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 29, 2013.

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. In § 180.589:

■ a. Remove from the table in paragraph (a)(1) the commodities bushberry subgroup 13B; caneberry subgroup 13A; canola, seed; cotton, undelinted seed; fruit, citrus, group 10; fruit, pome, group 11; grape; strawberry; sunflower, seed; vegetable, bulb, group 3; and vegetable, fruiting, group 8.

■ b. Remove from the table in paragraph (d) the commodities cotton, gin byproducts; cotton, undelinted seed, and flax, seed.

■ c. Add alphabetically the following commodities to the table in paragraph (a)(1). The additions read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	6.0
* * * * *	
Berry, low growing, subgroup 13–07G, except cranberry	4.5
* * * * *	
Bushberry subgroup 13–07B	13.0
Caneberry subgroup 13–07A	10.0
* * * * *	
Endive, Belgium	6.0
Fruit, citrus, group 10–10	2.0
Fruit, pome, group 11–10	3.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	5.0
* * * * *	
Oilseed group 20	3.5
* * * * *	
Persimmon	8.0
* * * * *	
Turnip, greens	40.0
* * * * *	
Vegetable, bulb, group 3–07	5.0
* * * * *	
Vegetable, fruiting, group 8–10	3.0
* * * * *	

* * * * *

[FR Doc. 2013–26765 Filed 11–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0876; FRL–9400–4]

Prothioconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prothioconozole in or on bushberries (crop subgroup 13–07B); low growing berries, except strawberry (crop subgroup 13–07H); and cucurbit vegetables (crop group 9). Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 8, 2013. Objections and requests for hearings must be received on or before January 7, 2014, 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–2012–0876, 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), EPA West 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: Lois Rossi, Registration Division (RD), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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–2012–0876, 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 January 7, 2014. 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–2012–0876, 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 19, 2012 (77 FR 75082) (FRL–9372–6), 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 2F8044 by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.626 be amended by establishing tolerances for residues of the fungicide prothioconazole, (2-(2-(1-chlorocyclpropyl)-3-(2-chlorophenyl)2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione), in or on bushberry, subgroup 13–07B at 2.0 ppm; berry, low growing, except strawberry subgroup 13–07H at 0.15 ppm; and vegetables, cucurbit, crop group 9 at 0.30 parts per million (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.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the 13–07H berry requested tolerance from 0.15 to 0.20 ppm. 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 prothioconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prothioconazole 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.

Prothioconazole has low acute toxicity by oral, dermal, and inhalation routes. It is not a dermal sensitizer, or a skin or eye irritant. Prothioconazole's metabolite, prothioconazole-desthio, also has low acute toxicity by oral, dermal, and inhalation routes. This metabolite is not a dermal sensitizer, or skin irritant, but it is a slight eye irritant. The subchronic and chronic studies show that the target organs at the lowest observable adverse effects level (LOAEL) include the liver, kidney, urinary bladder, thyroid, and blood. In addition, the chronic studies showed body weight and food consumption changes, and toxicity to the lymphatic and gastrointestinal systems.

Prothioconazole and its metabolites may be developmental toxicants producing effects including malformations in the conceptus at levels equal to or below maternally toxic levels in some studies, particularly those studies conducted using prothioconazole-desthio. Reproduction studies in the rat with prothioconazole and prothioconazole-desthio suggest that these chemicals may not be reproductive toxicants.

The available data show that the prothioconazole-desthio metabolite produces toxicity at lower dose levels in subchronic developmental, reproductive, and neurotoxicity studies as compared with prothioconazole and the two additional metabolites that were tested.

The available carcinogenicity and/or chronic studies in the mouse and rat, using both prothioconazole and prothioconazole-desthio, show no increase in tumor incidence. Therefore, EPA has concluded that prothioconazole and its metabolites are not carcinogenic, and are classified as ''Not likely to be carcinogenic to humans'' according to the 2005 Cancer Guidelines.

Specific information on the studies received and the nature of the adverse effects caused by prothioconazole as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Prothioconazole: Human Health Risk Assessment for Proposed Used on Low Growing Berry Subgroup (except Strawberry), Bushberry, Subgroup, and Cucurbit Vegetables'' dated June 15, 2013 in docket ID number EPA–HQ–OPP–2012–0876.

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 lowest dose at which adverse effects of concern 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 prothioconazole used for human risk assessment is discussed in Unit III. of the final rule published in the **Federal Register** of October 5, 2011 (76 FR 61587) (FRL–8884–2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to prothioconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing prothioconazole tolerances in 40 CFR 180.626. EPA assessed dietary exposures from prothioconazole 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 prothioconazole

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008, Nationwide Health and Nutrition Examination Survey. As to residue levels in food, EPA conducted a moderately refined acute dietary exposure assessment. The acute assessment utilized EPA-recommended tolerance values for all of the proposed uses, average field trial residue levels for the existing uses, empirical processing factors, and livestock commodity residues derived from feeding studies and a balanced dietary burden. The assessment assumed 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008, National Health and Nutrition Survey. As to residue levels in food, EPA conducted a moderately refined chronic dietary exposure assessment. Empirical processing factors, average field trial residues for existing uses, EPA-recommended tolerance values for all of the proposed uses, and livestock commodity residues derived from feeding studies and a reasonably balanced dietary burden were incorporated into the chronic assessment which assumed 100 PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that prothioconazole is ''Not Likely to be Carcinogenic to Humans.'' Therefore a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prothioconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prothioconazole. 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 Tier 1 Rice Model and the Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of prothioconazole for acute exposures are estimated to be 99.0 parts per billion (ppb) for surface water and 0.83 ppb for ground water.

Chronic exposures for non-cancer assessments are estimated to be 0.83 ppb for surface water and 91.9 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 99.0 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 91.9 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).

Prothioconazole 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.''

Prothioconazole is a member of the conazole (triazole) class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses are found; some are heptotoxic and hepatocarconogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanism of toxicity. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's Web site at *http//www.epa.gov/pesticides/cumulative.*

Prothioconazole is a triazole-derived pesticide. Triazole-derived pesticides can form the common metabolite, 2,3,4-triazole and three triazole conjugates (triazole alanine, triazole acetic acid, and triazolylpyruvic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, EPA conducted a health risk assessment for the exposure to 1,2,4-triazole, triazole alanine and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures). In addition, the Agency retained the additional 10X Food Quality Protection Act (FQPA) safety factor (SF) for the protection of infants and children. The Agency's prior risk assessment can be found in the propiconazole registration docket at *http://www.regulations.gov.* Updates to assess the addition of the commodities included in this rule may be found in docket ID number EPA–HQ–OPP–2012–0876 in the document titled ''Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address The New Section 3 Registrations For Use of Prothioconazole on Bushberry crop Subgroup 13–07B, Low Growing Berry, Except Strawberry, Crop Subgroup 13–07H, and Cucurbit Vegetables Crop Group 9; Use of Flutriafol on Coffee; and Ipconazole on Crop Group 6'' dated May 12, 2013.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is evidence of increased susceptibility following prenatal/or postnatal exposure in:

i. Rat developmental toxicity studies with prothioconazole as well as its prothioconozole-desthio and sulfonic acid K salt metabolites.

ii. Rabbit developmental toxicity studies with prothioconazole-desthio.

iii. A rat developmental neurotoxicity study with prothioconazole-desthio.

iv. Multi-generation reproduction studies in the rat with prothioconazole-destio effects, include skeletal structural abnormalities, such as cleft palate, deviated snout, malocclusion, extra ribs, and developmental delays. Available data also show that the skeletal effects such as extra ribs are not completely reversible after birth in the rat, but persist as development continues.

Although increased susceptibility was seen in these studies, the Agency concluded there is a low concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of prothioconazole because: Developmental toxicity NOAELs and LOAELs from prenatal exposure are well characterized after oral and dermal exposure; the off-spring toxicity NOAELs and LOAELs from postnatal exposures are well characterized; and the lowest NOAEL from the developmental studies, the NOAEL for the fetal effect malformed vertebral body and ribs in the rat dermal developmental study, is used for assessing acute risk of females 13 years and older.

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 prothioconazole is considered complete.

ii. Evidence of quantitative and qualitative susceptibility of offspring were observed in the developmental studies. However, basing the POD on the offspring in the most sensitive of these studies provides the needed protection of offspring.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and EPA-recommended tolerance values for all of the proposed uses, average field trial residue levels for the existing uses, empirical processing factors, and livestock commodity residues derived from feeding studies and a balanced dietary burden. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prothioconazole in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by prothioconazole.

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.

Based on the proposed and existing crop uses for prothioconazole, dietary aggregate exposures (i.e., food plus drinking water) are anticipated. There are no residential uses for prothioconazole and, therefore, no residential exposures are anticipated. Consequently, only dietary (food plus drinking water) exposures were aggregated for this assessment.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prothioconazole will occupy 30% of the aPAD for females, 13–49 years of age, 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 prothioconazole from food and water will utilize 57% of the cPAD for all infants (<1 year of age) the population group receiving the greatest exposure. There are no residential uses for prothioconazole.

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

4. *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 prothioconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, liquid chromatography methods with tandem mass spectrometry detection

(LC/MS/MS), are 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 Canadian, Codex, or Mexican maximum residue limits (MRLs) in/on the proposed commodities. Canada will be establishing the same tolerances for members of the subject groups or subgroups. Therefore, harmonization is not an issue for this petition.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance for the low growing berry, except strawberry, crop subgroup 13–07H was requested at 0.15 ppm. The Agency modified the requested 0.15 ppm tolerance to 0.20 ppm which is appropriate based on an evaluation of the crop field trial data with the Organization of Economic Cooperation and Development (OECD) Maximum Residue Level (MRL) Calculation Procedures.

V. Conclusion

Therefore, tolerances are established for residues of prothioconazole, (2-(2-(1-chlorocyclpropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione), in or on bushberry, subgroup 13–07B at 2.0 ppm; berry, low growing, except strawberry, subgroup 13–07H at 0.20 ppm; and vegetables, cucurbit, crop group 9 at 0.30 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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 22, 2013.

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. In § 180.626, add alphabetically the following new entries to the table in paragraph (a)(1) to read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Berry, low growing, except strawberry, subgroup 13–07H	0.20
Bushberry, subgroup 13–07B	2.0
* * * * *	
Vegetable, cucurbit, crop group 9	0.30

* * * * *

[FR Doc. 2013–26772 Filed 11–7–13; 8:45 am]

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