§ 3.4 Matters reserved for decision by the Governors.

* * * * *

(c) Election of the Chairman and Vice Chairman of the Board of Governors, 39 U.S.C. 202(a).

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PART 4—[AMENDED]

■ 3. The authority citation for part 4 continues to read as follows:

Authority: 39 U.S.C. 202–205, 401(2), (10), 402, 1003, 3013.

§ 4.2 [Amended]

■ 4. Amend § 4.2 by removing the words ''The Vice Chairman is elected by the Board'' and adding the words ''The Vice Chairman is elected by the Governors'' in their place.

PART 6—[AMENDED]

■ 5. The authority citation for part 6 continues to read as follows:

Authority: 39 U.S.C. 202, 205, 401(2), (10), 1003, 3013; 5 U.S.C. 552b(e), (g).

§ 6.1 [Amended]

■ 6 Amend § 6.1 by revising the first sentence to read as follows:

§ 6.1 Regular meetings, annual meeting.

The Board shall meet regularly on a schedule established annually by the Board. * * *

§ 6.6 [Amended]

■ 7. Amend § 6.6(f) by removing the numeral ''5'' and adding the numeral ''4'' in its place.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 04–21557 Filed 9–28–04; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0255; FRL–7681–3]

Fenamidone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) in or on garlic, bulb; garlic, great headed; grape (imported); leek; onion, dry bulb; onion, green; onion, welsh; shallot, bulb; shallot, fresh leaves; tomato; tomato, paste; tomato, puree; vegetable, cucurbit, group 09; vegetable, tuberous and corm, subgroup 01C and establishes tolerances for combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on fat (beef, goat, and sheep); meat (beef, goat, and sheep); meat byproducts (beef, goat, and sheep); milk; wheat, grain; wheat forage; wheat, hay; and wheat, straw. Wheat tolerances are being established for inadvertent residues in/on a rotated crop. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0255. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6742; e-mail address: *mcneilly.dennis@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of January 28, 2004 (69 FR 4138–4143) (FRL–7337–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F6300) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. This amended the petition previously

announced in the **Federal Register** of January 4, 2002 (67 FR 592–597) (FRL–6812–2) by including raw agricultural commodity subgroup 01C. The petition requested that 40 CFR 180.579 be amended by establishing tolerances for combined residues of the fungicide fenamidone, and its metabolites in or on the raw agricultural commodities: Potato, 0.05 parts per million (ppm), tomato, 1.0 ppm; tomato paste, 3.5 ppm, tomato puree, 3.5 ppm, bulb vegetable crop group, 1.5 ppm; cucurbit crop group, 0.1 ppm; head lettuce, 15.0 ppm; leaf lettuce, 20.0 ppm; wheat grain, 0.05 ppm, wheat straw, 0.5 ppm; wheat forage, 0.5 ppm, and wheat hay, 0.5 ppm. Tolerances were also proposed for fenamidone and its metabolite RPA 410193 on imported wine grapes at 0.5 ppm. Agency review of the residue data indicates that the following tolerance levels are appropriate: Fenamidone, 4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-, in or on garlic, bulb at 0.20 ppm; garlic, great headed at 0.20 ppm; grape (imported) at 1.0 ppm, leek at 1.5 ppm, onion, dry bulb at 0.20 ppm; onion, green at 1.5 ppm; onion, welsh at 1.5 ppm; shallot, bulb at 0.20 ppm; shallot, fresh leaves at 1.5 ppm; tomato at 1.0 ppm; tomato, paste at 2.2 ppm; tomato, puree at 2.0 ppm; vegetable, cucurbit, group 09 at 0.15 ppm and vegetable, tuberous and corm, subgroup 01C at 0.02 ppm and also for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on fat (beef, goat, and sheep) at 0.10 ppm; meat (beef, goat, and sheep) at 0,10 ppm, meat byproducts (beef, goat, and sheep) at 0.10 ppm; milk at 0.02 ppm; wheat forage at 0.15 ppm; wheat, grain at 0.10 ppm; wheat, hay at 0.50 ppm; wheat, straw at 0.35 ppm. The Agency is establishing tolerances for animal tolerances based on review of the residue data and evaluation of food animal diets, which could include wheat forage and hay. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of fenamidone, in or on garlic, bulb at 0.20 ppm; garlic, great headed at 0.20 ppm; grape (imported) at 1.0 ppm, leek at 1.5 ppm, onion, dry bulb at 0.20 ppm; onion, green at 1.5 ppm; onion, welsh at 1.5 ppm; shallot, bulb at 0.20 ppm; shallot, fresh leaves at 1.5 ppm; tomato at 1.0 ppm; tomato, paste at 2.2 ppm; tomato, puree at 2.0 ppm; vegetable, cucurbit, group 09 at 0.15 ppm and vegetable, tuberous and corm, subgroup 01C at 0.02 ppm and also for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on fat (beef, goat, and sheep) at 0.10 ppm; meat (beef, goat, and sheep) at 0,10 ppm, meat byproducts (beef, goat, and sheep) at 0.10 ppm; milk at 0.02 ppm; wheat forage at 0.15 ppm; wheat, grain at 0.10 ppm; wheat, hay at 0.50 ppm; wheat, straw at 0.35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 nature of the toxic effects caused by fenamidone are discussed in the **Federal Register** of September 27, 2002 (67 FR 7196–7198). There have been no changes in the toxicological profile since that **Federal Register** notice and therefore, the Agency will not repeat the entire table in this final rule but refers to the original document.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided

