and degradates, in or on squash/cucumber subgroup 9B at 0.50 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: August 10, 2011.

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. Section 180.609 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Squash/cucumber subgroup 9B	0.50
* * * * *	

* * * * *

[FR Doc. 2011–20835 Filed 8–16–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0621; FRL–8882–7]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metconazole in or on the bushberry subgroup 13–07B and the tuberous and corm vegetable subgroup 1C. The Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 17, 2011. Objections and requests for hearings must be received on or before October 17, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0621. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail 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*. To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under 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–2010–0621 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 17, 2011. 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–2010–0621, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54629) (FRL–8843–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7743) by Interregional Research Project Number 4 (IR–4) Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08450. The petition requested that 40 CFR 180.617 be amended by establishing tolerances for residues of the fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1 *H* -1,2,4-triazol-1-ylmethyl) cyclopentanol), measured as the sum of *cis*- and *trans* isomers, in or on bushberry subgroup 13–07B at 0.35 parts per million (ppm); and tuberous and corm vegetable subgroup 1C at 0.02 ppm. That notice referenced a summary of the petition prepared by Valent, 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 the tuberous and corm vegetables subgroup 1C and the bushberry subgroup 13–07B. Additionally, the commodity definition for the tuberous and corm vegetables subgroup 1C is being corrected. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for metconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metconazole 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.

Acute oral and dermal toxicities to metconazole are moderate, while acute inhalation toxicity is low. Metconazole is a moderate eye irritant and a mild skin irritant. It is not a skin sensitizer. The liver is the primary target organ in the mouse, rat and dog following oral exposure to metconazole via subchronic or chronic exposure durations. Developmental studies in rats and

rabbits show some evidence of developmental effects, but only at dose levels that are maternally toxic. Metconazole did not demonstrate the potential for neurotoxicity in the four species (mouse, rat, dog and rabbit) tested. Metconazole is considered non-genotoxic and liver tumors seen in a chronic mouse study appear to have been formed via a mitogenic mode of action and therefore, metconazole is classified as ''not likely to be carcinogenic to humans'' at levels that do not cause mitogenesis. There was no evidence of immunotoxicity at dose levels that produced systemic toxicity. No immunotoxic effects are evident for metconazole at dose levels as high as 52 milligrams/kilogram/day (mg/kg/day) in rats, which is 12 times higher than the chronic dietary point of departure (4.3 mg/kg/day). Metconazole did not demonstrate neurotoxicity in the subchronic neurotoxicity study or the other submitted studies including acute, subchronic and chronic studies in several species, developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. No effects were noted on brain weights and no clinical signs possibly related to neurotoxicity were noted up to and including the high doses in all studies.

Specific information on the studies received and the nature of the adverse effects caused by metconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2010–0621 on pages 44–50 of the document titled ''Metconazole: Human Health Risk Assessment for Proposed Uses on Tuberous and Corm Vegetables Subgroup 1C and Bushberry Subgroup 13–07B.''

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for metconazole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR METCONAZOLE 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 (General Population, including Infants and Children).	An appropriate dose/endpoint attributable to a single dose was not observed in the available oral toxicity studies reviewed.		
Acute dietary (Females 13–49 years of age).	NOAEL = 12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.12 mg/kg/day aPAD = 0.12 mg/kg/day	Developmental toxicity in rats: LOAEL = 30 mg/kg/day based on increases in skeletal variations.
Chronic dietary (All populations)	NOAEL = 4.3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day	Chronic oral toxicity study in rats: LOAEL = 13.1 mg/kg/day based on increased liver Males (M) weights and associated hepatocellular lipid vacuolation (M) and centrilobular hypertrophy (M). Similar effects were observed in Females (F) at 54 mg/kg/day, plus increased spleen weight.
Incidental oral short-term (1 to 30 days).	NOAEL = 9.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day oral toxicity study in rats: LOAEL = 90.5 mg/kg/day based on decreased body weight (M), increased liver and kidney weight and hepatocellular hypertrophy and vacuolation (M/F).
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 6.4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day oral toxicity study in rats: LOAEL = 19.2 mg/kg/day based on increased spleen wt (F) and hepatic vacuolation (M).
Inhalation short-term (1 to 30 days).	NOAEL= 9.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day oral toxicity study in rats: LOAEL = 90.5 mg/kg/day based on decreased body weight (M), increased liver and kidney weight and hepatocellular hypertrophy and vacuolation (M/F).

