§ 52.220 Identification of plan.

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(379) * * *

(i) * * *

(B) San Diego County Air Pollution Control District.

(*1*) Rule 2, "Definitions," Rev. Adopted and Effective on June 30, 1999, Table 1—Exempt Compounds: Rev. and Effective on November 4, 2009.

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[FR Doc. 2010–23128 Filed 9–16–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009—0623; FRL–8844–6]

Fenarimol; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fenarimol including its metabolites and degradates in or on vegetable, cucurbit, group 9. Gowan Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 17, 2010. Objections and requests for hearings must be received on or before November 16, 2010, 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–2009–0623. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. 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: Mary L. Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2009–0623 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 16, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0623, 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility'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 Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** issue of September 4, 2009 (74 FR 45848) (FRL–8434–4), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7566) by Gowan Company, 370 South Main St., Yuma, AZ 85364. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide fenarimol and its metabolites in or on cucurbits at 0.2 parts per million (ppm). That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA has revised the commodity expression for cucurbits and has revised the tolerance expression for all

established commodities to be consistent with current Agency policy. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 for fenarimol including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenarimol 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.

Fenarimol has a relatively low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a dermal sensitizer. It is a moderate eye irritant and causes corneal opacity in rabbits. Chronic studies indicate that the liver is a target organ for toxicity. Liver toxicity was manifested by liver weight increases and the presence of "fatty liver" in rats. In dogs, increased liver weights and increases in serum enzymes, indicative of liver toxicity, were noted. However, the effects of fenarimol on aromatase, an enzyme involved in the conversion of androgens to estrogens, is the basis for toxicity endpoints. The inhibition of aromatase by fenarimol results in adverse effects in both males and females as indicated in the reproduction and developmental studies. There were no indications of a direct effect of fenarimol on the immune system. Fenarimol has been classified as not likely to be a human carcinogen, and demonstrates no mutagenic effects.

Developmental and/or reproductive toxicity studies showed no evidence of increased sensitivity or susceptibility of young rats or rabbits. However, fenarimol affects the male's reproductive performance and in females results in dystocia. Fenarimol was evaluated in two special studies in females rats, a pubertal assay which screened for estrogenic and thyroid activity during sexual maturation and for abnormalities associated with sex organs, puberty markers, and thyroid tissue and an uterotrophic assay which screened for estrogenic effects including uterine weight changes measured in ovariectomised and immature animals. In the pubertal assay at 50 and 250 milligram/kilogram/day (mg/kg/day) for 21 days, no adverse effects were found except for a decrease in the thyroid hormone T4 and an increase in circulating thyroid-stimulating hormone (TSH) levels. In the uterotrophic assay, a dose of 200 mg/kg/day resulted in a significant increase of uterine weights which were accompanied by an increase in serum follicle-stimulating hormone (FSH) levels and a decrease in serum T3 levels but at much higher doses than the regulatory endpoints selected.

Specific information on the studies received and the nature of the adverse 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.regulations.gov* in document "Fenarimol. Human Health Risk Assessment for the Proposed New Food Use of Fenarimol in/on Imported Cucurbit Vegetables, Crop Group 9" at pp. 46–49 in docket ID number EPA–HQ–OPP–2009–0623.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.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 DOSES AND ENDPOINTS FOR FENARIMOL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	Not applicable	Not applicable	No appropriate hazard was identified for single-dose risk assessment.

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

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary (All populations)	NOAEL= 0.6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.006 mg/kg/day cPAD = 0.006 mg/kg/day	Rat reproduction LOAEL = 1.2 mg/kg/day based on decreased live born litter size
Dermal short-term (1 to 30 days)	LOAEL = 35 mg/kg/day (dermal absorption rate = 5% UF_A = 10x UF_H = 10x FQPA SF = 10x (as an UF_L)	LOC for MOE = 1,000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenarimol, EPA considered exposure under the petitioned-for tolerances as well as all existing fenarimol tolerances in 40 CFR 180.421. EPA assessed 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.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). The chronic dietary exposure assessment for fenarimol is highly refined using anticipated residues based on USDA Pesticide Data Program (PDP) monitoring data for apples, bananas, cherries, grapes, and pears. Field trial residue data were used for cantaloupe, cucumber, filberts, hops, pecans, and summer squash. Tolerance level residues were assumed for all other commodities. Percent crop treated (PCT) information was used for apples, cherries, grapes, and pears, and 100 PCT was assumed for all other crops.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenarimol does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *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 residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

- Apples – 15%.
- Cherries – 5%.
- Grapes – 20%.
- Pears – 5%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenarimol and its degradates (U-1, U-2, U-6, and U-7) in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenarimol. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) for

chronic exposures for non-cancer assessments are estimated to be 66 parts per billion (ppb) for surface water and 19 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 66 ppb was used to assess 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).

Fenarimol is currently registered for use on professionally managed turf areas, such as stadia and golf course tees, greens, and fairways. Short-term post-application dermal exposure to golfers is possible. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fenarimol to share a common mechanism of toxicity with any other substances, and fenarimol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenarimol does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The database for prenatal developmental (in rats and rabbits) and reproductive (in rats) toxicity is complete and includes special studies in addition to conventional guideline studies. The rat developmental study showed evidence of hydronephrosis in fetuses at dose levels equal to or possibly lower than doses causing maternal toxicity; however, a special study showed this effect to be reversible and therefore not considered an adverse effect.

