General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: July 18, 2012.

**G. Jeffery 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 § 180.940(a), the table is amended by adding alphabetically the following inert ingredient after the entry for ''Magnesium oxide'' to read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food contact surface sanitizing solutions).**

* * * * *

(a) * * *

| Pesticide chemical | CAS Reg. No. | Limits |
|---|---|---|
| * * * * | * | * * |
| 2-Methyl-1,3-propanediol | 2163–42–0 | None. |
| * * * * | * | * * |

* * * * *

[FR Doc. 2012–18506 Filed 7–31–12; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2011–0477; FRL–9354–7]**

## Pyrimethanil; Pesticide Tolerances

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

**ACTION:** Final rule.

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

**DATES:** This regulation is effective August 1, 2012. Objections and requests for hearings must be received on or before October 1, 2012, 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:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0477, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7509P) Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 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–2011–0477 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 October 1, 2012. 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–2011–0477, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL–8880–1), 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 1E7861) 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 the raw agricultural commodities onion, bulb, subgroup 03–07A at 0.1 parts per million (ppm), onion, green, subgroup 03–07B at 2.0 ppm, berry and small fruit, small fruit vine climbing subgroup, except fuzzy kiwifruit 13–07F at 5.0 ppm, berry and small fruit, low growing berry subgroup 13–07G at 3.0 ppm and ginseng at 2.5 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available 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 modified the levels at which tolerances are being established for some of the commodities. The reason for this change 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 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 pyrimethanil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrimethanil 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 lethality by the oral, dermal, and inhalation routes. It is a slight eye irritant, is not irritating to the skin, and it is not a dermal sensitizer. A single oral dose of 1,000 milligrams/kilogram (mg/kg) produced a number of acute signs of neurotoxicity, including ataxia, dilated pupils, and decreases in motor activity, hind limb grip strength, and body temperature. However, there was no evidence of neurotoxicity with repeated dosing in a subchronic neurotoxicity study in rats. Exposure to pyrimethanil in oral toxicity studies primarily resulted in decreased body weights and body-weight gain, often accompanied by decreases in food consumption. The major target organs of repeated oral exposure were the liver and the thyroid. No reproductive toxicity was observed, and developmental effects (e.g., decreased fetal weight, retarded ossification, extra ribs) were observed only at maternally toxic doses. Special short-term exposure studies demonstrated increased liver uridine diphosphate glucuronosyl transferase (UDPGT) activity leading to decreases in thyroid hormones (T3, T4) and compensatory increases in thyroid stimulating hormone (TSH) in adult rats. Thyroid adenomas were seen in rats following long-term exposure, and it was concluded that they were mediated via disruption of the thyroid/pituitary axis. There were no concerns for mutagenicity.

The EPA has classified pyrimethanil as ''Not Likely To Be Carcinogenic To Humans At Doses That Do Not Alter Rat Thyroid Hormone Homeostasis.'' This decision was based on the following:

1. There were treatment-related increases in thyroid follicular cell tumors in male and female Sprague-Dawley rats at doses which were considered adequate to assess carcinogenicity.

2. There were no treatment-related tumors were seen in male or female CD–1 mice at doses which were considered adequate to assess carcinogenicity.

3. There is no mutagenicity concern and there is no evidence for thyroid carcinogenesis mediated through a mutagenic mode of action.

4. The non-neoplastic toxicological evidence (i.e., thyroid growth, thyroid hormonal changes) indicated that pyrimethanil was inducing a disruption in the thyroid-pituitary hormonal status. The overall weight-of-evidence was considered sufficient to indicate that Pyrimethanil induced thyroid follicular tumors through an antithyroid mode of action.

5. Rats are substantially more sensitive than humans to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance. EPA determined that quantification of carcinogenic risk is not required since the thyroid tumors arise through a non-linear mode of action and the no observed adverse effect level (NOAEL) (17 mg/kg/day) established for deriving the chronic reference dose (cRfD) is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation.

Specific information on the studies received and the nature of the adverse effects caused by pyrimethanil as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Pyrimethanil Human-Health Risk Assessment for Proposed Uses on

Ginseng, Bulb Onion Subgroups 3–07A and B, and Small Berry Subgroups 13–07F and G,'' pp. 32–34 in docket ID number EPA–HQ–OPP–2011–0477.

*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 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 pyrimethanil used for human risk assessment is shown in the Table of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRIMETHANIL 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 (Females 13–49 years of age). | NOAEL = 45 mg/kg/day ....<br>$UF_A$ = 10X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Acute RfD = 0.45 mg/kg/day.<br>aPAD = 0.45 mg/kg/day | Developmental Toxicity—Rabbit:<br>LOAEL = 300 mg/kg/day based on increases in fetuses with 13 thoracic vertebrae and 13 pairs of ribs. |
| Acute dietary (General population including infants and children). | NOAEL = 100 mg/kg/day ..<br>$UF_A$ = 10X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Acute RfD = 1 mg/kg/day ..<br>aPAD = 1 mg/kg/day | Acute Neurotoxicity—Rat:<br>LOAEL = 1,000 mg/kg/day based on decreased motor activity, ataxia, decreased body temperature, hind limb grip strength, and dilated pupils. |
| Chronic dietar (All populations). | NOAEL= 17 mg/kg/day .....<br>$UF_A$ = 10X<br>$UF_H$ = 10X<br>FQPA SF = 1X | Chronic RfD = 0.17 mg/kg/day.<br>cPAD = 0.17 mg/kg/day | Chronic Toxicity—Rat:<br>LOAEL = 221 mg/kg/day based on decreased body-weight gains; increased serum cholesterol and GGT, increased relative liver/body weight ratios, necropsy and histopathological findings in the liver and thyroid. |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies).

*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.

Such effects were identified for pyrimethanil. 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 default processing factors (as necessary), empirical processing factors for orange and apple juice, tolerance level residues and 100 percent crop treated (PCT) for all commodities.

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 default processing factors (as necessary), empirical processing factors for orange and apple juice, tolerance level residues and 100 PCT for all commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pyrimethanil. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/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 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) of pyrimethanil for acute exposures are estimated to be 86.5 parts per billion (ppb) for surface water and 4.8 ppb for ground water. For chronic exposures for non-cancer assessments, they are estimated to be 29.4 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 86.5 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 29.4 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 Web site 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 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 toxicology database for pyrimethanil is complete.

ii A guideline immunotoxicity study has been submitted, and there is no evidence for immunotoxicity due to pyrimethanil treatment. Evidence of neurotoxicity was observed at a very high dose (the limit dose) in the acute neurotoxicity study in rats. However, the study has a clear NOAEL, which is being utilized as the POD for the acute dietary exposure scenario, and there was no evidence of neurotoxicity observed in the subchronic neurotoxicity study in rats up to the highest dose tested in that study (430 mg/k/day). A developmental neurotoxicity (DNT) study is not required.

iii. There is no evidence that pyrimethanil 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. Thyroid has been shown to be one of the target organs in adult animals for pyrimethanil-induced toxicity thus raising a potential concern for thyroid toxicity in the young. EPA, however, concluded that there is no concern for thyroid toxicity in the young based on the following weight of evidence considerations: the effects seen on the thyroid and the liver in the database, while treatment-related, are not severe in nature; and in each of the studies that show an effect on thyroid hormone levels, as well as in all studies chosen for PODs selection, there is a wide dose spread (~10-fold difference between NOAELs and LOAELs) which provides a measure of protection for any potential effects linked to decreased thyroid hormone levels in offspring.

v. There are no residual uncertainties with respect to exposure data. The dietary food exposure assessment utilizes tolerance-level residues (established or recommended) and 100 PCT for all proposed/established commodities. By using these assumptions, the acute and chronic exposures/risks will not be underestimated. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters that are designed to provide conservative, health-protective, high-end estimates of water concentrations that will not likely be exceeded. 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrimethanil will occupy 35% of the aPAD for all infants <1 year old, the population group receiving the greatest exposure.

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 64% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for pyrimethanil.

3. *Short-and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-and intermediate-term residential exposure plus chronic exposure to food

and water (considered to be a background exposure level). A short-and intermediate-term adverse effect was identified; however, pyrimethanil is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short-and intermediate-term risk is assessed based on short-and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-and intermediate-term risk), no further assessment of short-and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-and intermediate-term risk for pyrimethanil.

4. *Aggregate cancer risk for U.S. population.* The Agency determined that the thyroid tumors seen in rat studies arise through a non-linear mode of action and the NOAEL (17 mg/kg/day) established for deriving the cRfD is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation. Thus, the chronic risk assessment addresses any cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population 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; email address: *residuemethods@epa.gov.*

### *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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for pyrimethanil in or on strawberry at 3 ppm, bulb onions at 0.2 ppm, and spring onion at 3 ppm. These MRLs are the same as the tolerances established by this rule for pyrimethanil on the low growing berry subgroup 13–07G, the bulb onion subgroup 3–07A, and the green onion subgroup 3–07B in the United States.

