

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: March 20, 2006.

**James Jones,**

*Director, 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 180.616 is added to read as follows:

#### § 180.616 Fenpropimorph; tolerances for residues.

Tolerances are established for the residues of the fungicide fenpropimorph (rel-(2R,6S)-4-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine) in or on the following commodity:

Commodity	Parts per million
Banana* .....	2.0

\*No U.S. registration as of February 10, 2006.

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

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

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

[FR Doc. 06-3029 Filed 3-28-06; 8:45 am]

BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2004-0328; FRL-7769-6]

#### Fenhexamid; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of fenhexamid in or on ginseng and pear. The Interregional Research Project 4 (IR-4), Center for Minor Crop Pest Management

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 March 29, 2006. Objections and requests for hearings must be received on or before May 30, 2006.

**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 EPA-HQ-OPP-2004-0328. All documents in the

docket are listed on the [www.regulations.gov](http://www.regulations.gov) web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) 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:** Maria I. Rodriguez, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6710; e-mail address: [rodriguez.maria@epa.gov](mailto:rodriguez.maria@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/>.

##### **II. Background and Statutory Findings**

In the **Federal Register** of August 27, 2004 (69 FR 52684) (FRL-7675-2), 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 3E6799) by The Interregional Research Project 4 (IR-4), Center for Minor Crop Pest Management, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.553 be amended by establishing a tolerance for residues of the fungicide fenhexamid, in or on apple, wet pomace at 25 parts per million (ppm) and fruit, pome, group 11 at 10 ppm. That notice included a summary of the petition prepared by IR-4, the registrant. Comments were received from one individual in New Jersey opposing and objecting the establishment of tolerances for residues of fenhexamid. The individual criticized IR-4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. EPA's response to the public comments received is in Unit IV. of this document. It should be noted that the petition for apple, wet pomace will be addressed at a later time in another ruling.

In the **Federal Register** of November 30, 2005 (70 FR 71838) (FRL-7735-7), 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 4E6859 and PP 4E6860) by The Interregional Research Project 4 (IR-4), Center for Minor Crop Pest Management, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.553 be amended by establishing a tolerance for residues of the fungicide fenhexamid, in or on

cilantro (as part of crop subgroup 4A) at 30 ppm, ginseng at 0.3 ppm, non-bell pepper at 0.02 ppm, and pomegranate at 3.0 ppm. That notice included a summary of the petition prepared by IR-4, the registrant. It should be noted that the petition for cilantro, non-bell pepper, and pomegranate will be addressed at a later time in another ruling.

Currently, there is an expired time-limited tolerance for fenhexamid in or on pears that is still listed in the CFR. As part of this final rule, EPA is taking the ministerial action of removing that expired tolerance.

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 the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

##### **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 fenhexamid in/on ginseng at 0.3 ppm and pear at 10 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. Specific information on the studies received and the nature of the toxic effects caused by fenhexamid as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found in the **Federal Register** of April 13, 2000 (65 FR 19842) (FRL-6553-7).

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases.

A summary of the toxicological endpoints for fenhexamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 26, 2003 (68 FR 55513) (FRL-7326-7).

### 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. There are existing permanent tolerances (40 CFR 180.553(a)) for fenhexamid in/on almond, hull (2.0 ppm), almond (0.02 ppm), bushberry subgroup 13B (5.0 ppm), caneberry subgroup 13A

(20.0 ppm), cucumber (2.0 ppm), fruit, stone, group 12, except plum, prune, fresh, postharvest (10.0 ppm), grape (4.0 ppm), grape, raisin (6.0 ppm), junberry (5.0 ppm), kiwifruit, postharvest (15.0 ppm), leafy greens, subgroups 4A, except spinach (30.0), lingonberry (5.0 ppm), pistachio (0.02 ppm), plum, prune, dried (2.5 ppm), plum, prune, fresh (1.5 ppm), salal (5.0 ppm), strawberry (3.0 ppm), vegetable, fruiting, group 8, except nonbell pepper (2.0 ppm). Risk assessments were conducted by EPA to assess dietary exposures from fenhexamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure.

No such effects were identified in the toxicological studies for fenhexamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure 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. The following assumptions were made for the chronic exposure assessments: Tolerance level residues, 100% crop treated (CT) and incorporating estimated exposure concentrations (EECs). Default processing factors were used for all commodities. This represents an unrefined conservative approach for quantifying risk. For chronic dietary risk, HED's level of concern is >100% chronic population adjusted dose (cPAD).

iii. *Cancer.* EPA has classified fenhexamid as a "not likely" human carcinogen based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, a quantitative cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* 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.

Based on the FQPA Index Reservoir Screening Tool (FIRST), or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), and Screening Concentrations in Groundwater (SCI-GROW) models, the EECs of fenhexamid for acute exposures are estimated to be 29 parts per billion (ppb) for surface water and 0.0007 ppb for ground water. The EECs for chronic exposures are estimated to be 1.14 ppb for surface water and 0.0007 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).

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."

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 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 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.* Fenhexamid is not acutely toxic,

neurotoxic, carcinogenic or mutagenic and is not a developmental or reproductive toxicant. There is low concern for prenatal and/or postnatal toxicity resulting from exposure to fenhexamid. (See **Federal Register** of September 26, 2003 (68 FR 55513) (FRL-7326-7). In addition, there are no concerns for developmental neurotoxicity resulting from exposure to fenhexamid.

