EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and other topics.

List of Subjects in 40 CFR Part 82

Environmental protection, Chemicals, Halon, Ozone, Reporting and recordkeeping requirements, Treaties.

Dated: June 1, 2006

William L. Wehrum,

Acting Assistant Administrator for the Office of Air and Radiation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0297; FRL–8061–4]

Fenarimol; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fenarimol in or on filbert. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Fenarimol was reassessed and approved by the Agency effective August 1, 2002. To view the Tolerance Reassessment Progress and Risk Management Decision (TRED) and related supporting documents, please refer to docket number (EPA–HQ–OPP–2002–0250–0001) at *www.regulations.gov*.

DATES: This regulation is effective June 7, 2006. Objections and requests for hearings must be received on or before August 7, 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–2005–0297. 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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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*.

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–2006–0297 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 August 7, 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–2006–0297, 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 August 31, 2005 (70 FR 51802) (FRL–7733–1), 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 5E4573) by IR-4, 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.421 be amended by establishing a tolerance for residues of the fungicide fenarimol [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol] in or on filbert at 0.02 parts per million (ppm). That notice included a summary of the petition prepared by Gowan Company, 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 * * *.''

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 fenarimol on filbert at 0.02 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 fenarimol 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/EPA-PEST/2002/December/Day-04/p30471.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 fenarimol used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENARIMOL 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 13-50 years ofage)	NA	NA	Rat Developmental and Multi-generation Reproductive ToxicityStudy
Acute Dietary (General population including infants and children)	NA	NA	No appropriate endpoint was available to quantitate risk.
Chronic Dietary (All populations)	NOAEL = 0.6 mg/kg/day UF = 100 X Chronic RfD = 0.006 mg/kg/day	Special FQPA SF = 3X cPAD = chronic RfD/Special FQPA SF = 0.002 mg/kg/day	Multi-generation Reproduction Study LOAEL = 1.2 mg/kg/day based on decreased live born litter size in the F_1 and F_2 generations.
Short-Term Incidental Oral, Dermal, andInhalation (1 to 30 days) (Residential)	Dermal/oral study LOAEL = 35 mg/kg/day	LOC for MOE = 900 (Residential) FQPA factor = 3X UF= 300	Special Reproduction Study LOAEL = 35 mg/kg/day based on decreased fertilityand dystocia, an indicator of hormonal effects, observed in aspecial non-guideline cross breeding reproduction/developmentaltoxicity study in rats
Intermediate-Term Incidental Oral, Dermal, and Inhalation (1- 6 months) (Residential)	Dermal/oral study NOAEL = 0.6 mg/kg/day	LOC for MOE = 100 (Residential) FQPA factor = 3X	Multi-generation Reproduction Study LOAEL = 0.6 mg/kg/day based on decreased live born litter size in the F_1 and F_2 generations

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

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
Cancer (oral, dermal, inhalation)	NA	NA	Fenarimol has been classified as a "not likely" human carcinogen (Group E).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.421)(a)(1) for the residues of fenarimol, [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol] for the following raw agricultural commodities (RACs): Apple at 0.1; apple, dry pomace at 2.0; apple, wet pomace at 2.0; cattle, fat at 0.1; cattle, kidney at 0.1; cattle, meat at 0.01; cattle, meat byproducts, except kidney at 0.05; goat, fat at 0.1; goat, kidney at 0.1; goat, meat at 0.01; goat, meat byproducts, except kidney at 0.05; horse, fat at 0.1; horse, kidney at 0.1; horse, meat at 0.01; horse, meat byproducts, except kidney at 0.05; pear at 0.1; pecan at 0.1; sheep, fat at 0.1; sheep, kidney at 0.1; sheep, meat at 0.01; and sheep, meat byproducts, except kidney at 0.05.

Tolerances have also been established (40 CFR 180.421)(a)(2) for the combined residues of fenarimol [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol] and its metabolites [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-1,4-dihydro-5-pyrimidinemethanol and 5-[(2-chlorophenyl) (4-chlorophenyl)methyl]-3,4-dihydro-4-pyrimidinol measured as the total of fenarimol and 5-[(2-chlorophenyl)-(4-chlorophenyl)methyl]pyrimidine (calculated as fenarimol) for the following RACs: Banana (import) at 0.5; cherry at 1.0; grape, juice at 0.6; grape pomace (wet and dry) at 2.0; grape at 0.2; grape, raisin, waste at 3.0; grape, raisin at 0.6. Risk assessments were conducted by EPA to assess dietary exposures from fenarimol 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. No such effects were identified in the toxicological studies for fenarimol, therefore a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* The chronic dietary exposure assessment for fenarimol is highly refined using anticipated residues based on 1996–1999 Food and Drug Administration (FDA) monitoring data for apples, bananas, cherries, grapes and pears. Field trial residue data were used for pecans and filberts. Percent crop treated (%CT) information and processing factors, where available, were used in the assessment. There were no PDP monitoring data available for fenarimol.

