

**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 180.613 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

**§ 180.613 Fonicamid; tolerances for residues.**

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

Commodity	Parts per million
Brassica, head and stem, sub-group 5A .....	1.5
Mustard greens .....	11

\* \* \* \* \*

[FR Doc. 06-2977 Filed 3-28-06; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0105; FRL-7761-3]

**Fenpropimorph; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of fenpropimorph in or on bananas. BASF Corporation Agricultural Products requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

**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-2005-0105. 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:** Lana Coppolino, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0086; e-mail address: [coppolino.lana@epa.gov](mailto:coppolino.lana@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 at 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.gov/opptsfrs/home/guidelin.html>.

**II. Background and Statutory Findings**

In the **Federal Register** of June 22, 2005 (70 FR 36155)(FRL-7710-1), 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 7E4874) by BASF Corporation Agricultural Products, 26 Davis Drive, P.O. Box 13528; Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.616 be amended by establishing a tolerance for residues of the fungicide fenpropimorph, (+)-cis-4-(3-((4-tert-butylphenyl))-2-methylpropyl)-2,6-dimethylmorpholine, in or on bananas at 1.5 parts per million (ppm). This petition was previously published in the **Federal Register** on December 7, 1998, identified by the docket control number PF-848. That notice included a summary of the petition prepared by BASF Corporation Agricultural Products, 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 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](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 fenpropimorph on bananas 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. Specific information on the studies received and the nature of the toxic effects caused by fenpropimorph as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.epa.gov/opprd001/factsheets/>.

#### 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. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/oppfead1/trac/science>.

A summary of the toxicological endpoints for fenpropimorph used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENPROPIMORPH 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 (females 13-49 years of age)	NOAEL = 15 mg/kg/day UF = 100X Acute RfD = 0.15 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/Special FQPA SF = 0.15 mg/kg/day	Rabbit developmental study LOAEL = 30 mg/kg/day based on cleft palate
Chronic dietary (all populations)	NOAEL = 3.2 mg/kg/day UF = 100X Chronic RfD = 0.032 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.032 mg/kg/day	One year dog and chronic/carcinogenicity rat studies LOAEL = 9-11 mg/kg/day based on liver histopathology
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans." No increased incidences in tumors in a chronic/carcinogenicity rat study or a carcinogenicity mouse study.		

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* This final rule establishes the first tolerance for residues of fenpropimorph. There are no registered uses in the United States, therefore, the only expected exposure is from imported foods. Risk assessments were conducted by EPA to assess dietary exposures from fenpropimorph in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

The Dietary Exposure Evaluation Model (DEEM™-FDIC) Version 2.03 analysis evaluated the individual food consumption as reported by respondents in the U.S Department of

Agriculture (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 acute exposure assessments: The DEEM™-FCID assessment was based on tolerance-level residues in banana commodities, a processing factor of 3.9 for dried banana commodities, and 100% crop treated (CT) assumptions. An acute dietary dose and an endpoint attributable to a single dose were identified for only one population subgroup, females ages 13 through 49. An appropriate endpoint attributable to a single exposure was not identified for the general population.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM software with the FCID, Version 2.03, which incorporates

food consumption data as reported by respondents in the USDA 1994–1996, and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The DEEM-FCID assessment was based on tolerance-level residues in banana commodities, a processing factor of 3.9 for dried banana commodities, and 100% CT assumptions.

iii. *Cancer.* The Agency classified fenpropimorph as "not likely to be carcinogenic to humans." There were no increased incidences of benign or malignant tumors in either a rat chronic/carcinogenicity or a mouse carcinogenicity study. Therefore, a quantitative cancer exposure assessment was unnecessary.

2. *Dietary exposure from drinking water.* There is no expectation that

fenpropimorph residues would occur in surface water or ground water sources of drinking water. Fenpropimorph is proposed for use only on imported bananas, the sole anticipated exposure route for the U.S population is via dietary (food) exposure. There are no registered uses of fenpropimorph in the United States.

