Polymer	CAS No.
* * * * *	
Poly[oxy(methyl-1,2-ethanediyl)], α-[(9Z)-1-oxo-9-octadecen-1-yl]-ω-[[(9Z)-1-oxo-9-octadecen-1-yl]oxy]-, minimum number average molecular weight (in amu) 2,300	26571–49–3
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[FR Doc. 2015–26617 Filed 10–20–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0012; FRL–9935–11]

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 the tolerances associated with pesticide petition number (PP 4E8302), and Bayer CropScience requested the tolerances associated with PP 4F8291, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 21, 2015, except for the amendment to § 180.661 in amendatory instruction number 3, which is effective April 21, 2016. Objections and requests for hearings must be received on or before December 21, 2015, 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–2015–0012, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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.ecfr.gov/cgi-bin/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–2015–0012 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 December 21, 2015. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0012, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (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.html.*

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 December 17, 2014 (79 FR 75107) (FRL–9918–90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of (PP 4E8302) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide pyrimethanil, (4,6-dimethyl-*N*-phenyl-2-pyrimidinamine), in or on cucumber at 1.5 parts per million (ppm); fruit, pome, group 11–10 at 14 ppm; fruit, stone, group 12–12 at 10 ppm; grapefruit subgroup 10–10C at 10 ppm; lemon subgroup 10–10B at 11 ppm; orange subgroup 10–10A at 10 ppm; and tomato subgroup 8–10A at 0.5 ppm. Upon approval of the tolerances in this petition, the petition requested that the tolerances for fruit, citrus, group 10 except lemon, postharvest; fruit, pome, group 11 (preharvest and post-harvest); fruit, stone, group 12; lemon (preharvest and postharvest); and tomato be removed as they are superseded. This petition additionally requested that 40 CFR 180.518 be amended by revising the existing tolerance for onion, bulb, subgroup 3–07A from 2.0 ppm to 0.20 ppm. That document referenced a summary of the petition prepared on behalf of IR–4 by Bayer CropScience,

the registrant, which is available in the docket EPA–HQ–OPP–2014–0590 at *http://www.regulations.gov.* There were no comments received in response to this notice of filing.

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL–9927–39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of PP 4F8291 by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide pyrimethanil, in or on in or on caneberry (subgroup 13–07A) at 15.0 ppm and bushberry (subgroup 13–07B) at 8.0 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the petitioned-for tolerance in or on fruit, pome, group 11–10. The Agency has also determined that the separate subgroup tolerances proposed in or on orange subgroup 10–10A, lemon subgroup 10–10B, and grapefruit subgroup 10–10C should be established in or on fruit, citrus, group 10–10. The reasons for these changes are explained in Unit IV.D.

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.

The major target organs of repeated oral exposure to pyrimethanil were the liver, kidney and thyroid. By the oral route of exposure, the rat was the most sensitive species to pyrimethanil toxicity, followed by the dog and then the mouse. Effects observed including clinical signs (for example, vomiting, diarrhea and salivation in the dog), changes in clinical chemical parameters (liver enzymes), changes in organ weights (mostly relative), and macroscopic and microscopic organ changes. These effects were accompanied by decreased body weight. Clinical signs of neurotoxicity including ataxia and dilated pupils, and decreases in motor activity, hind limb grip strength and body temperature were observed in an acute neurotoxicity study in rats (females only) at the highest dose tested (HDT). However, there was no evidence of neurotoxicity with repeated dosing in a subchronic neurotoxicity study in rats.

Special short-term exposure studies conducted for pyrimethanil demonstrated increased liver uridine diphosphate glucuronosyl transferase activity, leading to decreases in thyroid hormones (T3, T4) and compensatory increases in thyroid-stimulating hormone (TSH) in adult rats. Although the effects on the thyroid raise a potential concern for thyroid toxicity in the young, EPA concluded there is no concern for thyroid toxicity in the young based on the following: (1) The effects are not severe in nature and; (2) the wide dose spread (*i.e.,* more than 10-fold difference between the no observed adverse effect levels (NOAELs) and the lowest-observed-adverse-effect-levels (LOAELs) in each of the studies showing effects on thyroid hormone levels (as well as the studies the Agency is using for its points of departure) provides a measure of protection for any potential effects linked to decreased thyroid hormone levels in offspring. Moreover, reproductive toxicity was not observed following pyrimethanil administration, and developmental effects (*e.g.,* decreased fetal weight, retarded ossification, extra ribs) were observed only at doses that caused maternally toxic effects (*e.g.,* death, decreased body weight and body-weight gain); therefore, pyrimethanil is not expected to result in increased quantitative or qualitative susceptibility for infants and children.

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; however, rats are substantially more sensitive than humans to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance.

2. There were no treatment-related tumors 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 a non-linear, antithyroid mode of action.

