([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.60
Cattle, fat	0.020
Cattle, kidney	0.050
Cattle, liver	0.15
Cattle, meat	0.030
Cattle, meat by-products	0.050
Cotton, gin byproducts	11.0
Cotton, undelinted seed	0.020
Fruit, pome, group 11	0.30
Goat, fat	0.020
Goat, kidney	0.050
Goat, liver	0.15
Goat, meat	0.030
Goat, meat byproducts	0.050
Horse, fat	0.020
Horse, kidney	0.050
Horse, liver	0.15
Horse, meat	0.030
Horse, meat by-products	0.050
Milk	0.030
Sheep, fat	0.020
Sheep, kidney	0.050
Sheep, liver	0.15
Sheep, meat	0.030
Sheep, meat by-products	0.050

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

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

[FR Doc. 03–24371 Filed 9–25–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0301; FRL–7326–7]

Fenhexamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenhexamid in or on cucumber; fruit, stone, group 12, except plum, prune, fresh, postharvest; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; plum, prune, dried; plum, prune, fresh; vegetable, fruiting, group 8, except nonbell pepper. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain fenhexamid tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0301, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@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:

- Industry (NAICS 111), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., Pesticide manufacturing.

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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0301. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access*. 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 at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 21, 2003 (68 FR 27799) (FRL–7308–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2E6463, 2E6496, 3E6532, and 3E6541) by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide

fenhexamid, *N*-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexane carboxamide, in or on food commodities as follows: cucumber at 2.0 parts per million (ppm) (PP 2E6496); fruit, stone, group 12, postharvest at 10.0 ppm (PP 3E6541); kiwifruit, postharvest at 15.0 ppm (PP 2E6463); leafy greens, subgroup 4A, except spinach at 30.0 ppm (PP 3E6532); vegetable, fruiting, group 8, at 2.0 ppm (PP2E6496). IR–4 subsequently amended PP 3E6541 to propose tolerances for fruit, stone, group 12, except plum, prune, fresh, postharvest at 10.0 ppm and separate tolerances for plum, prune, dried at 2.5 ppm and plum, prune, fresh at 1.5 ppm. IR–4 also amended PP 2E6496 to propose tolerances for vegetable, fruiting, group 8, except nonbell pepper at 2.0 ppm. EPA is deleting the established fenhexamid tolerance for fruit, stone, except plum, prune, fresh at 6.0 ppm. This tolerance is no longer needed since this action establishes a higher tolerance at 10.0 ppm to cover both pre- and postharvest application to stone fruit, except plum, prune, fresh.

EPA has received objections to tolerances it established for residues of fenhexamid on a variety of berry crops and pistachio (67 FR 19114) (FRL–6829–9). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7), which ended on October 16, 2002. Although that proceeding remains ongoing, prior to acting on this current tolerance action, EPA reviewed the fenhexamid-specific objections raised by NRDC and has addressed them at relevant points throughout this preamble.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 the 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 the 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 the FFDCA, for tolerances for residues of fenhexamid on cucumber at 2.0 ppm; fruit, stone, group 12, except plum, prune, fresh, postharvest at 10.0 ppm; kiwifruit, postharvest at 15.0 ppm; leafy greens subgroup 4A, except spinach at 30.0 ppm; plum, prune, dried at 2.5 ppm; plum, prune, fresh at 1.5 ppm; vegetable, fruiting, group 8, except nonbell pepper at 2.0 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 fenhexamid are discussed in Unit II.A. of the final rule on Fenhexamid; Pesticide Tolerance published in the **Federal Register** of April 13, 2000 (65 FR 19842) (FRL–6553–7).

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, 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 FQPA SF.

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 is expressed as 1×10^{-6} or one in a million). 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 fenhexamid used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENHEXAMID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population including infants and children)	None UF = NA Acute RfD = None	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = None	Not selected. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Chronic Dietary (All populations)	NOAEL = 17 mg ai/kg/day UF = 100 Chronic RfD = 0.17 mg/kg/day	1X cPAD = chronic RfD ÷ FQPA SF = 0.17 mg/kg/day	1-Year Feeding-Dog. Decreased RBC count, hemoglobin and hematocrit and increased Heinz bodies in males and females; increased adrenal weights and intracytoplasmic vacuoles in adrenal cortex in females at the LOAEL of 124 mg/kg/day.
Short-Term (1–30 days) and Intermediate-Term (1–6 months) Dermal	NOAEL = 1,000 mg ai/kg/day Dermal absorption rate = 20%	Residential MOE = Not applicable	21-Day Dermal-Rabbit. In the developmental toxicity study in rabbits, decreased body weight gain and food consumption at LOAEL of 1,500 mg/kg/day (dermal equivalent dose using 20% dermal absorption factor); NOAEL was 500 mg/kg/day (dermal equivalent dose). Dermal exposure is not expected since there are no residential uses.
Long-Term Dermal (> 6 months)	None Dermal absorption rate = 20%	Residential MOE = Not applicable	Not selected. Long-term dermal exposure is not expected since there are no residential uses.
Short-Term (1–30 days), Intermediate-Term (1–6 months), and Long-term (> 6 months) Inhalation	None	Residential MOE = Not applicable	Not selected. Inhalation exposure is not expected since there are no residential uses.
Cancer (oral, dermal, inhalation)	None	Not applicable	Fenhexamid is classified as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in mice and rats and the lack of genotoxicity in a battery of mutagenicity studies.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.553) for the residues of fenhexamid, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fenhexamid 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 one day or single exposure. An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified.

ii. *Chronic exposure.* In conducting this chronic 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 USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. An unrefined, Tier 1 chronic dietary exposure assessment was performed using tolerance level residues (established and recommended) and 100% crop treated. DEEM™ default processing/concentration factors were used for all processed commodities.

iii. *Cancer.* Fenhexamid has been classified as a ''not likely'' human carcinogen. Therefore, a quantitative cancer dietary exposure assessment was not performed.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenhexamid 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 fenhexamid.

2. *Dietary exposure from drinking water.* The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever 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) from these models 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 fenhexamid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of fenhexamid for acute and chronic surface water exposures are estimated to be 28.7 parts per billion (ppb) and 1.14 ppb, respectively. The EECs for acute and chronic ground water exposure is estimated to be 0.0007 ppb.

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). Fenhexamid 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.''

EPA does not have, at this time, available data to determine whether fenhexamid has a common mechanism of toxicity with other substances 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 fenhexamid and any other substances and fenhexamid 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 fenhexamid 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 Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 data base on toxicity and exposure unless EPA determines 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.

2. *Prenatal and postnatal sensitivity*. In the rat and the rabbit developmental toxicity studies, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to fenhexamid was observed. In the rat reproduction study, qualitative susceptibility was evidenced as significantly decreased pup body weights in both generations during the lactation period (on lactation days 7, 14, and 21 in the F_2 generation and lactation days 14 and 21 in the F_1 generation offspring) in the presence of lesser maternal toxicity (alterations in clinical chemistry parameters and decreased organ weights without collaborative histopathology). Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for fenhexamid, the degree of concern for the effects observed in this study was characterized as low, noting that there is a clear NOAEL and well-characterized dose response for the offspring effects observed and that these effects occurred in the presence of parental toxicity. No residual uncertainties were identified. The NOAEL of 17 mg/kg/day from the chronic dog study used to establish the chronic Reference Dose (cRfD) for the General Population (no aRfD was established for any population subgroup) is lower than the NOAEL of 38.2 mg/kg/day in the reproduction study in which the offspring effects of concern were observed (LOAEL = 406 mg/kg/day).

3. *Conclusion*. There is a complete toxicity data base for fenhexamid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X Safety Factor to protect infants and children should be reduced to 1X for the following reasons:

- There are no residual uncertainties for pre and/or post natal toxicities via the oral route since the doses selected for overall risk assessments would address the concerns for the developmental and offspring toxicities seen in the above mentioned studies.
- There are no residual uncertainties for pre and/or post natal toxicities via the dermal route since the dose/endpoint/study/species of concern was used for dermal-risk assessment.
- The toxicology data base is complete.
- Developmental neurotoxicity studies are not required for fenhexamid based on the following weight-of-the-evidence considerations:
  - Lack of evidence of abnormalities in the development of the fetal nervous system in the pre/post-natal studies.
  - Neither brain weight nor histopathological examination of the nervous system was affected in the subchronic and chronic studies.
  - Decreased body temperatures observed in male rats in the acute neurotoxicity study were not considered to be toxicologically significant.
- The dietary (food) exposure assessment utilizes existing and proposed tolerance level residues and assumes 100% of crops treated with fenhexamid. The assessment is based on reliable data and is not expected to underestimate exposure/risk.
- Conservative assumptions are used in the drinking water models. The drinking water exposure assessment is not expected to underestimate exposure/risk.
- Fenhexamid is not registered for use sites that would result in residential exposure.