iii. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Almonds 0.1%; apples 25%; bananas <1%; cherries, sweet 13%; cherries, tart 9%; grapes, raisin 21%; grapes, table 8%; grapes wine 9%; hazelnuts 9%; pecans 1%; and pears 10%. These PCT figures were derived from a quantitative usage analysis (QUA) for fenarimol by the Agency based on data years 1990–1999. The weighted average of percent crop treated (%CT) was used for estimating chronic dietary exposure. Additional information on imported bananas was obtained indicating that less than 1% of bananas consumed in the United States are treated with fenarimol. For pecans, a default 1% crop treated was assumed (0% CT reported in QUA).

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which fenarimol may be applied in a particular area.

iv. *Cancer*. Fenarimol has been classified as a ''not likely'' human carcinogen (Group E) and thus a quantitative exposure assessment as to cancer risk is unnecessary.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenarimol 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 fenarimol.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Groundwater models, the estimated environmental concentrations (EECs) of fenarimol chronic exposures are estimated to be 26 ppb for surface water and 16 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).

Fenarimol is not registered for use on any sites that would result in exposure in or around the home. Fenarimol is registered for use on turf however,. Applications to turf are limited to golf courses, and stadium fields or professional athletic fields only. Therefore, the Agency has determined that the only potential non-occupational postapplication exposure is short-term dermal exposure to adult golfers.

EPA's ''Standard Operating Procedures (SOPs) for Residential Exposure Assessments'' at *(http://www.epa.gov/fedrgstr/EPA-PEST/1999/January/Day-04/o-p34736.htm)* were used to estimate the exposures of adult golfers contacting treated turf. The SOPs for turf use transfer coefficients based on mowing studies. Chemical specific data from a turf transferable residue (TTR) study were available; however, these TTR data were unacceptable for use in postapplication exposure assessment. Therefore, default assumptions from the SOPs were used. Exposures were estimated for short-term dermal contact with treated turf during the low contact activity of golfing. The exposure estimates generated for the golfing turf use is based on some upper-percentile assumptions (i.e., duration of exposure and maximum application rate for this short-term assessment) and is considered to be representative of high end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide retained on turf, and assumptions regarding the transfer of fenarimol residues. The turf risk estimate is believed to be a reasonable and protective estimate. Therefore, the level of confidence is fairly high, and does not under estimate risk.

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 fenarimol and any other substances and fenarimol does not appear to produce a toxic metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism among fenarimol and other named pesticides that cause brain effects. EPA concluded that the evidence did not support a finding of common mechanism for fenarimol and the named pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that fenarimol 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*. The developmental and reproductive toxicity studies showed no evidence of increased sensitivity or susceptibility of young rats or rabbits following prenatal or postnatal exposure to fenarimol. However, the studies demonstrated that fenarimol is associated with hydronephrosis that is reversible.

3. *Conclusion*. The data base for prenatal developmental and reproductive toxicity is considered complete. Based upon the RED completed June 2002, the Agency reduced the FQPA Safety factor from 10X to 3X. It was determined that the 3X would be retained until a special developmental toxicity study was received and reviewed to confirm if the potential hormonal effects elicited by inhibition of aromatase would result in effects in the rat pups. However more recently, fenarimol has been evaluated in studies considered in EPA's Endocrine Disruptor Screening Program including the Pubertal Female and Uterotrophic Assays. The Pubertal Female Assay involves the use of rats to screen for estrogenic and thyroid activity in females during sexual maturation, and examines abnormalities associated with sex organs and puberty markers, as well as thyroid tissue. The Uterotrophic assay involves the use of female rats to screen for estrogenic effects. In this *in vivo* assay, uterine weight changes are measured in ovariectomised or immature female rats.