For these reasons, EPA determined that quantification of carcinogenic risk is not required and that the NOAEL established for deriving the chronic reference dose (cRfD) would be protective of cancer effects. Due to the non-linear mode of action of pyrimethanil, exposure at the NOAEL 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 LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Pyrimethanil. Human Health Risk Assessment for Proposed Uses on Greenhouse-Grown Cucumbers, Tomato Subgroup 8–10A, Lemon Subgroup 10–10B, Orange Subgroup 10–10A, Grapefruit Subgroup 10–10C, Pome Fruit Group 11–10, Stone Fruit Group 12–12 Caneberry Subgroup 13–07A, and Bushberry Subgroup 13–07B,'' in pp. 29–31 in docket ID number EPA–HQ–OPP–2015–0012.

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 the NOAEL and the LOAEL are identified. 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 discussed in Table 1 in Unit III.B. of the final rule published in the **Federal Register** of August 1, 2012 (77 FR 45499) (FRL–9354–7).

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) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed default processing factors, 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 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA assumed default processing factors, empirical processing factors for orange and apple juice, tolerance-level residues, and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyrimethanil is not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not performed.

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

2. *Dietary exposure from drinking water.* In drinking water, residues of concern are pyrimethanil and the degradate 2-amino-4,6-dimethylpyrimidine. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pyrimethanil and its degradate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrimethanil and its degradate. 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 Surface Water Concentration Calculator (SWCC) models, the estimated drinking water concentrations (EDWCs) of pyrimethanil and its degradate for acute exposures are estimated to be 156 parts per billion (ppb) for surface water and 128 ppb for ground water. For chronic exposures for non-cancer assessments, they are estimated to be 27.9 ppb for surface water and 117 ppb for ground water.

Current EPA policy typically recommends the EDWCs for use in dietary assessments be derived from the water source with the highest EDWCs, which for pyrimethanil is surface water for acute exposure and groundwater for chronic exposure. However, due to generally low leaching (EDWCs and incomplete breakthrough) identified in the 100-year simulation in groundwater, the surface water EDWCs are recommended for both acute and chronic exposure assessments. Therefore, for acute dietary risk assessment, the water concentration value of 156 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 27.9 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 Food Quality Protection Act Safety Factor (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 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 1X. That decision is based on the following findings:

i. The toxicity database for pyrimethanil is complete.

ii. Clinical signs of neurotoxicity (ataxia, decreased motor activity, decreased body temperature, decreased hind limb grip strength in males, and dilated pupils) were observed only in females in the acute neurotoxicity study in rats and only at the HDT (1,000 milligram/kilogram (mg/kg)). Although the limit dose was not tested in the subchronic neurotoxicity study, no clinical signs, behavioral changes, or neuropathology were seen at one-half of the limit dose (up to 430 milligram/kilogram/day (mg/kg/day)). In addition, no neurotoxic signs were seen in the rest of the toxicity database for pyrimethanil and the target organ for toxicity is the thyroid. The selected endpoints for pyrimethanil will be protective of any potential signs of neurotoxicity. Therefore, the concern for neurotoxicity is low, and there is no need for a developmental neurotoxicity study or additional uncertainty factors (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 young rats in the 2-generation reproduction study.

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 surface water modeling used to assess exposure to pyrimethanil in drinking water. 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 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrimethanil will occupy 40% of the aPAD for children one to two years 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 80% of the cPAD for children one to two years old, the population group receiving the greatest exposure. There are no residential uses for pyrimethanil.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, pyrimethanil is not registered for any use patterns that would result in short- or intermediate-term residential exposures. Short- and intermediate-term risk is assessed based on short- or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposures 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-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for pyrimethanil.

4. *Aggregate cancer risk for U.S. population.* EPA has 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. Based on the results of chronic risk assessment, EPA concludes that aggregate exposure to pyrimethanil will not cause a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, 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.

There are no Codex MRLs established for residues of pyrimethanil in or on cucumber or bushberry subgroup 13–07B or caneberry subgroup 13–07A commodities. A U.S. tolerance in or on pome fruit group 11–10 was petitioned-

for at 14 ppm; however, the EPA is establishing a tolerance at 15 ppm in order to harmonize with Codex MRLs established on associated pome fruit commodities at 15 ppm. The U.S. tolerance in or on bulb onion subgroup 3–07A at 0.20 ppm is harmonized with a Codex MRL on bulb onion. Although there is a Codex MRL at 0.7 ppm for tomato, EPA is establishing a tolerance for the tomato subgroup 8–10A at 0.50 ppm in order to harmonize with the Canadian MRL to facilitate trade with Canada. The U.S. tolerances for citrus fruit group 10–10 at 10 ppm and stone fruit group 12–12 at 10 ppm cannot be harmonized with Codex MRLs on the same commodities because the residue data supporting these uses result in tolerance calculations that are higher than the Codex MRLs for citrus (7 ppm) and the range of MRLs for stone fruit commodities (2 ppm to 4 ppm), which precludes harmonization.

C. Response to Comments

One comment was received to the Notice of Filing for PP 4F8291, which provided general support for the proposed tolerances. There were no concerns identified in this public comment.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petitions, EPA has revised the petitioned-for tolerance in or on fruit, pome, group 11–10 from 14 ppm to 15 ppm, in order to harmonize with the Codex MRL on associated pome fruit commodities. The Agency has also determined that the separate subgroup tolerances petitioned-for in or on orange subgroup 10–10A at 10 ppm, lemon subgroup 10–10B at 11 ppm, and grapefruit subgroup 10–10C at 10 ppm should be established in or on fruit, citrus, group 10–10 at 10 ppm. A citrus group 10–10 tolerance at 10 ppm is supported by available data and harmonizes the U.S. tolerance with the Canadian MRL.

E. International Trade Considerations

In this rulemaking, EPA is reducing the tolerance for the onion, bulb, subgroup 3–07A from 2.0 ppm to 0.20 ppm. The petitioner requested this reduction because it was a typographical error when the previous rule for pyrimethanil was published. EPA had assessed the tolerance at 0.20 ppm, but the rule was printed as 2.0 ppm. The reduction is appropriate based on available data and residue levels resulting from registered use patterns. In accordance with the World Trade Organization's Sanitary and Phytosanitary Measures Agreement, EPA is allowing the existing higher tolerance to remain in effect for 6 months following the publication of this rule in order to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. On April 21, 2016, the new reduced tolerance for subgroup 3–07A will go into effect. At that time, residues of pyrimethanil on commodities contained in subgroup 3–07A will need to comply with the new tolerance of 0.20 ppm. This reduction in tolerance is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

V. Conclusion

Therefore, tolerances are established for residues of pyrimethanil (4,6-dimethyl-*N*-phenyl-2-pyrimidinamine) in or on bushberry subgroup 13–07B at 8.0 ppm; caneberry subgroup 13–07A at 15 ppm; cucumber at 1.5 ppm; fruit, citrus, group 10–10 at 10 ppm; fruit, pome, group 11–10 at 15 ppm; fruit, stone group 12–12 at 10 ppm; and tomato subgroup 8–10A at 0.50 ppm. This regulation additionally revises the tolerance in or on onion, bulb, subgroup 3–07A from 2.0 ppm to 0.20 ppm. Finally, this regulation removes tolerances in or on fruit, citrus, group 10, except lemon, postharvest; fruit, pome, group 11 (pre-harvest and post-harvest); fruit, stone, group 12; lemon, preharvest and postharvest; and tomato.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 tolerances 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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: October 13, 2015.

Susan Lewis,

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 § 180.518, the table in paragraph (a)(1):

■ a. Remove the commodities ''fruit, citrus, group 10, except lemon, postharvest''; ''fruit, pome, group 11 (pre-harvest and post-harvest)''; ''fruit, stone, group 12''; ''lemon, preharvest and postharvest''; and ''tomato''; and

■ b. Add alphabetically the following commodities to the table.

The additions read as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Bushberry subgroup 13–07B	8.0
Caneberry subgroup 13–07A	15
* * * * *	
Cucumber	1.5
Fruit, citrus, group 10–10	10
Fruit, pome, group 11–10	15
* * * * *	
Fruit, stone, group 12–12	10
* * * * *	
Tomato subgroup 8–10A	0.50
* * * * *	

* * * * *

■ 3. In § 180.518, in the table in paragraph (a)(1), effective April 21, 2016, revise the existing tolerance ''Onion, bulb, subgroup 3–07A'' to read as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

(a) *General.*

(1) * * *

Commodity	Parts per million
* * * * *	
Onion, bulb, subgroup 3–07A	0.2
* * * * *	

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R06–RCRA–2015–0109; FRL–9936–00–Region 6]

Texas: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The State of Texas has applied to the United States Environmental Protection Agency (EPA) for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this direct final rule. In the ''Proposed Rules'' section of today's **Federal Register**, EPA is also publishing a separate document that serves as the proposal to authorize these changes. EPA believes this action is not controversial and does not expect comments that oppose it. Unless EPA receives written comments which oppose this authorization during the comment period, the decision to authorize Texas' changes to its hazardous waste program will take effect. If EPA receives comments that oppose this action, EPA will publish a document in the **Federal Register** withdrawing today's direct final rule before it takes effect, and the separate document in today's ''Proposed Rules'' section of this **Federal Register** will serve as the proposal to authorize the changes.

DATES: This final authorization is effective on December 21, 2015 unless the EPA receives adverse written comment by November 20, 2015. If the EPA receives such comment, EPA will publish a timely withdrawal of this direct final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- Email: [*insert name and email address of appropriate Regional contact*].
- Fax: (prior to faxing, please notify the EPA contact listed below).
- Mail: [*insert name and address of appropriate Regional contact*].
- Hand Delivery or Courier: Deliver your comments to [*insert name and address of appropriate Regional contact*].

Instructions: EPA must receive your comments by November 20, 2015. Direct your comments to Docket ID Number 0109. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov, or email. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. (For additional information about EPA's public docket, visit the EPA Docket Center homepage at *www.epa.gov/epahome/dockets.htm*).

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov,* or in hard copy.

You can view and copy Texas' application and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following locations: Texas Commission