

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: June 19, 2009.

**Steven Bradbury,**

*Acting Director, Office of Pesticide Programs.*

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

### PART 180—[AMENDED]

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

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

■ 2. Section 180.647 is added to read as follows:

#### § 180.647 d-Phenothrin; tolerances for residues.

(a) *General.* A tolerance of 0.01 parts per million is established for residues of the insecticide d-phenothrin in or on all food/feed crops following wide-area mosquito adulticide applications.

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

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

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

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0478; FRL-8423-6]

#### Pyrimethanil; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation replaces existing tolerances for residues of pyrimethanil on fruit, citrus, group 10 postharvest; and fruit, stone, group 12, except cherry with tolerances for residues of pyrimethanil in or on fruit, citrus, group 10, except lemon, postharvest; fruit, stone, group 12; and lemon, preharvest and postharvest. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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-2008-0478. 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:

Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite 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 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-2008-0478 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 as required by 40 CFR part 178 on or before September 8, 2009.

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 this copy, identified by docket ID number EPA-HQ-OPP-2008-0478, 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. Petition for Tolerance

In the **Federal Register** of July 9, 2008 (73 FR 39289) (FRL-8371-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7353) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.518 be amended by establishing tolerances for residues of the fungicide pyrimethanil, 4,6-dimethyl-N-phenyl-2-pyrimidinamine, in or on fruit, citrus, (except lemon), group 10 (postharvest) at 10 parts per million (ppm); lemon at 11 ppm; and fruit, stone, group 12 at 10 ppm; and removing existing tolerances for residues of pyrimethanil on fruit, citrus, group 10 postharvest at 10 ppm; and fruit stone, group 12, except cherry at 3.0 ppm. That notice referenced a

summary of the petition prepared by Bayer CropScience, the registrant, on behalf of IR-4, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has made minor changes to the citrus commodity definitions. The reason for these changes is 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 section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for residues of pyrimethanil on fruit, citrus, group 10, except lemon, postharvest at 11 ppm; fruit, stone, group 12 at 10 ppm; and lemon, preharvest and postharvest at 11 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Pyrimethanil is of low acute toxicity by the oral, inhalation, and dermal routes of exposure. It is slightly irritating to the eyes and non-irritating to the skin in rabbit studies.

Pyrimethanil is not a dermal sensitizer. Subchronic and chronic repeated oral toxicity studies in rats, mice, and dogs primarily resulted in decreased body weight and body-weight gains, often accompanied by decreased food consumption. The major target organs in rats and mice were the liver and thyroid. In subchronic studies in rats and mice, liver toxicity was manifested as increased absolute and relative liver weights. Histopathological changes in the liver were primarily associated with increased evidence of hypertrophy in centrilobular hepatocytes. In a subchronic toxicity study in mice, increases in absolute thyroid weight were observed, associated with exfoliative necrosis and pigmentation of follicular cells. In a subchronic toxicity study in rats, thyroid effects were manifested as an increased incidence and severity of follicular epithelial hypertrophy and follicular epithelial brown pigment.

EPA classified pyrimethanil as a Group C (possible human) carcinogen, based on an increased incidence of thyroid follicular cell tumors observed in the chronic/carcinogenicity study in rats. There was no evidence of carcinogenicity in mice; however, the dosing in this study was not considered to be adequate to assess the potential carcinogenicity. Therefore, EPA is requesting a repeat of the mouse carcinogenicity study. Based on the presence of thyroid tumors in rats, EPA has determined that a margin of exposure (MOE) approach is appropriate for quantification of risk. This determination is based on evidence that pyrimethanil appears to induce thyroid tumors through a disruption in the thyroid-pituitary status and thus may have a threshold for tumor development. This decision was supported by the weight of the evidence, considering the neoplastic, related nonneoplastic and/or hormonal effects in the male rat thyroid and liver. A point of departure (POD) of 17 milligrams/kilograms/day (mg/kg/day), based on the thyroid precursor lesions is used for establishing the chronic population adjusted dose (cPAD) for pyrimethanil. The cPAD will be protective of any potential cancer and non-cancer effects from exposure to pyrimethanil. At this time, there is less concern for the lack of a repeat mouse carcinogenicity study, since no toxicologically significant effects were

noted up to the highest dose tested (HDT) (254 mg/kg/day) in the existing mouse study, and the new study will be tested at higher doses. Consequently EPA does not believe that the new study will yield a POD lower than the current POD (17 mg/kg/day) used for risk assessment.

