ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0120; FRL–8885–4]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on wheat, grain; oats, grain; wheat, shorts; and wheat, germ. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 31, 2011. Objections and requests for hearings must be received on or before October 31, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0120. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Tracy Keigwin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–6605; *e-mail address: keigwin.tracy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2011–0120 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 31, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0120, by one of the following methods:

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 29, 2011 (76 FR 17374) (FRL–8867–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition 0F7792 by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.474 be amended by revising tolerances for residues of the fungicide tebuconazole in or on wheat, grain; and oats, grain to 0.15 ppm in order to harmonize with MRLs established in Canada by PMRA. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that tolerances on the following processed forms of wheat and oats are needed also: Wheat, shorts and wheat, germ, each at 0.20 ppm. Additionally, the Agency is establishing tolerances for tebuconazole of 0.20 ppm in shorts and germ of wheat. The reasons these additional tolerances are needed is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 or dermal route of exposure, and moderate toxicity by the inhalation route. It is not a dermal sensitizer or a dermal irritant; however, it is slightly to mildly irritating to the eye. With repeated dosing, the primary target organs of tebuconazole toxicity are the liver, the adrenals, the hematopoetic 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. Mutagenicity data did not demonstrate any evidence of mutagenic potential for tebuconazole.

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 document entitled ''Tebuconazole: Human Health Risk Assessment to harmonize Tolerances of Tebuconazole in/on Oats and Wheat with Canada,'' pp. 32–37 in docket ID number EPA–HQ–OPP–2011–0120.

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 the Table of this unit.

TABLE—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) (Females 13–50 years of age).	LOAEL = 8.8 mg/kg/day .... UF = 300 UF_A = 10x UF_H = 10x FQPA (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 = 300 UF_A = 10x UF_H = 10x FQPA (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/Intermediate term (1 to 30 days/1 to 6 months).	LOAEL = 8.8 mg/kg/day .... UF = 300 UF_A = 10x UF_H = 10x FQPA (UF_L) = 3x	Residential 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.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term/Intermediate term (1 to 30 days/1 to 6 months).	LOAEL = 8.8 mg/kg/day .... UF = 300 UF_A = 10x UF_H = 10x UF_L = 3x DAF = 23.1%	Residential 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.
Inhalation short-term/Intermediate term (1 to 30 days/1 to 6 months).	LOAEL = 8.8 mg/kg/day .... UF = 300 UF_A = 10x UF_H = 10x UF_L = 3x Inhalation and oral absorption are assumed to be equivalent.	Residential 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. Considering that there was no evidence of carcinogenicity in rats, there was no evidence of genotoxicity for tebuconazole, and tumors were only seen at a high and excessively toxic dose in mice, EPA concluded that the chronic RfD would be protective of any potential carcinogenic effect. The chronic RfD value is 0.029 mg/kg/day which is approximately 9,600 fold lower than the dose that would induce liver tumors (279 mg/kg/day).		

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. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DAF = dermal absorption factor.

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 tebuconazole 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, anticipated residues for bananas, grapes, raisins, nectarines, peaches, and peanut butter were derived using the 2002–2006 USDA Pesticide Data Program (PDP) monitoring data. Anticipated residues for all other registered food commodities were based on field trial data. For uses associated with PP 0F7792, 100 percent crop treated (PCT) was assumed. DEEM (ver. 7.81) default processing factors were assumed for processed commodities associated with petition 0F7792. For several other uses EPA used PCT data as specified in Unit III.C.1.iv.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the same data sources as stated in Unit III. C. 1. i. for acute exposure.

iii. *Cancer.* As explained in Unit III.B., the chronic risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer dietary risk assessment was not conducted.

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.

The Agency estimated the PCT for existing uses as follows:

Grapes: 25% acute assessment, 15% chronic assessment; grape, raisin: 25% acute assessment, 15% chronic assessment; nectarine: 25% acute assessment, 20% chronic assessment; peach: 20% acute assessment, 15% chronic assessment; and peanuts: 45% acute assessment, 15% chronic assessment.

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 one. 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 PCT information for tebuconazole on the following recently approved uses: Apples, apricots, cherries (preharvest), sweetcorn, hops, plums, and turnips. The PCT for each crop is as follows: Apples, acute assessment 44%, chronic assessment 41%; Apricots, acute assessment 56%, chronic assessment 43%; Cherries, preharvest, acute assessment 42%, chronic assessment 37%; Corn, sweet, acute assessment 22%, chronic assessment 14%; Hops, acute assessment 64%, chronic assessment 64%; Plum, acute assessment 26%, chronic assessment 24%; Turnip, acute assessment 68%, chronic assessment 44%. EPA estimates PCT for a new pesticide use by assuming that its actual PCT during the initial five years of use on a specific use site will not exceed the recent PCT of the market leader (*i.e.* ,the one with the greatest PCT) on that site. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment, while the maximum PCT from the same three recent surveys, if available, is used for acute risk assessment. The average and maximum market leader PCTs may each be based on one or two surveys if three are not available. Comparisons are only made among pesticides of the same pesticide type (*i.e.*, the leading fungicide on the use site is selected for comparison with the new fungicide). The market leader PCTs used to determine the average and the maximum may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment, and an estimated projected percent crop treated (PPCT), based on the maximum PCT of the market leaders, is appropriate for use in acute dietary risk assessment. This method of estimating PCTs for a new use of a registered pesticide or a new pesticide produces high-end estimates that are unlikely, in most cases, to be exceeded during the initial five years of actual use. Predominant factors that bear on whether the PCTs could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. Based on these factors, EPA has adjusted upward the estimates for three crops: Cherries post-harvest, hops and turnip greens.

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.*

Surface water estimated drinking water concentrations (EDWCs) resulting from the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) were used in the dietary assessment, since they were higher than the EDWCs resulting from the Screening Concentration in Ground Water (SCI GROW). A distribution of 30-year daily surface water concentrations was estimated for the EDWCs of tebuconazole for acute exposures. The EDWC for chronic, noncancer exposure is estimated to be 59.0 µg/L for surface 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 has currently registered uses that could result in residential exposures. Short-term dermal and inhalation exposures are possible for residential adult handlers mixing, loading, and applying tebuconazole products outdoors to ornamental plants. Short- and intermediate-term dermal postapplication exposures are also possible to golfers from treated golf turf and to adults and children from contact to treated wood structures. Children may also be exposed via the incidental oral route when playing on treated wood structures. Long-term exposure is not expected. As a result, risk assessments have been completed for residential handler scenarios as well as residential post-application scenarios.

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 triazoles (and more specifically, triazole-derivative fungicides). Although triazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In triazole-

derivative fungicides, however, a variable pattern of toxicological responses is found: Some are hepatotoxic and hepatocarcinogenic in mice; some induce thyroid tumors in rats; and some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the triazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that triazole-derivative fungicides share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the triazole-derivative fungicides. 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.*

However, the triazole-derivative fungicides can form the common metabolites 1,2,4-triazole and conjugated triazole metabolites. To support existing tolerances and to establish new tolerances for triazole-derivative fungicides, 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-derivative 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 at *http://www.regulations.gov*, docket ID number EPA–HQ–OPP–2011–0120 in the document entitled ''Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Amended Metconazole Section 3 Registration to Add Uses on Tuberous and Corm Vegetables (Group 1C) and Bushberry Subgroup 13–07B''. This document updates another EPA risk assessment on triazole-derived pesticides which can be found in the reregistration docket for propiconazole at *http://www.regulations.gov*, docket ID number EPA–HQ–OPP–2005–0497.

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 pre- and/or postnatal susceptibility.

3. *Conclusion.* The Agency has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3x for all potential exposure scenarios. The decision is based on the following findings:

i. The toxicity database for tebuconazole is complete with the exception of an immunotoxicity study requirement under the new 40 CFR part 158 guidelines for toxicity data. The available guideline studies do not suggest that tebuconazole directly targets the immune system. A peer-reviewed developmental neurotoxicity/immunotoxicity literature study found in high dose groups (60 mg/kg/day) increased spleen weights and alterations in splenic lymphocyte subpopulations. At the same dose there were no effects seen in the T-cell dependent antibody response to sheep red blood cells (SRBC) and natural killer (NK) cell activity indicating that tebuconazole did not alter the functional immune response in rats. Based on guideline and open literature, the overall weight of evidence suggests that tebuconazole does not directly target the immune system. The Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than currently used for overall risk assessment; therefore, a

database uncertainty factor (UFDB) is not needed to account for the lack of the study.

ii. 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.

iii. A 3x FQPA safety factor is needed to address the failure to achieve a NOAEL in the developmental neurotoxicity (DNT) study. Reduction of the FQPA safety factor from 10x to 3x is based on a Benchmark Dose (BMD) analysis of the datasets relevant to the adverse offspring effects (decreased body weight, decreases in absolute brain weights, changes in brain morphometric parameters, and decreases in motor activity) seen at the LOAEL in the DNT study. The BMD analysis models or estimates the dose (BMD) associated with a specified measure or change (*e.g.* a dose representing a 10% change) of a biological effect over the control. All of the BMDLs (the lower limit of a one-sided 95% confidence interval on the BMD) modeled successfully on statistically significant effects are 1–2x lower than the LOAEL. The results indicate that the use of the FQPA safety factor of 3x would not underestimate risk. Using a 3x FQPA safety factor in the risk assessment (8.8 mg/kg/day ÷ 3x = 2.9 mg/kg/day) is further supported by the NOAELs established in other studies in the tebuconazole toxicity database [*i.e.,* 3 and 2.9 mg/kg/day, from a DNT study in mice and a chronic toxicity study in dogs, respectively (respective LOAELs 10 and 4.5 mg/kg/day)].