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). Fenpropimorph 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 fenpropimorph and any other substances and fenpropimorph 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 fenpropimorph 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 formulating 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 margin of exposure 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 UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* Although there is evidence for increased qualitative susceptibility in the developmental rat and rabbit studies, the Agency concluded that there is a low degree of concern (and no residual uncertainty) because:

i. The increased susceptibility was seen at the LOAELs of 160 milligrams/kilogram/day (mg/kg/day) in the rat study and at 30 mg/kg/day in the rabbit study (NOAELs were 40 and 15 mg/kg/day for the rat and rabbit studies, respectively);

ii. Cleft palate was not reported in a second rabbit developmental study with doses up to 36 mg/kg/day;

iii. No mention was made of cleft palate in another developmental rat study at doses up to 160 mg/kg/day (however, there were no visceral or skeletal examinations of fetuses/pups);

iv. At doses up to 2.79 mg/kg/day in a 2-generation reproduction study in rats, cleft palate was not reported;

v. Developmental effects were observed only in the presence of maternal toxicity; and

vi. The doses selected for acute and chronic dietary exposure and risk assessment were considerably lower than the doses at which developmental effects were observed.

3. *Conclusion.* Based on the review of the toxicology database, the Agency recommends that the Special FQPA Safety Factor (10X) be removed (reduced to 1X). This recommendation is applicable to all population subgroups for all exposure routes and durations, and is based on the following factors:

i. There is a complete toxicity data base.

ii. There is a low degree of concern for the qualitative susceptibility in developmental rat and rabbit studies, because the fetal effects were observed only in the presence of maternal toxicity.

iii. There is no concern for prenatal/postnatal toxicity since no off-spring toxicity was seen in the 2 generation reproduction study.

iv. The endpoints of concern are addressed in this risk assessment.

v. The dietary exposure assessment assumed tolerance level residues and 100% CT.

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fenpropimorph will occupy 2.6% of the acute population adjusted dose (aPAD) for females ages 13 through 49. An appropriate endpoint attributable to a single exposure was not identified for the general population nor any of the other population subgroup. Aggregate risk is limited to dietary exposure (food only). EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenpropimorph from food will utilize 2.2% of the cPAD for the U.S. population, 9.1% of the cPAD for all infants <1 year, and 11% of the cPAD for children 1-2 years, the population subgroup having the highest exposure. Aggregate risk is limited to dietary exposure (food only). EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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).

Fenpropimorph is not registered for use on any sites that would result in residential exposure, and there is no expectation that fenpropimorph residues would occur via drinking water consumption. Therefore, the aggregate risk is the sum of the risk from food only, which does 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).

Fenpropimorph is not registered for use on any sites that would result in residential exposure, and there is no expectation that fenpropimorph residues would occur via drinking water consumption. Therefore, the aggregate risk is the sum of the risk from food only, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Fenpropimorph has not been shown to be carcinogenic. Therefore, fenpropimorph 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 fenpropimorph residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

The proposed method is adequate for collecting data on residues in bananas. Adequate method validation data were submitted. The method has been adequately radiovalidated, and has undergone a marginally successful independent laboratory validation (ILV) trial. The petitioner has been requested to submit acceptable recovery data from bananas using other suggested methods.

The method, gas chromatography with nitrogen-phosphorous detection (GC/NPD), 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 are no established Mexican or Canadian maximum residue limits (MRLs) for fenpropimorph residues. There are Codex MRLs established for fenpropimorph residues in various commodities, including an MRL of 2 mg/kg in bananas.

#### V. Conclusion

Therefore, the tolerance is established for residues of fenpropimorph, [rel-(2R,6S)-4-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine], in or on banana at 2.0 ppm with no U.S. registration.

#### VI. Objections and Hearing Requests

Under section 408(g) of FFDCAs, 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 FFDCAs 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 FFDCAs 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 FFDCAs, as was provided in the old sections 408 and 409 of FFDCAs. 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-2005-0105 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.

2. *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.

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 ADDRESSES. Mail your copies, identified by docket ID number EPA-HQ-OPP-2005-0105, to: Public Information and Records Integrity Branch, Information Technology and Resource 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. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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 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 FFDCAs 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 FFDCFA, 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 FFDCFA. 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]

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**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