3. *Conclusion.* Because 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, and there is low concern for prenatal or postnatal toxicity, the additional 10X safety factor has been removed. (See September 26, 2003).

#### *E. Aggregate Risks and Determination of Safety*

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 10% of the cPAD for the U.S. population, 0.55% of the cPAD for all infants < 1 year old, and 68% of the cPAD for children 1-2 years old. There are no residential uses for fenhexamid that result in chronic residential exposure to fenhexamid. 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 the following Table.

#### 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	10	1.14	0.0007	5,328
All Infants (<1 year old)	0.17	55	1.14	0.0007	839
Children (1-2 years)	0.17	68	1.14	0.0007	547

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

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

Fenhexamid 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.* The Agency has classified fenhexamid as a "not likely" human carcinogen based on lack of evidence of carcinogenicity in male and female rats as well as in male and female mice, and on the lack of genotoxicity in an

acceptable battery of mutagenicity studies. Therefore, fenhexamid is not expected to pose a cancer risk.

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 fenhexamid residues.

#### IV. Other Considerations

##### A. *Analytical Enforcement Methodology*

Adequate enforcement methodology (LC with MS detection or HPLC/ECD) 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](mailto:residuemethods@epa.gov).

##### B. *International Residue Limits*

There is a Canadian maximum residue level (MRL) of 0.3 ppm for fenhexamid in/on ginseng. There are no Mexican, or Codex MRL's. As such,

there are no issues regarding international harmonization.

##### C. *Response to Public Comments Received Regarding Notice of Filing*

Comments were received from one individual in New Jersey opposing and objecting the establishment of tolerances for residues of fenhexamid. The individual criticized IR-4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. The comments were in response to the notice of filing published in the **Federal Register** of August 27, 2004.

One comment indicated that IR-4 and Rutgers University are profiteering by registering pesticides. The Interregional Research Project Number 4 (IR-4) Program was created by Congress in 1963 in order to assist minor crop growers in the process of obtaining pesticide registrations. IR-4 National Coordinating Headquarters is located at Rutgers University in NJ and receives the majority (90%) of its funding from the U.S. Department of Agriculture (USDA). It is the only publicly funded program that conducts research and

submits petitions for tolerances. IR-4 operates in collaboration with USDA, the Land Grant University System, the agrochemical industry, commodity associations, and the EPA. IR-4 identifies needs, prioritizes accordingly, and conducts research. The majority (over 80%) of IR-4's research is conducted on reduced-risk chemicals. Under the Pesticide Registration Improvement Act (PRIA), IR-4 works in cooperation with the registrant to request a waiver for the registration services. The waiver may be granted if the application is solely associated by simultaneous submission with a tolerance petition in connection with IR-4 and if it is in the public interest. This fee waiver serves as an incentive to pursue registration of minor uses supported by the IR-4 Program. In addition to the work done in pesticide registration, IR-4 develops risk mitigation measures for existing registered products. Therefore, IR-4 and Rutgers University are not profiteering from registering pesticides.

An additional comment indicated that during animal testing, rabbits are abused, tortured, and fed toxic chemicals. The EPA Test Guidelines recommend rabbits as test animals in acute eye irritation studies as well as in longer term studies such as developmental toxicity and reproduction studies. Results obtained from studies conducted with animals (in general) are relevant to humans because cells and molecules of humans can be very similar to those of animals. Therefore, if a pesticide causes toxicity in animals, it is likely to do so in humans as well. The EPA supports the use of the least possible number of animals in the pertinent studies. In addition, it should be noted that currently there are no *in vitro* studies that can address the concerns these studies satisfy. The EPA is working with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to investigate *in vitro* methods to determine the toxicological concerns associated with the use of pesticides.

## V. Conclusion

Therefore, the tolerances are established for residues of fenhexamid in or on ginseng at 0.3 ppm and pear at 10 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 EPA-HQ-OPP-2004-0328 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 March 30, 2006.

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 issue(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 14<sup>th</sup> 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 EPA-HQ-OPP-2004-0328, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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**. 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 issue(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, *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: March 20, 2006.

**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 180.553(a) is amended by alphabetically adding entries for the commodities "ginseng" and "pear" to the table in paragraph (a); removing the text in paragraph (b); and reserving paragraph (b) with the paragraph heading to read as follows:

#### § 180.553 Fenhexamid; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Ginseng .....	* 0.3
* * *	* *
Pear .....	* 10
* * *	* *

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

\* \* \* \* \*

[FR Doc. 06-2975 Filed 3-28-06; 8:45 am]

**BILLING CODE 6560-50-S**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 0 and 1

### Nomenclature Changes to the Code of Federal Regulations

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document makes several nomenclature changes throughout the Commission's title of the Code of Federal Regulations. This action is necessary in order to update several addresses and office designations.

**DATES:** Effective March 29, 2006.

**FOR FURTHER INFORMATION CONTACT:** Alethea Small, Office of the Secretary, (202) 418-0310.

**SUPPLEMENTARY INFORMATION:** This amendment is made pursuant to § 0.231(b) of the Commission's rules, 47 CFR 0.231. Because the rule amendments adopted here are a matter of agency practice and procedure, compliance with the notice and comment and effective date provisions of the Administrative Procedure Act is not required.<sup>1</sup>

#### List of Subjects

##### 47 CFR Part 0

Reporting and recordkeeping requirements.

<sup>1</sup> 5 U.S.C. 553(b)(A); (d).