BILLIING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0427; FRL-9392-1]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on the fruiting vegetable group 8-10 and amends the existing tolerances for barley grain and the cucurbit vegetable group 9. Interregional Research Project Number 4 (IR-4) requested this tolerance and amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0427, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P)**,** Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's eCFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0427 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 [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0427, 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.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL-9358-9), 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 2E8012) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, including its metabolites and degradates, in or on barley, grain at 0.3 parts per million (ppm); vegetable, cucurbit group 9 at 0.4 ppm; and vegetable, fruiting group 8–10 at 1.3 ppm. The petition also requested the removal of the established tolerance, in or on vegetable, fruiting, group 8 at 1.3 ppm once the proposed tolerance for vegetable, fruiting group 8–10 at 1.3 ppm, has been established since the proposed new tolerance will supersede the existing tolerance. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 tebuconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tebuconazole 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.

Tebuconazole has low acute toxicity by the oral and dermal routes of exposure and moderate toxicity by the inhalation route. It is not a dermal sensitizer nor a dermal irritant; however, it is slightly to mildly irritating to the eye. The primary target organs of tebuconazole toxicity are the liver, the adrenals, the hematopoietic system, and the nervous system. Effects on these target organs were seen in both rodent and non-rodent species. In addition, ocular lesions were seen in dogs (including lenticular degeneration and increased cataract formation) following subchronic or chronic exposure.

Oral administration of tebuconazole caused developmental toxicity in all species evaluated (rat, rabbit and mouse), with the most prominent effects in the nervous system. The developmental toxicity studies, including the developmental neurotoxicity study, demonstrated an increase in susceptibility in developing fetuses both quantitatively and qualitatively.

Tebuconazole was classified as a Group C possible human carcinogen, based on an increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in male and female mice. This classification is generally used for chemicals with limited evidence of carcinogenicity in animals in the absence of human data. EPA has determined that quantification of risk using a non-linear approach, i.e., reference dose (RfD), for tebuconazole will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to tebuconazole. That conclusion is based on the following considerations: (1) No carcinogenic response was seen in either sex in an acceptable rat cancer study; (2) the tumors found in the mouse are

commonly seen in the mouse; (3) both tumors types were found only at the high dose, which was considered to be excessive for carcinogenicity testing based on the non-neoplastic findings; and (4) tebuconazole is not mutagenic.

Specific information on the studies received and the nature of the adverse effects caused by tebuconazole 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-2012-0427 on pages 33-36 of the document titled "Tebuconazole: Human Health Risk Assessment for Tolerance Increases Based on Submission of Condition of Registration Requirements for Barley and Cantaloupe; and Crop Group Expansion for Fruiting Vegetable Crop Group 8-10."

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of

exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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

Table 1.--Summary of Toxicological Doses and Endpoints for Tebuconazole 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)	LOAEL = 8.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 3x	Acute RfD = 0.029 mg/kg/day aPAD = 0.029 mg/kg/day	Developmental Neurotoxicity Study - Rat LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring
Chronic dietary (All populations)	LOAEL = 8.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 3x	Chronic RfD = 0.029 mg/kg/day cPAD = 0.029 mg/kg/day	Developmental Neurotoxicity Study - Rat LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring
Incidental oral short-term (1 to 30 days)	LOAEL = 8.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 3x	LOC for MOE = 300	Developmental Neurotoxicity Study - Rat LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring
Dermal short-term (1 to 30 days)	Oral study LOAEL = 8.8mg/kg/day (dermal absorption rate = 13% UF_A = 10x	LOC for MOE = 300	Developmental Neurotoxicity Study - Rat LOAEL = 8.8 mg/kg/day based on decreases in body

	UF_H = 10x FQPA SF (UF_L) = 3x		weights, absolute brain weights, brain measurements and motor activity in offspring
Inhalation short-term (1 to 30 days)	Oral study LOAEL = 8.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 3x	LOC for MOE = 300	Developmental Neurotoxicity Study - Rat LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring
Cancer (Oral, dermal, inhalation)	Classification: Group C- possible human carcinogen based on statistically significant increase in the incidence of hepatocellular adenoma, carcinoma, and combined adenoma/carcinomas in both sexes of NMRI mice. The chronic risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to tebuconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tebuconzole tolerances in 40 CFR 180.474. EPA assessed dietary exposures from tebuconazole in food as follows:

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

Such effects were identified for tebuconazole. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, a

somewhat refined, acute probabilistic dietary exposure assessment was conducted for all existing food uses of tebuconazole. EPA assumed tolerance levels residues for some commodities and used field trial and USDA PDP data for others. EPA also assumed 100% crop treated levels for most commodities and used percent crop treated (PCT) data for other commodities as described in Unit III.C.1.iv. below.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the 2003-2008 NHANES/WWEIA. As to residue levels in food, a somewhat refined chronic dietary exposure assessment was conducted for all existing food uses of tebuconazole. EPA assumed tolerance levels residues for some commodities and used field trial and USDA PDP data for others. EPA also assumed 100% crop treated levels for most commodities and used PCT data for other commodities as described in Unit III.C.1.iv. below.

iii. *Cancer*. The Agency determined that cancer dietary risk concerns due to long-term consumption of tebuconazole residues are adequately addressed by the chronic dietary exposure analysis using the reference dose; i.e., the chronic dietary risk assessment is considered to be protective of any cancer effects, and therefore, a separate cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels

anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment, the Agency estimated the PCT for existing uses as follows:

Grapes: 25%; grape, raisin: 25%; nectarine: 25%; peach: 20%; peanuts: 45%.

For the chronic assessment, the Agency estimated the PCT for existing uses as follows:

Grapes: 15%; grape, raisin: 15%; nectarine: 20%; peach: 15%; peanuts: 35%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency also used 2006 PCT information for tebuconazole on the following uses for the acute dietary assessment (apples, 44%; apricots 56%; cherries, (babyfood),42%; cherries (all other food forms), 100%; corn, sweet, 22%; hops 64%; plum 26%; turnip 68%) and for the chronic dietary assessment (apples, 41%; apricots, 43%; cherries, (babyfood), 37%; cherries (all other food forms), 66%; corn, sweet, 14%; hops, 64%; plum, 24%; turnip, 44%). For further explanation of EPA's process for developing these PCT estimates, see the 2011 final rule for tebuconazole tolerances (76 FR 54127) (August 31, 2011) and its supporting documents.

Subsequently, EPA considered the maximum and average PCT estimates for tebuconazole from the most recent (2011) screening level usage analysis available. Based on that information, EPA concludes that its risk assessments do not underestimate

the overall actual PCT for uses of tebuconazole or exposure from the use of tebuconazole.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tebuconazole may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tebuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tebuconazole. 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 tebuconazole for acute exposures are estimated to be 96.6 parts per billion (ppb) for surface water and 1.56 ppb for ground water and for chronic exposures are estimated to be 59 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment a distribution of 30-year daily surface water concentrations was estimated for the EDWCs of tebuconazole. For chronic dietary risk assessment, the water concentration of value 59 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).

Tebuconazole is currently registered for the following uses that could result in residential exposures: Turf, flower gardens, trees, ornamentals, and pressure-treated wood. EPA assessed residential exposure using the following assumptions: For residential handlers, exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Dermal and inhalation exposures were combined since the same endpoint and point of departure (POD) is used for both routes of exposure. Residential dermal and incidental oral post-application exposure was assessed for adults and children golfing, working in gardens, and performing physical activities on pressure-treated wood after application of

tebuconazole may receive exposure to tebuconazole residues. Post-application exposure is expected to be short-term in duration. 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."

Tebuconazole 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. 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 website at *http://www.epa.gov/pesticides/cumulative*.

Tebuconazole 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 tebuconazole, 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 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 and completed in May 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.

After addition of tolerances associated with this action to the exposure analyses, the increased tolerances for tebuconazole in/on barley, grain and vegetables, cucurbits, group 9 along with the crop group conversion covered by this action do not significantly *http://www.regulations.gov* by searching for the following titles and docket numbers: "Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations For Use of Prothioconazole on Bushberry Crop Subgroup 13-07B, Low Growing Berry, Except Strawberry, Crop Subgroup 13-07H, and Cucurbit Vegetables Crop Group 9; Use of Flutriafol on Coffee; and Ipconazole on Crop Group 6" (located in docket ID number EPA-HQ-OPP-2012-0876); "Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Revised Tolerance for Residues of Fenbuconazole in Peppers" (docket ID number EPA-HQ-OPP-2012-0520).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The toxicity database for tebuconazole includes prenatal developmental toxicity studies in three species (mouse, rat, and rabbit),

a reproductive toxicity study in rats, acute and subchronic neurotoxicity studies in rats, and a developmental neurotoxicity study in rats. The data from prenatal developmental toxicity studies in mice and a developmental neurotoxicity study in rats indicated an increased quantitative and qualitative susceptibility following *in utero* exposure to tebuconazole. The NOAELs/LOAELs for developmental toxicity in these studies were found at dose levels less than those that induce maternal toxicity or in the presence of slight maternal toxicity. There was no indication of increased quantitative susceptibility in the rat and rabbit developmental toxicity studies, the NOAELs for developmental toxicity were comparable to or higher than the NOAELs for maternal toxicity. In all three species, however, there was indication of increased qualitative susceptibility. For most studies, minimal maternal toxicity was seen at the LOAEL (consisting of increases in hematological findings in mice, increased liver weights in rabbits and rats, and decreased body weight gain/food consumption in rats) and did not increase substantially in severity at higher doses. However, there was more concern for the developmental effects at each LOAEL, which included increases in runts, increased fetal loss, and malformations in mice; increased skeletal variations in rats; and increased fetal loss and frank malformations in rabbits. Additionally, more severe developmental effects (including frank malformations) were seen at higher doses in mice, rats and rabbits. In the developmental neurotoxicity study, maternal toxicity was seen only at the high dose (decreased body weights, body weight gains, and food consumption, prolonged gestation with mortality, and increased number of dead fetuses), while offspring toxicity (including decreases in body weight, brain weight, brain measurements and functional activities) was seen at all doses.

Available data indicated greater sensitivity of the developing organism to exposure to tebuconazole, as demonstrated by increases in qualitative sensitivity in prenatal developmental toxicity studies in rats, mice, and rabbits, and by increases in both qualitative and quantitative sensitivity in the developmental neurotoxicity study in rats with tebuconazole. However, the degree of concern is low because the toxic endpoints in the prenatal developmental toxicity studies were well characterized with clear NOAELs established and the most sensitive endpoint, which is found in the developmental neurotoxicity study, has been used for overall risk assessments. Therefore, there are no residual uncertainties for prenatal and/or postnatal susceptibility.

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 3x. That decision is based on the following findings:

i. The toxicity database for tebuconazole is considered complete. An immunotoxicity study in rats has been submitted to the Agency and the study is currently under review. With preliminary evaluation, tebuconazole tested up to 1,000 ppm (78.4 milligrams/kilogram/day (mg/kg/day) produced no immunotoxicity under the conditions of this study.

ii. Tebuconazole demonstrated neurotoxicity in the acute neurotoxicity study in rats; the LOAEL of 100 mg/kg/day was based on increased motor activity in male and female rats and decreased footsplay in female rats. Malformations indicative of nervous system development disruption were seen in developmental toxicity studies in mice, rats, and rabbits. Neurotoxicity was also seen in offspring in the developmental neurotoxicity study in rats. The LOAEL of 8.8 mg/kg/day was based on decreases in body weights,

decreases in absolute brain weights, changes in brain morphometric parameters, and decreases in motor activity. A NOAEL could not be established. However, the LOAEL (8.8 mg/kg/day) was employed as the point of departure in assessing the risk for all exposure scenarios, and the FQPA SF is retained as a UF_L (i.e., use of a LOAEL to extrapolate a NOAEL). A Benchmark Dose (BMD) analysis of the datasets relevant to the adverse offspring effects (decreased body weight and brain weight) seen at the LOAEL in the DNT study was conducted. All of the BMDLs (benchmark dose limit) modeled successfully on statistically significant effects are 1-2X lower than the LOAEL. The results also indicate that an extrapolated NOAEL is not likely to be 10X lower than the LOAEL and that use of an UF_L of 3X would not underestimate risk. Therefore, the analysis supports reducing the UF_L from 10X to 3X. Using an UF_L of 3X in risk assessment (8.8 mg/kg/day ÷ 3x = 2.9 mg/kg/day) is further supported by other studies in the tebuconazole toxicity database: Those studies with the lowest NOAELs were a developmental toxicity study in mice at 3 mg/kg/day and a chronic toxicity study in dogs at 2.9 mg/kg/day, with effects being seen at respective LOAELs of 10 and 4.5 mg/kg/day.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of tebuconazole. The degree of concern for residual uncertainties for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. EPA utilized a tiered approach in estimating exposure to tebuconazole. While some refinements were incorporated into dietary and residential exposure calculations, EPA is

confident that the aggregate risk from exposure to tebuconazole in food, water and residential pathways will not be underestimated. The acute and chronic dietary exposure assessments incorporated refined estimates of residues in food commodities from reliable field trial data reflecting maximum use conditions, recent monitoring data from USDA's Pesticide Data Program (PDP), and relevant market survey data on the percentage of crops treated. Estimated concentrations of tebuconazole in drinking water were incorporated into the chronic dietary analysis as the upper bound point estimate and into the probabilistic acute dietary analysis as a distribution. For the residential exposure pathway (ornamentals, golf course turf, and treated wood products), potential exposure resulting from tebuconazole outdoor uses in the residential setting was assessed using screening-level inputs that assumes an adult or child will come in contact with turf and other surfaces immediately after application.