Signs of potential neurotoxicity (ataxia, decreased motor activity, decreased body temperature, decreased hind limb grip strength in males, and dilated pupils in females) were observed at the HDT (1,000 mg/kg/day) in the acute neurotoxicity study in rats. No signs of neurotoxicity were evident at doses up to 392 mg/kg/day in the subchronic neurotoxicity study in rats; and there was no evidence of neuropathology in either the acute or subchronic neurotoxicity study or in any of the subchronic and chronic toxicity studies in mice, rats and dogs.

There was no quantitative or qualitative evidence of increased susceptibility of fetuses in the developmental toxicity studies in rats and rabbits or of offspring in the 2-generation reproduction toxicity study in rats. In the rat developmental toxicity study, maternal effects (decreased body weight and weight gain) and fetal effects (decreases in mean litter weight and mean fetal weight) were observed at the same dose. Similarly, in the rabbit developmental toxicity study, fetal effects (decreased body weight, weight gain, food consumption, and production and size of fecal pellets; increase in fetal runts; retarded ossification; 13 thoracic vertebrae and pairs of ribs; and deaths) occurred at a dose that produced similar maternal toxicity (decreased body weight, weight gain, food consumption, and production and size of fecal pellets, and deaths). There were no effects on fertility or reproduction in the 2-generation reproduction study in rats. In this study, adverse effects (decreased body weight/weight gain) also occurred at the same dose in parental animals and pups.

Specific information on the studies received and the nature of the adverse effects caused by pyrimethanil 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 the document *Pyrimethanil Human-Health Risk Assessment for Proposed Uses on Stone Fruits and Citrus Fruits*, page 39 in docket ID number EPA-HQ-OPP-2008-0478.

## B. Toxicological Endpoints

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

risk, a toxicological POD is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and cPAD. The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 pyrimethanil used for human risk assessment can be found at <http://www.regulations.gov> in the document *Pyrimethanil Human-Health Risk Assessment for Proposed Uses on Stone Fruits and Citrus Fruits*, page 20 in docket ID number EPA-HQ-OPP-2008-0478.

## C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrimethanil, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrimethanil tolerances in 40 CFR 180.518. EPA assessed dietary exposures from pyrimethanil 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. EPA identified such effects for the general population (decreased motor activity, ataxia, decreased body temperature, hind limb grip strength, and dilated pupils observed in the acute neurotoxicity study) and for females 13 to 49 years old (increase in fetuses with 13 thoracic vertebrae and 13 pairs of ribs observed in the rabbit developmental toxicity study that are presumed to occur after a single exposure). The aPAD for the general population has been established at 1 mg/kg/day; whereas, the aPAD for females 13 to 49 years old is lower (0.45 mg/kg/day) due to the more sensitive endpoint on which it is based.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that pyrimethanil residues are present in all commodities at tolerance levels and that 100% of all crops are treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that pyrimethanil residues are present in all commodities at tolerance levels and that 100% of all crops are treated.

iii. *Cancer.* EPA classified pyrimethanil as a Group C (possible human) carcinogen but determined that the chronic dietary risk assessment based on the cPAD would be protective of any potential cancer effects. Therefore, a separate exposure assessment to evaluate cancer risk is unnecessary. The weight of the evidence supporting this determination is discussed in unit III.A.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for pyrimethanil. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyrimethanil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrimethanil. 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 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) of pyrimethanil for acute exposures are estimated to be 37.8 parts per billion (ppb) for surface water and 4.8 ppb for ground water. EDWCs of pyrimethanil for chronic exposures for non-cancer assessments are estimated to be 5.1 ppb for surface water and 4.8 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 37.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.1 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). Pyrimethanil is not registered for any specific use patterns that would result in residential exposure.

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 pyrimethanil to share a common mechanism of toxicity with any other substances, and pyrimethanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrimethanil 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 Food Quality Protection Act of 1996 (FQPA) safety factor (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 prenatal and postnatal toxicology database for pyrimethanil includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. As discussed in unit III.A., there was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring following exposure to pyrimethanil in these studies.

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. That decision is based on the following findings:

i. The toxicity database for pyrimethanil is adequate to assess the prenatal and postnatal toxicity of pyrimethanil. In accordance with 40 CFR part 158's toxicological data requirements, an immunotoxicity testing study (OPPTS Guideline 870.7800) is required for pyrimethanil. The evidence for immunotoxicity in the existing database is limited to a slight decrease in thymus weight observed at the HDT (529 mg/kg/day) in the subchronic study in rats. There were no corroborative histopathological findings noted in the thymus in this study, and there were no effects on the thymus in the chronic/carcinogenicity study in rats at doses up to and including 221 mg/kg/day or in any other study with pyrimethanil. Since the observed thymus weight increase is an isolated finding, EPA does not believe that conducting immunotoxicity testing will result in a POD lower than the POD already selected for evaluating chronic exposures to pyrimethanil (17 mg/kg/day), and an additional database UF is not needed to account for potential immunotoxicity.