iv. There are no residual uncertainties identified in the exposure databases. Although the acute and chronic food exposure assessments are refined, EPA believes that the assessments are based on reliable data and will not underestimate exposure/risk. The drinking water estimates were derived from conservative screening models. The residential exposure assessment utilizes reasonable high-end variables set out in EPA's Occupational/Residential Exposure SOPs (Standard Operating Procedures). The aggregate assessment is based upon reasonable worst-case residential assumptions, and is also not likely to underestimate exposure/risk to any subpopulation, including those comprised of infants and children.

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 33% of the aPAD for the U.S. population and 62% of the aPAD for the population group (children 3–5 years old) 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 8.8% of the cPAD for the U.S. population and 16% of the cPAD for the most highly exposed population group (all infants (< 1 year old).

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 that the short-term aggregate MOE from dietary exposure (food + drinking water) and non-occupational/residential handler exposure for adults using a hose-end sprayer on ornamentals is 370. The short-term aggregate MOE from dietary exposure and exposure from golfing is 1,900. The likelihood of a residential handler treating ornamentals with tebuconazole and then playing golf on a tebuconazole-treated course is considered low; therefore, each scenario is considered separately with background dietary exposure. The short-term aggregate MOE to children from dietary exposure and exposure from wood surfaces treated at the above ground use rate is 470. The short-term aggregate MOE to children from dietary exposure and exposure to wood surfaces treated at the below ground use rate is 220. The combined and aggregate MOEs for wood treated for below ground uses are lower than the target MOE (300) and thus indicate a potential risk of concern. However, the combined MOE for wood treated for above-ground uses is not lower than the target MOE, and therefore is not of concern. Exposure to above-ground wood is expected to more closely represent actual exposures to children. Frequency of exposures to above-ground wood should greatly exceed any exposures to below-ground wood, and exposures to below ground wood would be minimal, or negligible. It is unrealistic to expect a full duration of exposure to below ground wood. Therefore, EPA concludes that there is not a concern for short-term aggregate risk.

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). Tebuconazole is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to tebuconazole. Since the POD, relevant exposure scenarios and exposure assumptions used for intermediate-term aggregate risk assessments are the same as those used for short-term aggregate risk assessments, the short-term aggregate risk assessments represent and are protective of both short and intermediate-term exposure durations.

5. *Aggregate cancer risk for U.S. population.* As discussed in this unit, the chronic risk assessment is considered to be protective of any cancer effects; therefore, because the chronic risk assessment indicates exposure is lower than the cPAD, tebuconazole does not pose a cancer risk of concern.

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 gas chromatography/nitrogen phosphorous detector (GC/NPD) and liquid chromatography/mass

spectrometry/mass spectrometry (LC/MS/MS) methods are available for both collecting and enforcing tolerances for tebuconazole and its metabolites in plant commodities, livestock matrices and processing studies. The methods have been adequately validated by an independent laboratory in conjunction with a previous petition. 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; *e-mail address: residuemethods@epa.gov.*

B. International Residue Limits

Codex and Canada have established maximum residue limits (MRLs) for tebuconazole in/on a variety of plant and livestock commodities. The tolerance expression for tebuconazole is harmonized between U.S., Codex, and Canada. The proposed tolerances will harmonize established U.S. tolerances on oat and wheat with current Canadian MRLs.

There are currently no Codex MRLs for wheat and oats.

C. Revisions to Petitioned-For Tolerances

The Agency concluded that residues of tebuconazole do not concentrate in wheat bran, flour or middlings, but do concentrate in shorts and germ (2.5X). As a result, a tolerance in/on wheat, shorts and wheat, germ, each at 0.20 ppm (highest average field trial (HAFT) value = 0.08 ppm), is required.

V. Conclusion

Therefore, tolerances are established for residues of tebuconazole, in or on wheat, grain, and oat, grain at 0.15 ppm and wheat, shorts, and wheat, germ at 0.20 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 17, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.474, paragraph (a)(1) is amended by:

■ i. Revising the introductory text;

■ ii. Revising the entries for ''oat, grain'' and ''wheat, grain'' in the table; and

■ iii. Alphabetically adding entries for ''wheat, shorts'' and ''wheat, germ'' to the table.

The amendments read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *

(1) Tolerances are 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 commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only tebuconazole [α-[2-(4-chlorophenyl) ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol], in or on the commodity.

Commodity	Parts per million
* * * * *	
Oat, grain	0.15
Wheat, grain	0.15
Wheat, shorts	0.20
Wheat, germ	0.20
* * * * *	

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