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation (1 to 6 months)	NOAEL= 6.4 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day oral toxicity study in rats: LOAEL = 19.2 mg/kg/day based on increased spleen wt (F) and hepatic vacuolation (M).
Cancer (Oral, dermal, inhalation) ..	Classification: ''Not likely to be Carcinogenic to Humans.''		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = actue, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing metconazole tolerances in 40 CFR 180.617. EPA assessed dietary exposures from metconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for metconazole for the general U.S. population including infants and children; therefore, a quantitative acute dietary exposure assessment is unnecessary for these population subgroups. However, such effects were identified for metconazole for females 13–49 years of age. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that metconazole residues are present in all registered and proposed food commodities at tolerance levels and that 100% of the crops were treated.

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

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for metconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of metconazole. 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 metconazole for acute exposures are estimated to be 45.48 parts per billion (ppb) for surface water and 0.064 ppb for ground water. For chronic exposures for non-cancer assessments they are estimated to be 38.16 ppb for surface water and 0.064 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 45.48 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 38.16 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). Metconazole is currently registered for the following uses that could result in residential exposures: Turf and ornamentals. EPA assessed residential exposure using the following assumptions: Adults, adolescents, and children may be exposed to metconazole from its currently registered uses on turf and ornamentals. No dermal toxicity endpoints for short- and intermediate-term durations were identified up to the limit dose. Therefore, only residential handler and postapplication inhalation exposures for adults, and residential post-application incidental oral exposures for children have been assessed. For adults applying metconazole to turf, short- and intermediate-term exposures were assessed for mixer/loader/applicators with a low pressure handwand sprayer. Post-application risks to children following the application of metconazole to home lawns were calculated for short- and intermediate-term incidental oral exposures. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

Metconazole is a member of the triazole-containing 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. In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic 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 mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. 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.*

Metconazole is a triazole-derived pesticide. Triazole-derived pesticides can form the common metabolite, 1,2,4-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 metconazole, EPA conducted a human health risk assessment for 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 (*i.e.,* high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA SF for the protection of infants and children. The assessment included evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov,* Docket Identification Number EPA–HQ–OPP– 2005–0497 and an update to assess the addition of the commodities included in this action may be found in docket ID number EPA–HQ–OPP–2010–0621 in the document titled ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment To Address Tolerance Petitions for Metconazole.''

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.* Acceptable developmental toxicity studies are available in the rat and rabbit as well as a 2-generation reproductive toxicity study in the rat. There is no evidence of susceptibility following *in utero* exposure in the rabbit. In the rat there is qualitative evidence of susceptibility, however the concern is low since the developmental effects are characterized as variations (not malformations), occur in the presence of maternal toxicity, the NOAELs are well defined, and the dose/endpoint is used for acute dietary risk assessment for the sensitive population. There is no evidence of increased susceptibility in the offspring based on the result of the 2-generation reproduction study.

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 metconazole is complete except for a neurotoxicity study. Changes to 40 CFR 180.158 make the acute neurotoxicity testing (OPPTS Guideline 870.6200) required for pesticide registration. Although this study is not yet available for metconazole, the available data do not show any evidence of neurotoxicity. Metconazole did not demonstrate neurotoxicity in the subchronic neurotoxicity study or the other submitted studies including acute, subchronic and chronic studies in several species, developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. No effects were noted on brain weights and no clinical signs possibly related to neurotoxicity were noted up to and including the high doses in all studies. Therefore, EPA does not believe that conducting the acute neurotoxicity study will result in an endpoint lower than the ones used in risk assessment for metconazole. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no evidence of susceptibility following *in utero* exposure in the rabbit. In the rat there is qualitative evidence of susceptibility, however the concern is low since the developmental effects are characterized as variations (not malformations), occur in the presence of maternal toxicity, the NOAELs are well defined, and the dose/endpoint is used for acute dietary risk assessment for the sensitive population. There is no evidence of increased susceptibility in the offspring based on the result of the 2-generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metconazole 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 metconazole.

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 aPAD and 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 metconazole will occupy 3.8% of the aPAD for females 13–49, the only population subgroup of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metconazole from food and water will utilize 12.6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of metconazole is not expected.

3. *Short- and intermediate-term risk.* Short- 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).

Metconazole is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to metconazole.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded, that the short-and intermediate-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential handler exposure (inhalation) for adults are 1,700 for both.

The short-and intermediate-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential post-application exposure (incidental oral) for children 1–2 years old are 420 and 460, respectively. Because EPA's level of concern for metconazole is a MOE of 100 or below, these MOEs are not of concern.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography method with nitrogen-phosphorus-detection (GC/NPD) is available for data collection and enforcement of tolerances for residues of metconazole parent isomers (*cis*- and *trans*-metconazole) in plant commodities based on Valent Method RM–41C–1, ''Determination of *cis* and *trans*-Metconazole in Crops.'' An adequate high performance liquid chromatography (HPLC) method is available for data collection and enforcement of tolerances for residues of 1,2,4-triazole (T), triazole alanine (TA), and triazole acetic acid (TAA). The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

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 U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for metconazole on potato or blueberry or the respective crop subgroups.