ii. Although there were signs of potential neurotoxicity (ataxia, decreased motor activity, decreased body temperature, decreased hind limb grip strength in males, and dilated pupils in females) observed at the HDT

(1,000 mg/kg/day) in the acute neurotoxicity study, there were no signs of neurotoxicity at doses up to 392 mg/kg/day in the subchronic neurotoxicity study; and there was no evidence of neuropathology in either the acute or subchronic neurotoxicity study or in any of the subchronic and chronic toxicity studies in mice, rats and dogs. Based on these findings, EPA has determined that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that pyrimethanil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in offspring in the 2-generation reproduction study. There are no residual uncertainties for prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyrimethanil in drinking water. Pyrimethanil is not registered for any uses that would result in residential exposures to the pesticide. These assessments will not underestimate the exposure and risks posed by pyrimethanil.

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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, EPA performed two different acute risk assessments—one focusing on females 13 to 49 years old and designed to protect against prenatal effects and the other focusing on acute effects

relevant to all other population groups. For females 13 to 49 years old, the acute dietary exposure to pyrimethanil from food and water will occupy 13% of the aPAD addressing prenatal effects. As to acute effects other than prenatal effects, the acute dietary exposure to pyrimethanil from food and water will occupy 35% of the aPAD for infants less than 1-year old, the population group with the highest estimated acute dietary exposure to pyrimethanil.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyrimethanil from food and water will utilize 63% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for pyrimethanil.

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). Pyrimethanil is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to pyrimethanil through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyrimethanil is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to pyrimethanil through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* The Agency has determined that the chronic risk assessment based on the established cPAD is protective of potential cancer effects from exposure to pyrimethanil. Based on the results of the chronic risk assessment discussed in Unit III.E.2. EPA concludes that pyrimethanil is not expected to pose a cancer risk.

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography (HPLC)) 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*.

##### B. International Residue Limits

Codex maximum residue limits (MRLs) have been established for pyrimethanil *per se* in/on plant commodities associated with this petition, including citrus fruit at 7 ppm (postharvest); cherry (postharvest), peach and nectarine at 4 ppm; apricot at 3 ppm; and plum at 2 ppm. Due to differences in application rates and use patterns, harmonization of U.S. tolerances with the lower Codex MRLs is not possible at this time.

##### C. Revisions to Petitioned-For Tolerances

IR-4 petitioned for tolerances for residues of pyrimethanil on "fruit, citrus, (except lemon), group 10, (postharvest)" and on "lemon." EPA revised the group tolerance to read "fruit, citrus, group 10, except lemon, postharvest" to agree with the accepted nomenclature in the Agency's Food and Feed Vocabulary Database. The tolerance for lemon was revised to read "lemon, preharvest and postharvest" to comply with the regulation at 40 CFR 180.1(h), which requires EPA to specify those tolerances intended to cover postharvest use of a pesticide.

#### V. Conclusion

Therefore, tolerances are established for residues of pyrimethanil, 4,6-dimethyl-N-phenyl-2-pyrimidinamine, in or on fruit, citrus, group 10, except lemon, postharvest at 10 ppm; fruit, stone, group 12 at 10 ppm; and lemon, preharvest and postharvest at 11 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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 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.

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 section 408(n)(4) of FFDCA. 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: June 26, 2009.

**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. The table in paragraph (a)(1) of § 180.518 is amended by removing the commodities "Fruit, citrus, group 10 postharvest" and "Fruit, stone, group 12, except cherry" and alphabetically adding the following commodities to read as follows:

**§ 180.518 Pyrimethanil; tolerances for residues.**

(a)	*	*	*
(1)	*	*	*
Commodity	Parts per million		
* * * *	*		
Fruit, citrus, group 10, except lemon, postharvest .....	*	10	
* * * *	*		
Fruit, stone, group 12 .....	*	10	
* * * *	*		
Lemon, preharvest and postharvest .....	*	11	
* * * *	*		

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2008-0731; FRL-8423-5]

**Cyazofamid; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of cyazofamid and its metabolite, CCIM, expressed as cyazofamid in or on fruiting vegetable group 8 and okra. Additionally, it establishes a tolerance with regional restrictions in or on grape. Finally, this regulation removes the established grape import and tomato tolerances, as a regional tolerance on grape and fruiting vegetable group tolerance replaces them, respectively. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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-2008-0731. 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:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001; telephone number: (703) 305-7390; e-mail address: [nollen.laura@epa.gov](mailto:nollen.laura@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 Access Electronic Copies of this Document?*

In addition to accessing electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite 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 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