the original claim does not exceed $10,000,000; and

* * * * *

§ 0.169 [Amended]

■ 5. Amend paragraph (b) of § 0.169 by removing the words ''Customs Service's'' and adding in their place the words ''United States Customs and Border Protection's''.

Dated: May 21, 2015.

Loretta E. Lynch,

Attorney General.

[FR Doc. 2015–12991 Filed 5–28–15; 8:45 am]

BILLING CODE 4410–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0230; FRL–9927–11]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metconazole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action, and deletes expired tolerances.

DATES: This regulation is effective May 29, 2015. Objections and requests for hearings must be received on or before July 28, 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–2014–0230, 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 Publishing 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–2014–0230 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 July 28, 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–2014–0230, 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 May 23, 2014 (79 FR 29729) (FRL–9910–29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8244) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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, in or on fruit, stone, group 12–12 at 0.2 parts per million (ppm); nut, tree, group 14–12 at 0.04 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; rapeseed subgroup 20A at 0.08 ppm; and sunflower subgroup 20B at 0.9 ppm. The petition also requested that current established tolerances for residues of the fungicide metconazole in or on canola seed at 0.04 ppm; fruit, stone, group 12 at 0.20 ppm; pistachio at 0.04 ppm; and nut, tree, group 14 at 0.04 ppm be removed once the proposed tolerances were approved. That document referenced a summary of the petition prepared by Valent U.S.A Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's

response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has determined the tolerance for the sunflower subgroup 20B should be 0.7 ppm. The reason for this change is 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 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. Metconazole affects the liver, kidney, spleen, and various blood parameters at various dose levels across species. Specifically, in the mouse, rat, and dog, liver toxicity was seen after oral exposure in both subchronic and chronic exposures. Metconazole produces liver tumors in mice through a mitogenic mode of action (*i.e.,* non-genotoxic), and in the absence of a genotoxic mode of action, metconazole is classified as ''not likely to be carcinogenic to humans'' at levels that do not cause mitogenesis.

Oral studies revealed critical effects of metconazole on body weight and blood erythrocyte and/or platelet parameters in the mouse, rat, dog and/or rabbit. Hyperplasia and increased weight were observed in the spleen in the mouse, rat, and dog at dose levels where liver affects were also observed. Lenticular degeneration (cataracts) were observed at the highest dose tested 114 milligrams/kilogram/day (mg/kg/day) in dogs. In addition, there was evidence that at high dietary levels metconazole is a gastrointestinal irritant in the dog.

In rats and rabbits developmental studies displayed some evidence of developmental effects but largely at dose levels that are maternally toxic. There was no quantitative or qualitative susceptibility in rabbit fetuses after *in utero* exposure to metconazole. In prenatal developmental toxicity studies in rabbits there was an increase in post-implantation loss and reduced fetal body weights at the same dose level that caused maternal toxicity. In rats, the developmental study showed skeletal variations at the lowest-observed-adverse-effect-level (LOAEL) in the absence of maternal toxicity. The 2-generation reproduction studies revealed offspring and parental toxicity only at the highest tested dose. There is low concern for quantitative susceptibility (skeletal variations in the absence of maternal toxicity in the developmental study) because the endpoint and point of departure are based on the effects in the fetus, for which there is a clear NOAEL. Therefore, it is concluded that there are no residual uncertainties for pre- and/or post-natal toxicity.

Metconazole did not demonstrate neurotoxicity in the subchronic neurotoxicity study, or any of the other studies in the toxicity data base. The requirement for an acute neurotoxicity study has been waived because of the absence of neurotoxic signs throughout the database, even at the highest dose levels tested.

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 (mg/kg/day) in rats, which is 12 times higher than the chronic dietary point of departure (4.3 mg/kg/day).

EPA has classified metconazole as: ''Not Likely to be Carcinogenic to Humans'' based on convincing evidence demonstrating the following: (1) That a non-genotoxic mode of action for liver tumors was established in the mouse; (2) that the carcinogenic effects were not likely to occur below a defined dose that does not cause mitogenesis based on bioassays in the rat and the mouse; and (3) a lack of *in vitro* or *in vivo* mutagenicity. The established chronic RfD, which is below the level at which mitogenesis occurred in the rat and mouse, is deemed to be protective of mitogenesis/carcinogenesis, and no quantification is required.

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 LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document at ''Metconazole. Human Health Risk Assessment for a Section 3 Registration of New Uses on Dry Shelled Pea and Beans (Except Soybean) Crop Subgroup 6C and Sunflower Crop Subgroup 20B; Crop Group Expansion to Rapeseed Subgroup 20A; and Crop Group Conversion to Fruit, Stone, Group 12–12; and Nut, Tree, Group 14–12'' in docket ID number EPA–HQ–OPP–2014–0230.