C. Revisions to Petitioned-For Tolerances

IR–4 proposed establishing tolerances on the bushberry subgroup 13–07B at 0.35 ppm and the tuberous and corm vegetable subgroup 1C at 0.02 ppm. Upon review, these levels are being revised to 0.40 ppm and 0.04 ppm, respectively. EPA used the tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* to determine the appropriate tolerance level for bushberries. The tolerance spreadsheet was not used to calculate the tolerance for tuberous and corm vegetables because residues in potatoes were below the LOQ (< 0.04 ppm). The proposed tolerance of 0.02 ppm for tuberous and corm vegetables is too low. The tolerance should be established at 0.04 ppm, reflecting the combined LOQs of the metconazole enforcement method of 0.02 ppm for each of the *cis*- and *trans*-isomers of metconazole. Also, the correct commodity definition for tuberous and corm vegetables subgroup 1C is ''Vegetable, tuberous and corm, subgroup 1C'' and is being changed accordingly. Finally, EPA has revised the tolerance expression in paragraph (a)(1) to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of metconazole 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. Because the tolerance expressions in paragraphs (a)(1) and (a)(2) are now identical, EPA is combining (a)(1) and (a)(2) into a newly designated paragraph (a) and placing all the commodities from these two paragraphs into a single table.

V. Conclusion

Therefore, tolerances are established for residues of metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, measured as the sum of *cis*- and *trans*- isomers, in or on the bushberry subgroup 13–07B at 0.40 ppm, and vegetable, tuberous and corm, subgroup 1C at 0.04 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments,

on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: August 9, 2011.

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. Section 180.617 is amended by revising paragraph (a) to read as follows:

§ 180.617 Metconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of metconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only metconazole [5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol] as the sum of its *cis*- and *trans*-isomers in or on the following commodities:

Commodity	Parts per million
Almond, hulls	4.0
Banana [1]	0.1
Barley, grain	2.5
Barley, hay	7.0
Barley, straw	7.0
Beet, sugar, dried pulp	0.70
Beet, sugar, molasses	0.08
Beet, sugar, roots	0.07
Bushberry subgroup 13–07B	0.40
Canola seed	0.04
Cattle, meat byproducts	0.04
Corn, field, forage	3.0
Corn, field, grain	0.02
Corn, field, stover	4.5
Corn, pop, grain	0.02
Corn, pop, stover	4.5
Corn, sweet, forage	3.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	4.5
Cotton, gin byproducts	8.0
Cotton, undelinted seed	0.25
Egg	0.04
Fruit, stone, group 12	0.20
Goat, meat byproducts	0.04
Grain, aspirated grain fractions	7.0
Horse, meat byproducts	0.04
Nut, tree, group 14	0.04
Oat, grain	1.0
Oat, hay	17
Oat, straw	6.0
Peanut	0.04
Peanut, refined oil	0.05
Pistachio	0.04
Rye, grain	0.25
Rye, straw	14
Sheep, meat byproducts	0.04
Soybean, forage	3.0
Soybean, hay	6.0
Soybean, hulls	0.08
Soybean, seed	0.05
Vegetable, tuberous and corn, subgroup 1C	0.04
Wheat, grain	0.15
Wheat, hay	16
Wheat, milled byproducts	0.20
Wheat, straw	18

[1] No U.S. registration as of August 30, 2006.

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[FR Doc. 2011–20841 Filed 8–16–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0481; FRL–8874–9]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiamethoxam in or on peanut; peanut, hay; peanut, meal; alfalfa, forage; alfalfa, hay; and in food/feed commodities in food/feed handling establishments. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 17, 2011. Objections and requests for hearings must be received on or before October 17, 2011, 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: This final rule addresses three petitions for tolerances. EPA has established a docket under docket identification (ID) number EPA–HQ–OPP–2011–0481 which contains only this final rule and is a summary docket used to lead the user to the individual docket established for each of the three petitions for tolerances addressed in this final rule: EPA–HQ–OPP–2010–0041 (peanut), EPA–HQ–OPP–2010–0324 (alfalfa), EPA–HQ–OPP–2010–0602 (food/feed commodities in food/feed handling establishments). The user should look in the individual dockets to view the previous **Federal Register** publications and supporting documents for each tolerance petition. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket