

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 final 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 final rule.

#### IV. 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 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 the rule in the **Federal Register**. This 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: July 24, 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.

#### § 180.910 [Amended]

■ 2. In § 180.910, the table is amended by removing the entry for "Wheat bran."

[FR Doc. E6-12345 Filed 8-1-06; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2005-0245; FRL-8079-2]

### Fenhexamid; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fenhexamid in or on nonbell pepper, pomegranate, and cilantro leaves. Interregional Research Project No.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).

**DATES:** This regulation is effective August 2, 2006. Objections and requests for hearings must be received on or before October 2, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0245. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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:** Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site 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.htm>.

##### C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions

provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0245 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 October 2, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2005-0245, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

## II. Background and Statutory Findings

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 pesticide petitions (PP 4E6859 and 4E6860) by Interregional Research Project No. 4 (IR-4), Technology Center of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition 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 cyclohexanecarboxamide in or on cilantro, leaves at 30.0 parts per million (ppm) (4E6859); pepper, nonbell at 0.02 ppm (4E6860) and pomegranate at 3.0 ppm (4E6859). That notice included a summary of the petition prepared by Arvesta Corporation, the registrant. There were no comments received in response to the notice of filing. Petition

4E6859 was subsequently amended to lower the residue level for pomegranate to 2.0 ppm.

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 on cilantro, leaves at 30.0 ppm; pepper, nonbell at 0.02 ppm; and pomegranate 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

fenhexamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies in the **Federal Register** of April 13, 2000 (65 FR 19842) (FRL-6553-7) \*<http://www.epa.gov/fedrgstr/EPA-PEST/2000/April/Day-13/p9144.htm>.

### 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/pesticides/health/human.htm>.

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. 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: one hundred percent of proposed and registered crops are treated with fenhexamid, default processing factors, average (chronic) concentration estimates for drinking water and tolerance-level residues for all commodities.

iii. *Cancer.* Fenhexamid is classified as “not likely” to be a human carcinogen. Therefore, a 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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of fenhexamid for acute exposures are estimated to be 29 parts per billion (ppb) for surface water and 0.0007 ppb for groundwater. The EECs for chronic exposures are estimated to be 1.1 ppb for surface water and 0.0007 ppb for groundwater. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For chronic dietary risk assessment, the annual average concentration of 1.1 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). 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.* 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<sub>2</sub> generation and lactation days 14 and 21 in the F<sub>1</sub> 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 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:

- i. Lack of evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies.

- ii. Neither brain weight nor histopathological examination of the nervous system was affected in the subchronic and chronic studies.

iii. 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

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but 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. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf>.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and groundwater EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

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 and water will utilize 11% of the cPAD for the U.S. population, 21% of the cPAD for all infants less than 1 year old, and 28% of the cPAD for children 1-2 years old, the subpopulation at greatest exposure. There are no residential uses for fenhexamid. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk and Intermediate-term.* Short-term and intermediate-term aggregate exposures take 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. *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.

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.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology Bayer AG Method 00362 (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

Fenhexamid *per se* is the residue to be regulated in pomegranate, cilantro or non-bell pepper. There are no Canadian, Mexican, or Codex MRLs for fenhexamid "for these crops", therefore, there are no issues for international harmonization.

#### V. Conclusion

Therefore, the tolerance is established for residues of fenhexamid, (N-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide, in or on cilantro, leaves at 30.0 ppm; pepper,

nonbell at 0.02 ppm; and pomegranate at 2.0.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 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.

## VII. 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: July 21, 2006.

**Daniel J. Rosenblatt**,  
Acting Director, Registration Division, Office of Pesticide Programs.

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

## PART 180—AMENDED

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

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

■ 2. Section 180.553 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

### § 180.553 Fenhexamid; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Cilantro, leaves	30.0
* * *	* *
Pepper, nonbell	0.02
* * *	* *
Pomegranate	2.0
* * *	* *

[FR Doc. E6-12348 Filed 8-1-06; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0307; FRL-8079-9]

### Inert Ingredients; Revocation of Two Tolerance Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking two exemptions from the requirement of a tolerance that are associated with two inert ingredients (ethylene glycol monomethyl ether and methylene blue) because these substances are no longer contained in active Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide product registrations. These ingredients are subject to reassessment by August 2006 under section 408(q) of the Federal Food, Drug, and Cosmetic

Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The two tolerance exemptions are considered "reassessed" for purposes of FFDCA's section 408(q) and count as a tolerance reassessment toward the August 2006 review deadline.

**DATES:** This rule is effective August 2, 2006. Objections and requests for hearings must be received on or before October 2, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0307. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

### FOR FURTHER INFORMATION CONTACT:

Karen Angulo, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0404; e-mail address: [angulo.karen@epa.gov](mailto:angulo.karen@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).