The Codex has established an MRL for pyrimethanil in or on grapes at 4 ppm which is less than tolerance of 5.0 ppm set on the small vine climbing fruit subgroup 13–07F of which grape is a member. The reason for this is due to the fact that the European PHI is 21 days and the U.S. PHI is 7 days. Residues are thus higher in U.S. residue trials, necessitating a higher tolerance.

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

Using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures for the residue data set indicates that the requested tolerance of 2.5 ppm for residues of pyrimethanil in/on ginseng is too high and that a tolerance of 1.5 ppm is appropriate. Also, the tolerance levels for the bulb onion subgroup 3–07A and green onion subgroup 3–07B were modified to harmonize with existing Codex Maximum Residue Levels (MRLs). Lastly, EPA has revised the tolerance expressions to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyrimethanil not specifically mentioned; and

2. 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, tolerances are established for residues of pyrimethanil (4,6-dimethyl-*N*-phenyl-2-pyrimidinamine) in or on onion, bulb, subgroup 03–07A at 0.20 ppm; onion, green, subgroup 03–07B at 3.0 ppm; fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwifruit 13–07F at 5.0 ppm; berry, low growing, subgroup 13–07G at 3.0 ppm and ginseng at 1.5 ppm.

Also, due to the tolerances established in this unit by this document, the following existing tolerances are removed as unnecessary; strawberry; grape; onion, bulb; and onion, green.

## 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) (Pub. L. 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: July 18, 2012.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. Section 180.518 is amended as follows:

■ a. Revising the introductory text to paragraph (a)(1);

■ b. Removing the entries for ''Grape''; ''Onion, bulb''; and ''Onion, green; and ''Strawberry'' from the table in paragraph (a)(1);

■ c. Alphabetically adding the following commodities to the table in paragraph (a)(1); and

■ d. Revising the introductory text for paragraphs (a)(2) and (3).

The amendments read as follows:

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

(a) *General.* (1) Tolerances are established for residues of the fungicide pyrimethanil, 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 pyrimethanil (4,6-dimethyl-*N*-phenyl-2-pyrimidinamine).

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Berry, low growing, subgroup 13–07G | 3.0 |
| * * * * * | |
| Fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwifruit | 5.0 |
| * * * * * | |
| Ginseng | 1.5 |
| * * * * * | |
| Onion, bulb, subgroup 3–07A | 2.0 |
| Onion, green, subgroup 3–07B | 3.0 |
| * * * * * | |

(2) Tolerances are established for residues of the fungicide pyrimethanil, 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 the sum of pyrimethanil and its metabolite 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol, calculated as the stoichiometric equivalent of pyrimethanil.

* * * * *

(3) Tolerances are established for residues of the fungicide pyrimethanil, 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 the sum of pyrimethanil and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol, calculated as the stoichiometric equivalent of pyrimethanil.

* * * * *

[FR Doc. 2012–18388 Filed 7–31–12; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 90

**[WP Docket No. 07–100; PS Docket No. 06–229; WT Docket No. 06–150; FCC 12–61]**

### 4.9 GHz Band

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission adopts rule changes to three aspects of the technical provisions of part 90 of the Commission's rules pertaining to public safety operations. All of these changes are designed to correct typographical or other ministerial errors in these provisions. First, the Commission reinstates a rule provision that exempted 4940–4990 MHz (4.9 GHz) band applicants from certified frequency coordination. Next, the Commission corrects the bandwidth of Channel 14 in the 4.9 GHz band plan from five megahertz to one megahertz, and amends the band plan to list the center frequencies for each channel aggregation permitted in the rules. Finally, the Commission corrects minor errors in the Public Safety Pool Frequency Table and associated list of limitations. All of these changes are designed to correct typographical or other ministerial errors in these provisions. These changes affecting the 4.9 GHz band in particular will improve spectrum efficiency and clarify the rules so as to encourage greater use of the 4.9 GHz band.

**DATES:** Effective August 31, 2012.

**FOR FURTHER INFORMATION CONTACT:** Thomas Eng, Policy and Licensing Division, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554, at (202) 418–0019, TTY (202) 418–7233, or via email at *Thomas.Eng@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Fourth Report and Order* in WP Docket No. 07–100; PS Docket No. 06–229; WT Docket No. 06–150; adopted and released on June 13, 2012. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., in person at 445 12th Street SW., Room CY–B402, Washington, DC 20554, via telephone at (202) 488–5300, via