No adverse effects were found in the female pubertal assay when SD rats were treated at 50 and 250 milligram/kilogram (mg/kg) day for 21 days, except for a decrease in T4 and an increase in circulating TSH levels. In the Uterotrophic assay, a dose of 200 mg/kg day results in a significant increase of uterine weights which were accompanied by an increase in serum FSH levels and a decrease in serum T3 levels. The uterotrophic response and the effects found on thyroid hormone levels are found at much higher doses than the regulatory endpoints based on the rat multi-generation study where fenarimol reduced fertility of males at 1.2 mg/kg per day with a NOAEL of 0.6 mg/kg per day. The 0.6 mg/kg NOAEL

is over 300-fold lower than the uterotrophic response found in rats at 200 mg/kg.

In conclusion, there is greater confidence in the current NOAEL of 0.6 mg/kg per day given these recent studies on the reproductive, developmental and endocrine effects of fenarimol. It is therefore recommended that the 3X FQPA safety factor be removed because there are adequate data evaluating the potential endocrine effects of fenarimol during development and in the young animal. As a result, the Agency no longer requires a special developmental study.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. No acute risk is expected from exposure to fenarimol since no acute endpoints were identified for the general U.S. population (including infants and children) or the females 13–50 years old population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenarimol from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year old, and <1% of the cPAD for children 1-6 years old. There are no residential uses for fenarimol that result in chronic residential exposure to fenarimol. In addition, there is potential for chronic dietary exposure to fenarimol in drinking water. After calculating Drinking Water Level of Comparison (DWLOCs) and comparing them to the EECs for surface water and ground water, infants and children, the most sensitive population subgroups slightly exceed the chronic DWLOC of 20. However, the chronic EECs were estimated using Tier I modeling and only slightly exceed the DWLOC. Additional data are being required that will provide important information on the mobility of fenarimol and its degradates. These studies will help to refine the chronic surface and ground water drinking water risk assessments.

The EECs are based on a Tier 1 model FIRST for a turf use scenario with maximum application rates. The estimated EEC for surface water is a very conservative estimate. It represents the 1-in-10 year mean yearly surface water concentration. The Agency's surface water modeling for drinking water uses a default percent cropped area factor (PCA) for turf, which represents the fraction of the watershed that is cropped and treated with the pesticide being modeled. In the absence of a crop-specific PCA factor, a default PCA of 0.87 is used. The 0.87 factor represents the maximum fraction of a watershed in the US that is agriculturally cropped. This default PCA was used for fenarimol modeling on turf. The Agency is currently attempting to develop PCA factors specific for turf scenarios, and recognizes that it is unlikely that 87% of a watershed used for drinking water would be grown to turf and treated with fenarimol at the maximum rate allowed only for turf applications especially since applications to turf are limited to golf courses, and stadium fields or professional athletic fields only.

The default PCA factor assumed and used in fenarimol modeling is most likely overestimated and adds to the conservatism of the assessment. Given the relatively low usage of fenarimol across the country it is highly unlikely that the amount applied to the watershed in the model will be concentrated in any real watershed used to derive drinking water. Therefore, the EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit. The results indicated in the table below are based upon the RED, and are considered over estimates. Therefore, the risk estimates shown below are actually lower than what the table reports.

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

Population/Subgroup	cPAD/mg/kg/day	%/cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.002	<1%	26	16	70
All Infants <1 year old	0.002	<1%	26	16	20
Children (1-6 years old)	0.002	<1%	26	16	20

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). Fenarimol is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fenarimol. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOE of 1,400 for adult golfers. This aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food and residential uses.

4. *Aggregate cancer risk for U.S. population*. Fenarimol has been classified as a ''not likely'' human carcinogen (Group E).

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 fenarimol residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for data collection and enforcement of tolerances for residues of fenarimol per se in/on plants and livestock. Adequate methods are also available for determination of residues of fenarimol and Metabolites B and C in plants Pesticide Analytical Manual (PAM) Volume II, Methods I (AM-AA-CA-R039-AB-755), II (AM-AA-CA-R072-AA-755), and III (AM-AA-CA-R124-AA-755.

B. International Residue Limits

There is no CODEX maximum residue limit for filbert.

V. Conclusion

Therefore, the tolerance is established for residues of fenarimol, [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol], in or on filbert at 0.02 ppm.

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 recordkeepingrequirements.

Dated: May 22, 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 180.421 is amended by alphabetically adding a commodity to the table in paragraph (a)(1) to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

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

Commodity	Parts per million
* * * *	*
Filbert	0.02
* * * *	*

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[FR Doc. E6–8659 Filed 6–6–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0056; FRL–8070–2]

Pendimethalin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pendimethalin, [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenyzl alcohol in or on pistachio. Interregional Research Project Number 4 (IR-4) 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 June 7, 2006. Objections and requests for hearings must be received on or before August 7, 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–2005–0056. All documents in the