by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

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 DOSE AND ENDPOINTS FOR FENAMIDONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 125 milligram/kilogram/day (mg/kg/day) UF = 1,000 Acute RfD = 0.13 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD (0.13)/Special FQPA SF 1X = 0.13 mg/kg/day	Acute Neurotoxicity Study 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 male/femal (M/F) mg/kg/day UF = 1,000 Chronic RfD = 0.003 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD (0.003)/Special FQPA SF 1X = 0.003 mg/kg/day	2-Year Chronic Toxicity/Carcinogenicity Study in Rats LOAEL = 7.07/9.24 mg/kg/day based on increase in severity of diffuse thyroid C-cell hyperplasia in both sexes.
Short-Term Dermal (1 to 7 days) (Residential)	Dermal (or oral) study NOAEL= 10.4 mg/kg/day	LOC for MOE = 1,000 (Residential)	90-Day Feeding Study in Rats LOAEL = 68.27 mg/kg/day based on increased liver weights and incidences of ground glass appearance of the hepatocytes in males.
Intermediate-Term Dermal (1 week to several months) (Residential)	Dermal (or oral) study NOAEL = 5.45 mg/kg/day	LOC for MOE = 1,000 (Residential)	2-Generation Reproduction Study in Rats LOAEL = 89.2 mg/kg/day based on decreased absolute brain weight in female F1 adults and females F2 offspring.
Long-Term Dermal (Several months to lifetime) (Residential)	Dermal (or oral) study NOAEL= 2.83 mg/kg/day	LOC for MOE = 1,000 (Residential)	2-Year Chronic Toxicity/Carcinogenicity Study 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.
Short-Term Inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL= 10.4 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	90-Day Feeding Study in Rats LOAEL = 68.27 mg/kg/day based on increased liver weights and incidences of ground glass appearance of the hepatocytes in males.
Intermediate-Term Inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = 5.45 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	2-Generation Reproduction Study in Rats LOAEL = 89.2 mg/kg/day based on decreased absolute brain weight in female F1 adults and female F2 offspring.
Long-Term Inhalation (Several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL= 2.83 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	2-Year Chronic Toxicity/Carcinogenicity Study 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)	Classification: ''Not likely''		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.579) for residues of fenamidone, in or on head and leaf lettuce. Risk assessments were conducted by EPA to assess dietary exposures from fenamidone in food as follows:

i. *Acute exposure.* Acute dietary 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 conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute analysis assumed 100% crop treated and field trial residue data treated at maximum labeled rate, minimum preharvest interval. Therefore, the acute analysis is considered conservative. The results, reported in Unit III.E. are for the general U.S. population, all infants (< 1 year old), children 1–2, children 3–5, children 6–12, youth 13–19, females, 13–49, adults 20–49, and adults 50+ years. The acute dietary exposure estimates were ≤ 24% aPAD (95th percentile; children 1–2 years old were the most highly exposed population).

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis was refined through the use of projected percent crop treated (PCT) estimates and average field trial residues. Since the chronic analysis assumed that all meat/milk commodities will contain fenamidone residues (i.e., no adjustment for feed PCT) and since the analysis made use of field trial residues (treated at maximum labeled rate, minimum preharvest interval), the Agency concludes that the chronic exposure estimates are conservative.

iii. *Cancer.* Fenamidone is classified as ''not likely to be carcinogenic to humans'' by all relevant routes of exposure based on adequate studies in two animal species.

