classified fenamidone as a ''not likely'' human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

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 pursuant to FFDCA section 408(f)(1) require 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 this tolerance.

2. *Dietary exposure from drinking water*. Biotransformation (metabolism) under aerobic conditions and direct photolysis in water are the major routes of transformation of fenamidone in the environment. Fenamidone half-lives were 5 to 8 days in aerobic soils, 67 to 128 days in aerobic water-sediments, and 5 to 8 days in water exposed to summer sunlight (direct photolysis). Fenamidone is highly persistent in anaerobic water-sediment systems (half-life longer than 1,000 days). Adsorption of fenamidone onto soils is moderate (mean K_{oc} less than 388). Therefore, fenamidone is not persistent in soil or in shallow water under aerobic conditions. Under field conditions, the half-lives of fenamidone ranged from 9 to 82 days. Given that biotransformation is the major route of degradation and considering the widespread, potential use areas of different soils, microbial population and activity, water bodies, climates/meteorology, and agricultural practices, high variability in persistence in soil and water-sediment systems is to be expected. Likewise, variability in type and relative amount of products would also be expected. EPA reviewed the environmental fate data for fenamidone and concluded that the residues of concern in water are RPA 412636, RPA 412708, RPA 411639, RPA 413255, and RPA 409446, RPA 410995RPA-412636.

The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for fenamidone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of fenamidone. 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 the Screening Concentration in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of fenamidone for acute exposures are estimated to be 41.66 parts per billion (ppb) for surface water and 178 ppb for ground water. The EECs for chronic exposures are estimated to be 11.88 ppb for surface water and 178 ppb for ground water. Estimates were performed for combined residues of parent fenamidone and the residues of concern previously mentioned.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute and chronic dietary risk assessment, the water concentration value of 178 ppb (highest estimate; based on three applications at 0.267 pounds of active ingredient per acre) was used to access 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 use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fenamidone and 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 not assumed that fenamidone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. No quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental toxicity studies was observed. There was no developmental toxicity in rabbit fetuses up to 100 mg/kg/day (HDT), which resulted in an increased absolute liver weight in the does. 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 LOAELs were based on decreased absolute brain weight in female F_1 adults and female F_2 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 DNT study conducted with Wistar rats showed no maternal toxicity up to 429 mg/kg/day. The offspring systemic toxicity manifested as decreased body weight (9 to 11%) and body weight gain (8 to 20%) during pre-weaning and decreased body weight (4 to 6%) during post-weaning with a NOAEL of 92.3 mg/kg/day. The results of this DNT study suggest increased susceptibility of offspring to fenamidone; however, the concern for increased susceptibility is low since there is a well established NOAEL protecting the offspring and the NOAEL used for establishing the chronic reference dose (cRfD; see below) is approximately 45x below the NOAEL observed for the offspring toxicity in the DNT study.

There is confidence that the sensitivity of any developmental neurological effects have been identified. EPA required a DNT based on a marginal decrease in brain weight in high dose males in the subchronic neurotoxicity study in rats, decreased brain weight in female adults and female offspring in the 2-generation reproduction study, and clinical signs that may be indicative of neurotoxic effects at relatively high doses in several studies. A DNT was conducted and showed no neurotoxic effects. Because, however, the DNT was conducted in a different strain of rat (Wistar) than the studies that showed brain effects (Sprague-Dawley), EPA has required that an abbreviated DNT be conducted in the Sprague-Dawley rat that focuses on brain effects. Due to the clear NOAEL from the existing DNT as well as the clear NOAELs in the studies evidencing brain effects, EPA regards the abbreviated DNT as confirmatory in nature and unlikely to change the characterization or magnitude of the risk for fenamidone.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicology database is complete other than the confirmatory DNT study.

ii. No qualitative or quantitative increased susceptibility in the developmental toxicity studies (rat and rabbit).

iii. No qualitative or quantitative increased susceptibility in the 2-generation reproduction study (rat).

iv. Low concern for residual uncertainties in the DNT study (rat) since there is a well established offspring NOAEL which is 45X greater than the NOAEL used to establish the chronic dietary endpoint.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues or maximum levels from crop field trials. Conservative ground and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by fenamidone.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 5% of the aPAD for the population group children 1 to 2 years old, the highest estimated acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenamidone from food and water will utilize 82% of the cPAD for the population group children 1 to 2 years old, the highest estimated chronic risk. There are no residential uses for fenamidone that result in chronic residential exposure to fenamidone.

3. *Aggregate cancer risk for U.S. population*. EPA has classified fenamidone as a ''not likely'' human carcinogen. EPA does not expect fenamidone to pose a cancer risk.

4. *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 (a liquid chromatograph/mass spectrometer/mass spectrometer (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 currently no established Codex maximum residue limits for the proposed tolerances.

C. Explanation of Tolerance Revisions

1. *Sunflower*. The geographical representation of the sunflower field trial data fulfill the data requirements suggested in OPPTS 860.1500 for sunflower. Based on the sunflower seed field trial data, EPA concludes that a sunflower seed tolerance for residues of fenamidone *per se* of 0.02 ppm is appropriate.

2. *Brassica, head and stem, subgroup 5-A*. The geographical representation of the broccoli, cabbage, and mustard green field trial data fulfill the data requirements suggested in OPPTS 860.1500 for a Brassica (cole) leafy vegetables crop group registration or crop subgroup 5a and 5b tolerances. EPA notes that these field trials employed 1.0x the proposed single application rate but 1.4x the proposed seasonal rate. Based on the residue decline data which indicated that combined residues of fenamidone, RPA 717879, RPA 408056, and RPA 405862 reduced 52% (broccoli), 43% (cabbage), and 87% (mustard green) as the pre-harvest (PHI) increased from 0 to 7 days, EPA concludes that the final application, which was conducted at 1x the proposed rate, will drive the magnitude of the residue in or on the Brassica (cole) leafy vegetables. Based on the broccoli, cabbage, and mustard green field trial data and the tolerance spreadsheet calculator, tolerances for residues of fenamidone *per se* of 5.0 ppm, 1.3 ppm, and 55 ppm were recommended. Since the maximum residues and recommended tolerances are not within 5x, EPA concludes that a crop group tolerance is not appropriate but that crop subgroup tolerances are appropriate. EPA concludes that a head and stem Brassica crop subgroup 5a tolerance of 5.0 ppm and a leafy Brassica greens crop subgroup 5b tolerance of 55 ppm for residues of fenamidone *per se* are appropriate.

3. *Vegetable, fruiting, group 8*. The geographical representation of the tomato and pepper field trial data fulfill the data requirements suggested in OPPTS 860.1500 for a fruiting vegetable crop group registration. EPA notes that these field trials employed 1.0x the proposed single application rate but 1.4x the proposed seasonal rate. Based on the residue decline data which indicated that combined residues of fenamidone, RPA 717879, RPA 408056, and RPA 405862 reduced 65% (bell pepper) and 34 to 73% (tomato) as the PHI increased from 0 to 21 (bell pepper) and 7 to 35 days (tomato; nonbell pepper decline data were not submitted), EPA concludes that the final application, which were conducted at 0.7 to 1.0x the proposed rate, will drive the magnitude of the residue in or on fruiting vegetables.

4. *Pepper, nonbell*. Based on the tomato, bell pepper, and nonbell pepper field trial data and the tolerance spreadsheet calculator, tolerances for the residues of fenamidone *per se* of 1.0 ppm, 0.40 ppm, and 3.5 ppm were recommended. Since the pepper and nonbell pepper maximum residues and recommended tolerances are not within 5X, EPA concludes that a fruiting vegetable crop group tolerance is not appropriate. Based on the residue data and since tomato is the major food commodity in the fruiting vegetable crop group, EPA concludes that it is appropriate to set nonbell pepper and fruiting vegetable (except nonbell pepper) tolerances. Therefore, EPA concludes that the following tolerances for residues of fenamidone *per se* are appropriate: fruiting vegetable (except nonbell pepper) - 1.0 ppm and nonbell peppers - 3.5 ppm (the currently established tomato tolerance should be deleted).

5. *Vegetable, leafy, except Brassica, group 4*. The geographical representation of the lettuce (head and leaf), celery, and spinach field trial data fulfill the data requirements suggested in OPPTS 860.1500 for leafy vegetables (except Brassica) crop group registration. EPA notes that these field trials employed 1.0x the proposed single application rate but 1.3 to 1.4x the proposed seasonal rate. Based on the residue decline data which indicated that combined residues of fenamidone, RPA 717879, RPA 408056, and RPA 405862 reduced 36% (celery), 70% (spinach), and 99% (leaf lettuce) as the PHI increased from 0 to 7 days, EPA concludes that the final application, which was conducted at 1x the proposed rate, will drive the magnitude of the residue in or on leafy vegetables (except Brassica). Based on the head lettuce, leaf lettuce, celery, and spinach field trial data and the tolerance spreadsheet calculator, tolerances for the residues of fenamidone *per se* of 18 ppm, 45 ppm, 45 ppm, and 60 ppm were recommended. EPA concludes that a leafy vegetables (except Brassica) crop group tolerance of 60 ppm for residues of fenamidone *per se* is appropriate (the currently established lettuce, leaf and lettuce, head tolerances should be deleted).

V. Conclusion

Therefore, the tolerances are established for residues of fenamidone, (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-(S)-), in or on carrot at 0.15 ppm; sunflower at 0.02 ppm; Brassica, head and stem, subgroup 5A at 5.0 ppm; Brassica, leafy greens, subgroup 5B at 55 ppm; vegetable, fruiting, group 8, except nonbell pepper at 1.0 ppm; pepper, nonbell at 3.5 ppm; vegetable, leafy, except Brassica, group 4 at 60 ppm; cotton, gin byproducts at 0.02 ppm; and cotton, undelinted seed at 0.02 ppm.

The tolerance is also established for combined residues of fenamidone, (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methlthio)-5-phenyl-3-(phenylamino, (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on strawberry at 0.02 ppm.

Tolerances should be deleted for lettuce, leaf; lettuce; head; and tomato as these commodities are included in the newly established ''vegetable, fruiting, group 8, except nonbell peppers,'' group, and vegetable, leafy, except Brassica, group 4.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) 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 FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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 FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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: October 5, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.579 is amended by alphabetically adding the commoditiesBrassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B;carrot; cotton, gin byproducts; cotton, undelinted seed, pepper, nonbell; sunflower; vegetable, fruiting, group 8, except nonbell pepper; vegetable, leafy, except Brassica, group 4; and by removing lettuce, head; lettuce, leaf; and tomato from the table in paragraph (a)(1) and by alphabetically adding strawberry to the table in paragraph (d) to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	55
Carrot	0.15
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
* * * *	*
Pepper, nonbell	3.5
* * * *	*
Sunflower	0.02
* * * *	*
Vegetable, fruiting, group 8, except nonbell pepper	1.0
Vegetable, leafy, except Brassica, group 4	60
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* * * * *

(d) * * *

Commodity	Parts per million
* * * *	*
Strawberry	0.15
* * * *	*

[FR Doc. E7–20670 Filed 10–23–07; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 06–123; FCC 07–174]

Establishment of Policies and Service Rules for the Broadcasting-Satellite Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this *Order on Reconsideration,* the Federal Communications Commission (Commission) reconsiders, in part, *sua sponte,* its *Report and Order* in this proceeding in which it adopted processing and service rules for the 17/24 GHz Broadcasting-Satellite Service (BSS). In the *Report and Order,* the Commission adopted a framework in which 17/24 GHz BSS space stations would operate at orbital locations spaced at four-degree intervals, as set forth in Appendix F of the *Report and Order.* In this Order on Reconsideration, the Commission provides additional flexibility to 17/24 GHz BSS space station operators by allowing them to operate their space stations, upon request, at locations other than those specified in Appendix F of the *Report and Order.* Specifically, the Commission will assign space stations to orbital locations that are offset from the Appendix F locations by up to one degree, without requiring them to reduce power or accept additional interference, if there are no licensed or prior-filed applications for 17/24 GHz BSS space stations less than four degrees away from the proposed offset space station.

DATES: Effective November 23, 2007.

ADDRESSES: You may submit comments, identified by IB Docket No. 06–123, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.