B. Toxicological Points of Departure/Levels of Concern

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

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 (Females 13–50 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. At 75 mg/kg/day (the next higher dose level) increased incidence of post-implantation loss, hydrocephaly and visceral anomaliea (cranial hemorrhage, dilated renal pelvis, dilated ureters, and displaced testis) were reported.
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.		
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 (M) weights and associated hepatocellular lipid vacuolation (M) and centrilobular hypertrophy (M). Similar effects were observed in females 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	Residential 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).
Dermal short-term (1 to 30 days).	Quantification of dermal risk is not required due to lack of systemic or dermal toxicity at the Limit Dose in a 21-day dermal toxicity study in the rat, the lack of neurotoxicity, and the lack of developmental and/or reproductive toxicity in the absence of parental effects, which were not looked for in the dermal toxicity.		
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 9.1 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 10x (UF_{DB})	Residential LOC for MOE = 1000.	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).
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans''.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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 population including infants and children; therefore, a quantitative acute dietary exposure assessment is unnecessary for the general population.

Such effects were identified for metconazole for females 13–49 years old. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM–FCID). This software incorporates 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for most crops. For cereal grains and livestock commodities, maximum residue levels of metabolites from field trials were added to the metconazole tolerance levels.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the DEEM–FCID. This software incorporates 2003–2008 food consumption data from the NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for most crops. For cereal grains and livestock commodities, maximum residue levels of metabolites from field trials were added to the metconazole tolerance levels.

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.

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

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for 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 Tier I Pesticide Root Zone Model-Ground Water (PRZM–GW), the estimated drinking water concentrations (EDWC) of metconazole are estimated to be 51.8 parts per billion (ppb) for acute exposures and not applicable for chronic (non-cancer) exposures. Based on the Tier II Surface Water Concentration Calculator (SWCC) model, the EDWCs are estimated to be 49.6 ppb for acute exposures and 43.9 ppb for chronic (non-cancer) exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment for females, the water concentration value of 51.8 ppb-was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 43.9 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).

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: For residential handler exposure, the Agency assumed that residential use will result in short-term (1–30 days) dermal and inhalation exposures. Because there was no dermal endpoint chosen for metconazole, residential handler risk from exposure to metconazole was assessed for the inhalation route only.

The Agency assumed that post-application exposure in residential settings is short-term in duration only. No dermal endpoint was chosen for metconazole; therefore a dermal post-application risk assessment was not conducted for adults or children. Residential post-application inhalation exposure in outdoor settings is considered negligible. The scenarios evaluated were short-term post-application incidental oral exposure to children 1 to <2 years old from granular and water dispersible granular metconazole formulations.

In the previous tolerance action for metconazole which published in the **Federal Register** of August 17, 2011 (76 FR 50898) (FRL–8882–7), the Agency also assessed intermediate-term exposures. However, in 2012 the EPA revised the residential standard operating procedures (SOPs) and based on these revisions has determined that intermediate-exposures are not expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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, the conazoles. Although conazoles act similarly in plants 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 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 conclusive data 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. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic 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, triazolylalanine, and triazolylacetic 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 safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov,* Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was conducted in October 2013, in association with a registration request for several other triazole fungicides. That analysis concluded that risk estimates were below the Agency's level of concern for all population groups. The proposed new uses of metconazole did not result in an increase in the dietary exposure estimates for free triazole or conjugated triazoles. Therefore, this last dietary exposure analysis for free triazole or conjugated triazoles did not need to be updated. A copy of this assessment may be found in the docket for this action at *http://www.regulations.gov.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of

safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* For analyzing the developmental and reproductive impact and toxicity of metconazole, two developmental studies in the rat, two developmental studies in the rabbit, and one multi-generation reproduction study were used. There was evidence of quantitative susceptibility in one developmental rat study, but not in the four other studies. Concern is for susceptibility low since susceptibility was not corroborated by the other studies; concern is low also because the NOAELs are well defined, and the dose/endpoint is used for acute dietary risk assessment for the sensitive population.