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 tebuconazole will occupy 55% of the aPAD for children 12 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tebuconazole 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 tebuconazole 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).

Tebuconazole 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 tebuconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined chronic food, water, and short-term residential exposures result in aggregate MOEs of 1,500 for adult handlers; 400 for children 11-16 years old (post-application); 360 for children 6-11 years old (post-application); 310 for adults (post-application); and 330 for children 3-5 years old (post-application). Because EPA's level of concern for tebuconazole is a MOE of 300 or below, these MOEs are 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**,** tebuconazole 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 tebuconazole**.**

5. *Aggregate cancer risk for U.S. population*. Tebuconazole has been classified as a possible human carcinogen based on statistically significant increase in the incidence of hepatocellular adenoma, carcinoma, and combined adenoma/carcinomas in both sexes of NMRI mice. The Agency has determined that the chronic risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required

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 tebuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography/Nitrogen Phosphorus Detector (GC/NPD)) 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.

Codex MRLs have been established for residues of tebuconazole in or on barley grain at 2 ppm. The Codex MRLs are based on field trials conducted in Europe with a maximum of two foliar applications and a pre-harvest interval (PHI) of 28 days. The U.S. tolerance of 0.3 ppm for barley grain is based on field trials conducted in the U.S. and Canada on barley as a single application with a 30-day PHI. The U.S. use pattern has a total seasonal application rate 25% of that of Europe. This explains the large difference in the recommended U.S. tolerance and the Codex MRL, and thus, harmonization is not possible.

Codex MRLs are established on cucumber (0.15 ppm), summer squash (0.2 ppm), and melons (except watermelon) (0.15 ppm), which are crops included in EPA crop group vegetable, cucurbit, group 9. The Codex MRLs are based on field trials conducted in Europe with a maximum of four foliar applications and a PHI of 3 days for cucumbers and squash and 7 days for melon. The U.S. tolerance for vegetable, cucurbit, group 9 is based on field trials conducted in the U.S. on cucumber, summer squash, and melons where tebuconazole was applied three times with a 2-8 day PHI. A tolerance of 0.4 ppm is recommended for cucurbit vegetables using the OECD statistical calculation procedures. Harmonization cannot be achieved since Codex MRLs are established on individual crops rather than on crop groups and have lower MRLs.

Codex MRLs are established for sweet peppers (1 ppm), and tomatoes (0.7 ppm), which are crops included in EPA's crop grouping of vegetable, fruiting, group 8-10. The Codex MRLs are based on field trials conducted in Europe with a maximum of three foliar applications and a PHI of 3-7 days. The U.S. tolerance (1.3 ppm) was based on field trials conducted in the U.S. on bell peppers, non-bell peppers, and tomatoes where tebuconazole was applied as six broadcast foliar applications with a 6-7 day PHI. Harmonization cannot be achieved since Codex MRLs are established on individual crops rather than on crop groups and have lower MRLs.

V. Conclusion

Therefore, a tolerance is established for residues of tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, including its metabolites and degradates, in or on the vegetable, fruiting group 8–10 at 1.3 ppm. The existing tolerance for barley, grain is modified from 0.15 ppm to 0.3 ppm; and the

existing tolerance for vegetable, cucurbit group 9 is modified from 0.09 ppm to 0.4 ppm. Also, due to the establishment of the crop group tolerance for the vegetable, fruiting, group 8-10, the existing tolerances on okra and the vegetable, fruiting, group 8 are removed as unnecessary.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 30, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.474, the table in paragraph (a) is amended by:

a. Revising the entries for "Barley, grain", and "Vegetable, cucurbit, group 9."

b. Removing the entries for "Okra" and "Vegetable, fruiting, group 8."

c. Adding alphabetically the commodity "Vegetable, fruiting, group 8-10."

The amendments read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Barley, grain	0.3
* * *	* *
Vegetable, cucurbit, group 9	0.4
Vegetable, fruiting, group 8-10	1.3
* * *	* *

* * * * *

[FR Doc. 2013-27147 Filed 11/14/2013 at 8:45 am; Publication Date: 11/15/2013]