Additionally, the decreased live born litter size and survival indices in the rat multi-generation reproduction study are considered to be a secondary consequence of parental effects (e.g., dystocia and fertility), and is not an indicator of increased susceptibility. Therefore, there is no evidence of increased susceptibility of fetuses following *in utero* exposure in the rat or rabbit developmental toxicity study or of offspring following prenatal and postnatal exposure in the rat reproduction study, and there are no concerns or residual uncertainties for prenatal and/or postnatal toxicity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for assessing chronic risk. That decision is based on the following findings:

i. The toxicity database for fenarimol is complete except for immunotoxicity testing. Changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Harmonized Test Guideline 870.7800) required for pesticide registration; however, the available data for fenarimol do not show the potential for immunotoxicity. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database UF does not need to be applied.

ii. There is no indication that fenarimol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenarimol results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilized tolerance-level residues, anticipated residue data that are based on reliable field trial data, or food monitoring data collected by USDA under the PDP. For several currently registered commodities, the chronic assessment also utilized PCT data that have a valid basis and are considered to be reliable. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenarimol in drinking water. EPA used similarly conservative assumptions to assess post-application residential exposure. These assessments will not underestimate the exposure and risks posed by fenarimol.

EPA has retained a 10X FQPA SF for assessing short-term risk because the study used in assessing short-term risk did not identify a NOAEL for the effects observed. The Agency is confident that the 10X FQPA SF is adequate (as opposed to a larger SF) for assessing risks from short-term exposure to fenarimol based on the following weight of evidence considerations.

- The most sensitive endpoint for target organ toxicity (potential interaction with the androgen and/or estrogen pathway) is being used for these (short-term) exposure scenarios and this selection is supported by and comparable to the endpoint (reproductive effects) used in assessing dietary and non-dietary risks for intermediate and chronic exposures.
- Fenarimol has been evaluated in two of the Tier 1 assays developed by the Agency's Endocrine Disruption Screening Program, the "Female Pubertal Assay" and the "Uterotrophic Assay."
- In the female pubertal assay, following oral exposure for 21 days- (which is comparable to the short-term exposure scenario of concern)- no adverse effects on sexual maturation, abnormalities associated with sex organ, or pubertal markers were seen at doses up to and including 250 mg/kg/day.
- In the uterotrophic assay, following oral exposure for 3 days, a dose of 200 mg/kg/day resulted in increased uterine weight.
- As noted in Unit III.A., the uterotrophic response was seen at a much higher dose (200 mg/kg/day) than the regulatory doses used for overall risk assessments: Extrapolated NOAEL of 3.5 mg/kg/day for short-term and a NOAEL of 0.6 mg/kg/day for assessing intermediate and long-term dietary and non-dietary risks.

• Specifically, the extrapolated NOAEL of 3.5 mg/kg/day used for short-term assessments is approximately 60–fold lower than the uterotrophic response found in rats at 200 mg/kg/day.

This weight of evidence provides sufficient confidence that the default 10X FQPA SF is adequate (i.e, the LOC is a MOE of 1,000) and it would not underestimate short-term risk from exposure to fenarimol.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, fenarimol is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenarimol from food and water will utilize 77% of the cPAD for all infants < 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fenarimol is not expected.

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

Fenarimol is currently registered for use on professionally managed turf, including stadia and golf course tees, greens, and fairways which could result in short-term post-application dermal exposure to golfers. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fenarimol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,800 for adults 20–49 years old. While the residential scenario is based on an adult population, careful analyses of body weight-to-surface area ratios and durations of exposure resulted in the conclusion that mitigation for this population subgroup will also be protective for all population subgroups including young adults and children. Because EPA's LOC for fenarimol is a MOE of 1,000 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenarimol is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) with an electrolytic conductivity detector (ECD)) is available to enforce the tolerance expression. PAM Volume II lists three GC/ECD methods, designated as Methods I (AM-AA-CA-R039-AB-755), II (AM-AA-CA-R072-AA-755), and III (AM-AA-CA-R124-AA-755) for tolerance enforcement.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by section 408(b)(4) of FFDCA. The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for fenarimol in or on melons, except watermelon at 0.05 ppm. This MRL is different than the tolerance of 0.20 ppm for vegetable, cucurbit, group 9 established for fenarimol in the United States. The tolerances cannot be harmonized because the field trial data demonstrated higher residues than the Codex MRL.

C. Revisions to Petitioned-For Tolerances

EPA has revised the petitioned-for tolerance "cucurbits" to "vegetable, cucurbit, group 9" to agree with the Agency's Food and Feed Commodity Vocabulary. Additionally, the Agency has revised the tolerance expression to clarify that, as provided in section 408(a)(3), of FFDCA the tolerance covers metabolites and degradates of fenarimol not specifically mentioned, and that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, a tolerance is established for residues of fenarimol, alpha-(2 chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on vegetable, cucurbit, group 9 at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 9, 2010.

G. Jeffrey Herndon,

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. In § 180.421, revise the introductory text of paragraph (a) and add alphabetically the entry "vegetable, cucurbit, group 9" to the table in paragraph (a) to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

(a) *General.* Tolerances are established for residues of fenarimol, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only fenarimol alpha-(2 chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol.

Commodity	Parts per million
* *	* * *
Vegetable, cucurbit, group 9*	0.20 ppm

*There are no U.S. registrations as of August 27, 2010.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0814; FRL–8842–3]

S-metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of S-metolachlor in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 17, 2010. Objections and requests for hearings must be received on or before November 16, 2010, 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–2009–0814. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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