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 the model estimates of a pesticide's concentration

in water (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 USEPA 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 groundwater 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*. An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified. Therefore, acute risk from exposure to fenhexamid is not expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenhexamid from food will utilize 9.9 % of the cPAD for the U.S. population, 19.6 % of the cPAD for all infants < 1 year, 21.8% of the cPAD for children 1 to 2 years, the population subgroup at greatest exposure, and 8.8% of the cPAD for females 13 to 50 years old. There are no residential uses for fenhexamid that result in chronic residential exposure to fenhexamid. However, there is potential for chronic dietary exposure to fenhexamid 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 cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENHEXAMID

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.17	9.9	1.14	0.0007	5,363
All infants < 1 year	0.17	19.6	1.14	0.0007	1,367
Children 1 to 2 years	0.17	21.8	1.14	0.0007	1,330
Females 13–50 years	0.17	8.8	1.14	0.0007	4,980

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). In its objections to a separate fenhexamid tolerance action, NRDC claims that residential short-term and intermediate-term risk assessments are data gaps for fenhexamid. EPA did not conduct short-term and intermediate-term risk assessments for fenhexamid since the pesticide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of risk from chronic exposure to residues in food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. EPA has classified fenhexamid as a ''not likely'' human carcinogen. The Agency concludes that pesticidal uses of fenhexamid do not pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Bayer AG Method 00362 has previously undergone a successful method trial and method validation, and is the enforcement method for all the fenhexamid established tolerances. 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*.

V. Conclusion

Therefore, the tolerance is established for residues of fenhexamid, *N*-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide, in or on cucumber at 2.0 ppm; fruit, stone, group 12, except plume, prune, fresh, postharvest at 10.0 ppm; kiwifruit, postharvest at 15.0 ppm; leafy greens subgroup 4A, except spinach at 30.0 ppm; plum, prune, dried at 2.5 ppm; plum, prune, fresh at 1.5 ppm; vegetable, fruiting group 8, except nonbell pepper at 2.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made.

The new section 408(g) of the 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 the 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–2003–0301 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 25, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *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 Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0301, 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 Unit I.B.1. 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 the 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, *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 the 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 the 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 10, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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), 346(a) and 371.

■ 2. Section 180.553 is amended as follows:

a. By revising the commodities plum, prune, dried and plum, prune, fresh in the table in paragraph (a).

b. By removing the commodity fruit, stone, except plum, prune, fresh in the table in paragraph (a).

c. By alphabetically adding commodities in the table in paragraph (a).

§ 180.553 Fenhexamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cucumber	2.0
Fruit, stone, group 12, except plum, prune, fresh, postharvest	10.0
* * *	* *
Kiwifruit, postharvest	15.0
* * *	* *
Leafy greens, subgroup 4A, except spinach	30.0
* * *	* *
Plum, prune, dried	2.5
Plum, prune, fresh	1.5
* * *	* *
Vegetable, fruiting, group 8, except nonbell pepper	2.0

* * * * *

[FR Doc. 03–24013 Filed 9–25–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0146; FRL–7320–8]

Chlorfenapyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] in or on vegetables, fruiting, group 8. BASF Agro Research, now BASF Corporation 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 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0146, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address: *sibold.ann@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you grow fruiting vegetables in commercial greenhouses, consume vegetables that were raised in commercial greenhouses, or provide pest control services to commercial greenhouses. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Pesticide manufacturing (NAICS 32532)
- Other food crops grown under cover (NAICS 111419)
- Entomological services, agricultural; insect control for crops (NAICS 115112)
- Agricultural production or harvesting crews (NAICS 115115)

This listing is not intended to be exhaustive, but rather provides a guide