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, except for inhalation exposure scenarios for which the Agency is retaining the 10X. That decision is based on the following findings:

i. The toxicity database for metconazole is complete, except for the subchronic inhalation study. A 10x uncertainty factor has been retained for purposes of determining the inhalation endpoint to account for the absence of this data. However, only adult handlers are expected to be exposed via the inhalation route.

ii. There is no indication that metconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although one developmental rat study showed indications of quantitative susceptibility, EPA has determined that additional safety factors are not necessary to account for any potential risk because that susceptibility was not corroborated by the other developmental and reproduction studies and the developmental NOAEL for the study that showed quantitative susceptibility is well defined. Moreover, the dose/endpoint identified in the rat developmental study is being used for acute dietary risk assessment for the sensitive population.

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 for most crops. For cereal grains and livestock commodities, maximum residue levels of metabolites from field trials were added to the metconazole tolerance levels. 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 post application exposure of children as well as incidental oral exposure of children 1 to <2 years old. 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 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 metconazole will occupy 4.6% of the aPAD for females 13 to 49 years old, the only population subgroup of potential 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 14% 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-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Metconazole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to metconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOEs of 630 for children 1 to <2 years old, which is not of concern. For adults, oral dietary and inhalation risk estimates were combined using the total aggregated risk index (ARI) methodology since the levels of concern (LOC) for oral dietary exposure (LOC = 100) and inhalation exposure (LOC = 1,000) are different. The short-term aggregate ARI for adults is 5.3, which is greater than 1 and is therefore not of concern.

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

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., metconazole is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Nitrogen-Phosphorus-Detection (GC/NPD) method, Valent Method RM–41C–1–1) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905;

email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for metconazole.

C. Response to Comments

EPA received two comments to the Notice of Filling. One comment concerned a chemical other than metconazole and therefore is not relevant to this action. The other was a request to reconsider ''loosening tolerances'' for several pesticide petitions, including for metconazole. The commenter points to an American Academy of Pediatrics Policy statement regarding pesticide exposure in children, a Centers for Disease Control and Prevention report on human exposure to environmental chemicals, and a President's Cancer Panel regarding reducing environmental cancer risks in supporting the request to reconsider the tolerance amendments proposed for metconazole.

The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food, or that pesticide tolerances should be ''significantly tightened'' as the commenter notes. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when EPA determines that aggregate exposure to that pesticide is safe, *i.e.,* that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. When making this determination, EPA considers the toxicity, including any potential carcinogenicity, of the pesticide and all anticipated dietary exposures and all other exposures for which there is reliable information. EPA also gives special consideration to the potential susceptibility and exposures of infants and children to the pesticide chemical residue when making this determination. For metconazole, the Agency has considered all the available data, including all available data concerning the potential for carcinogenicity of metconazole and its metabolites, and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to metconazole and that, accordingly, the metconazole tolerances are safe.

D. Revisions to Petitioned-For Tolerances

The petitioner requested a tolerance on the sunflower subgroup 20B at 0.9 ppm. EPA is establishing a tolerance for that subgroup at 0.7 ppm based on the Organisation for Economic Co-operation and Development (OECD) tolerance calculation procedures.

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, in or on fruit, stone, group 12–12 at 0.2 ppm; nut, tree, group 14–12 at 0.04 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; rapeseed subgroup 20A at 0.08 ppm; and sunflower subgroup 20B at 0.7 ppm. Additionally, the existing tolerances for canola seed; fruit, stone, group 12; nut, tree, group 14; and pistachio are being removed since they are superseded by this action.

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: May 19, 2015.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.617:

■ a. Remove the entries in the table in paragraph (a) for ''Canola seed,'' ''Fruit, stone, group 12,'' ''Nut, tree, group 14,'' and ''Pistachio;''

■ b. Add alphabetically the entries for ''Fruit, stone, group 12–12'', ''Nut, tree, group 14–12'', ''Pea and bean, dried shelled, except soybean, subgroup 6C'', ''Rapeseed subgroup 20A'', and ''Sunflower subgroup 20B'' to the table in paragraph (a).

■ c. Revise paragraph (b).

The additions and revision read as follows:

§ 180.617 Metconazole; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Fruit, stone, group 12–12	0.2
* * * * *	
Nut, tree, group 14–12	0.04
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
* * * * *	
Rapeseed subgroup 20A	0.08
* * * * *	
Sunflower subgroup 20B	0.7
* * * * *	

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

* * * * *

[FR Doc. 2015–12936 Filed 5–28–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0303; FRL–9927–75]

Mesotrione; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mesotrione in or on almond, hulls, fruit, citrus, group 10–10; fruit, pome, group 11–10; fruit, stone, group 12–12; and nut, tree, group 14–12. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 29, 2015. Objections and requests for hearings must be received on or before July 28, 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–2014–0303, 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 Publishing 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–2014–0303 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 July 28, 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–2014–0303, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online