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 chemicals that have been measured in food. If EPA relies on such information, EPA must 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information in Table 2 of this unit as follows:

TABLE 2.—PERCENT CROP TREATED ESTIMATES FOR FENAMIDONE

Commodity	Acute % Crop Treated	Chronic % Crop Treated
Tomato	100%	31%
Potato	100%	20%
Lettuce	100%	24%

TABLE 2.—PERCENT CROP TREATED ESTIMATES FOR FENAMIDONE—Continued

Commodity	Acute % Crop Treated	Chronic % Crop Treated
Cucurbits	100%	9%
Bulb crops	100%	19%

For each crop, EPA projected a PCT estimate for fenamidone by assuming that fenamidone would duplicate the PCT of the fenamidone alternative that had the highest PCT and, like fenamidone, is a relatively new pesticide, targets the same pests as fenamidone, and tends to replace the same older pesticides (e.g., chlorothalonil and EBDCs). Further, fenamidone had to be price competitive with the alternative on which the projection was based.

The Agency believes that the three conditions listed in Unit III.C.1.iv. have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data on fenamidone alternatives, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the

regional consumption of food to which fenamidone may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure 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 physical characteristics of fenamidone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fenamidone they are further discussed in the aggregate risk sections in Unit III.E.2.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of fenamidone for acute exposures are estimated to be 10.47 parts per billion (ppb) for surface water and 8.19 ppb for ground water. The EECs for chronic exposures are estimated to be 2.58 ppb for surface water and 8.19 ppb for ground 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 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 the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that there is not a concern for pre- and/or postnatal toxicity resulting from exposure to fenamidone. 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 highest dose tested (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 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).

3. *Conclusion*. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The toxicity database is not complete because EPA has required that a developmental neurotoxicity (DNT)

study be conducted due to evidence from fenamidone studies of clinical signs of neurotoxicity and decreased brain weight. EPA has retained the FQPA additional 10X safety factor for the protection of infants and children because of the absence of the DNT study. This FQPA safety factor is in the form of a database uncertainty factor. A 1,000-fold uncertainty factor (10x UF_{DB} for lack of a (DNT) study; 10X for interspecies extrapolation; and 10x for intraspecies variation) were incorporated into the acute and chronic RfD . The reference dose (RfD) for acute and chronic risks from fenamidone is equal to the applicable NOAEL divided by the 1000x uncertainty factor.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/ 70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fenamidone the highest exposed population subgroup was children 1-2 years old which accounted for 24% of the aPAD. The acute aggregate risk associated with the proposed use of fenamidone does not exceed the Agency's level of concern for the general U.S. population or any population subgroups.. In addition, there is potential for acute dietary exposure to fenamidone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FENAMIDONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food DEEM)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.13	16%	10.47	8.19	3800
Children 1–2 yearsold	0.13	24%	10.47	8.19	990
Youth 13–19 yearsold	0.13	15%	10.47	8.19	330
Adults 20–49 yearsold	0.13	17%	10.47	8.19	3800
Females 13–49 years old	0.13	17%	10.47	8.19	3200

1. Maximum water exposure (mg/kg/day) = aPAD (mg/kg/day) - food exposure (mg/kg/day).
2. The crop producing the highest level was used.
3. DWLOC calculated as follows:
DWLOC = (maximum water exposure (mg/kg/day)) x (body weight (kg)) x (1,000 μg (gram)/mg) ÷ water consumption (L/day)

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that the chronic dietary exposure analysis was partially refined through the use of projected PCT estimates and average field trial residues. Since the chronic analysis assumed that all meat/ milk commodities will contain fenamidone residues (i.e. no adjustment for feed PCT) and since the analysis made use of field trial residues (treated at maximum labeled rate, minimum preharvest interval, samples frozen upon collection and remained frozen until analysis), EPA concludes that the chronic exposure estimates are conservative. The highest exposed population subgroup was children 1–2 years old which occupies 69% of the cPAD. There are no residential uses for fenamidone that result in chronic residential exposure to fenamidon. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENAMIDONE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.003	29%	2.58	8.19	74

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENAMIDONE—Continued

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children 1–2 years old	0.003	69%	2.58	8.19	9.2
Youth 13–19 years old	0.003	26%	2.58	8.19	67
Adults 20–49 years old	0.003	26%	2.58	8.19	78
Females 13–49 years old	0.003	26%	2.58	8.19	67

3. *Short-term risk*. Short-term risk assessment was not performed because there are no existing or proposed residential uses for fenamidone.

Fenamidone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term risk assessment was not performed because there are no existing or proposed residential uses for fenamidone.

Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fenamidone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. A cancer aggregate risk assessment was not performed because fenamidone is not considered to be carcinogenic.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The registrant has proposed a liquid chromatograph/mass spectroscopy (LC/MS) method for the enforcement of the plant tolerances (the method does not distinguish the S- and R-enantiomers). Adequate method validation, radiovalidation, and independent method validation (ILV) of the proposed enforcement method have been submitted.

The Agency concludes that livestock tolerances are necessary. The petitioner has proposed a livestock enforcement method and submitted an ILV for this method. The Agency notes that methods AR 200-99 (milk) and AR 178-98 (tissue) have been adequately radiovalidated for the determination of fenamidone, RPA 717879, and RPA 408056. An ILV study has been submitted for the livestock enforcement method and it indicates that the method is satisfactory for enforcement purposes.

Adequate enforcement methodology 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, Canadian, or Mexican maximum residue limits (MRLs) for fenamidone in/on requested crops; therefore, harmonization is not an issue for this petition.

C. Conditions

1. *Toxicity data requirements*. A DNT study in rats is required. The Agency concluded that the DNT was required based on the following:

i. Clinical signs of neurotoxicity were seen in the mutagenicity studies with parent and plant metabolites, particularly RPA 412636 and RPA 412708.

ii. In the acute neurotoxicity study in rats, decreased brain weight in male rats was observed.

iii. In the 2-generation reproduction study in rats, decreased absolute brain weight was observed in the female F1 adults and the female F2 offspring.

The Agency reassessed the requirement for a DNT study in rats for fenamidoene in response to the waiver request by Bayer CropSciences.

2. *Residue chemistry data requirements*—i. The Agency is requesting that the petitioner hydrolyze the extractable and non extractable residues from the N-phenyl studies to determine if conjugated aniline(s) are present (data validating the storage interval are also required).

ii. The Agency is also requiring additional identification/characterization on the N-phenyl livestock samples to determine the metabolic fate of the N-phenyl ring in livestock (data validating the storage interval are also required).

iii. Submission of storage stability data for confined accumulation in rotational crop study.

V. Conclusion

Therefore, the tolerance is established for residues of fenamidone, 4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-, in or on garlic, bulb at 0.20 ppm; garlic, great headed at 0.20 ppm; grape (imported) at 1.0 ppm, leek at 1.5 ppm, onion, dry bulb at 0.20 ppm; onion, green at 1.5 ppm; onion, welsh at 1.5 ppm; shallot, bulb at 0.20 ppm; shallot, fresh leaves at 1.5 ppm; tomato at 1.0 ppm; tomato, paste at 2.2 ppm; tomato, puree at 2.0 ppm; vegetable, cucurbit, group 09 at 0.15 ppm and vegetable, tuberous and corm, subgroup 01C at 0.02 ppm and also for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on fat (beef, goat, and sheep) at 0.10 ppm; meat (beef, goat, and sheep) at 0,10 ppm., meat byproducts (beef, goat, and sheep) at 0.10 ppm; milk at 0.02 ppm; wheat forage at 0.15 ppm; wheat, grain at 0.10 ppm; wheat, hay at 0.50 ppm; wheat, straw at 0.35 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate

adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0255 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 on or before November 29, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0255, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. 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 due to its lack of significance, this 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: September 21, 2004.

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 designating the text of paragraph (a) as paragraph (a)(1) and alphabetically adding new commodities to the table in paragraph (a)(1) and by adding new paragraph (a)(2) and text to paragraph (d) to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) * * *

(1) Tolerances are established for residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) from the application of the fumgicide fenamidone in or on the following raw agricultural commodities:

Commodity	Parts per million
garlic, bulb	0.20
garlic, great headed	0.20
Grape (imported)	1.0
Leek	1.5
* * * * *	
Onion, dry bulb	0.20
Onion, green	1.5
Onion, welsh	1.5
Shallot, bulb	0.20
Shallot, fresh leaves	1.5
Tomato	1.0
Tomato, paste	2.2
Tomato, puree	2.0
Vegetable, cucurbit, group 09	0.15
Vegetable, tuberous and corm, subgroup 01C	0.02

(2) Tolerances are established for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
beef, fat	0.10
beef, meat	0.10
beef, meat byproducts	0.10
goat, fat	0.10
goat, meat	0.10
goat, meat byproducts	0.10
milk	0.02
sheep, fat	0.10
sheep, meat	0.10
sheep, meat byproduct	0.10

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for 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 the following agricultural commodities when present therein as a result of application of fenamidone to the crops in paragraph (a)(1).

Commodity	Parts per million
Wheat, grain	0.10
Wheat, hay	0.50
Wheat, forage	0.15
Wheat, straw	0.35

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0300; FRL–7677–6]

Citrate Esters; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of acetyl tributyl citrate (ATBC) also known as citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77–90–7) and triethyl citrate (TEC) also known as citric acid, triethyl ester (CAS Reg. No. 77–93–0) when used as inert ingredients in pesticide products. Morflex submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting the exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ATBC or TEC.

DATES: This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0300. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is