[1] This date is June 15, 2004, unless otherwise noted.
[2] This date is June 4, 2010.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0611; FRL–8821–4]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on vegetable, fruiting, group 8. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 5, 2010. Objections and requests for hearings must be received on or before July 6, 2010, 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–2009–0611. 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 cite at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2009–0611 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 6, 2010.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0611, 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. Petition for Tolerance

In the **Federal Register** of September 4, 2009 (74 FR 45848) (FRL–8434–4), 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 (PP 9F7515) by Bayer CropScience, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide tebuconazole in or on the raw agricultural commodity vegetables, fruiting, group at 1.4 parts per million (ppm). That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerance to 1.3 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 the petitioned-for tolerances for residues of tebuconazole on vegetables, fruiting, group 8 at 1.3 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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. The main target organs 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 are 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 seen in the developing nervous system. In the available toxicity studies on tebuconazole, there was no toxicologically significant evidence of endocrine disruptor effects. 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. Submitted mutagenicity studies 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 the document entitled "Tebuconazole: Human Health Risk Assessment to support tolerances in/on Asparagus, Barley, Beans, Beets, Brassica leafy greens, Bulb Vegetables, Coffee (import), Commercial Ornamentals, Corn, Cotton, Cucurbits, Hops, Lychee, Mango, Okra, Pome fruit, Soybean, Stone fruit, Sunflower, Tree Nut Crop Group, Turf, Turnips and Wheat," pages 83–105 in docket ID number EPA–HQ–OPP–2005–0097–0004.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 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 milligram/kilogram/day (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/1–6 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.
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 toxicity 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.

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, peanut butter and wheat were derived using the latest USDA Pesticide Data Program (PDP) monitoring data. Anticipated residues for all other registered and proposed food commodities were based on field trial data. For uses associated with PP 9F7515, 100 percent crop treated (PCT) was assumed. Dietary Exposure Evaluation Model (ver. 7.81) default processing factors were assumed for processed commodities associated with petition 9F7515. 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 assumptions 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 section 408(f)(1) of FFDCA 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Grapes: 25%; grape, raisin: 25%; nectarine 25%; oats 2.5%; peach: 20%; and peanuts 45%.

In most cases, EPA uses available data from the USDA's National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 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 used projected percent crop treated (PPCT) information for tebuconazole on apples, apricots, cherries (preharvest), sweetcorn, hops, plums, and turnips. The PPCT 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 PPCT for a new pesticide use by assuming that its actual PCT during the initial 5 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 types (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 PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment, and an estimated PPCT, based on the maximum PCT of the market leaders, is appropriate for use in acute dietary risk assessment. This method of estimating PPCTs 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 5 years of actual use. Predominant factors that bear on whether the PPCTs could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors have been considered for tebuconazole on cherries, resulting in adjustments to the initial estimates for three crops to account for lack of confidence in projections based on less than three observations, old data and/or data based on expert opinion.

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 47.23 micrograms/Liter (µg/L) for surface water and 0.447 µg/L for ground water. The EDWCs for chronic, noncancer are estimated to be 16.97 µg/L for surface water and 0.447 µg/L for ground water. The EDWCs for chronic, cancer exposures are estimated to be 12.14 for surface water and 0.447 µg/L for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 47.23 µg/L was used to assess the contribution to drinking water. For the chronic dietary risk assessment (which is protective of any possible cancer effects), the water concentration value of 16.97 µg/L 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 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 to adults and children are also possible during golfing and/or playing on 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.

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 website 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 the Food Quality Protection Act (FQPA) Safety Factor (SF) 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.

In connection with the pending new uses of tebuconazole (and other triazole-derivative fungicides), the Agency has revised the triazole dietary assessment to include the new uses of tebuconazole and has determined that aggregate risk (food, water and residential) remains below the Agency's level of concern. This revised assessment can be found at *http://www.regulations.gov* in docket ID EPA–HQ–OPP–2009–0061.

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 FQPA SF. In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicity database for tebuconazole is complete, and 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 from the developmental neurotoxicity study is used for overall risk assessments. Therefore, there are no residual uncertainties for prenatal and/or postnatal susceptibility.

There is a concern with regard to the DNT study because of the failure to achieve a NOAEL in that study. This concern is addressed by the retention of FQPA SF in the form of UF_L of 3x. 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. 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 extrapolated NOAEL is not likely to be 10x lower than the LOAEL and that the use of the FQPA SF of 3x would not underestimate risk. Using a 3x FQPA SF 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 developmental toxicity study in mice and a chronic toxicity study in dogs, respectively (respective LOAELs 10 and 4.5 mg/kg/day)].

3. *Conclusion*. The Agency has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 3x for all potential exposure scenarios. That 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 (Moser et al., 2001) 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 SRBC (sheep red blood cells) 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 risk assessment team 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.The FQPA SF is retained as a UF_L. Reduction of the UF_L from 10 to 3x is based on a BMD analyses of the datasets relevant to the adverse offspring effects (decreased body weight and brain weight) seen at the LOAEL in the DNT study. All of the BMDLs modeled successfully on statistically significant effects are 1–2x lower than the LOAEL. The results 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. 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 [with the lowest NOAELs being 3 and 2.9 mg/kg/day, from a developmental toxicity 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 56% 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 exposure to tebuconazole from food and water will utilize 4.9% of the cPAD for the U.S. population and 7.5% of the cPAD for the most highly exposed population group (children 1–2 years 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 390. The short-term aggregate MOE from dietary exposure and exposure from golfing is 1,700. The short-term aggregate MOE to children from dietary exposure and exposure from wood surfaces treated at the above ground use rate is 520. The short-term aggregate MOE to children from dietary exposure and exposure to wood surfaces treated at the below ground use rate is 230. The combined and aggregate MOEs for wood treated for below ground uses exceed the Agency's LOC, and indicate a potential risk of concern. However, the combined MOE for wood treated for above-ground uses does not exceed the LOC, 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, this assessment should be characterized as a conservative screening-level assessment.

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 phosphorus detector (GC/NPD) and liquid chromatography/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; email 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 the United States, Codex, and Canada. There are currently no established Codex, Canadian, or Mexican MRLs for tebuconazole on fruiting vegetables. However, there are CODEX MRLs for chili pepper at 5 ppm and sweet pepper and tomato at 0.5 ppm. The Codex MRLs are based on European field trials, where the single application rate is approximately equivalent to the U.S. single application rate but the pre-harvest interval (PHI) is 3 days in the European Union as opposed to a PHI of 0 days in the United States. Given these different use practices, international harmonization is not possible at this time.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerances for vegetable, fruiting, group 8, should be reduced to 1.3 ppm from 1.4 ppm. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency's "Tolerance Spreadsheet" in accordance with the Agency's "Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP)."

V. Conclusion

Therefore, tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on vegetable, fruiting, group 8 at 1.3 ppm Compliance with the tolerance levels specified in Unit IV.C. is to be determined by measuring only tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol), in or on vegetable, fruiting, group 8.

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) (Public Law 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: April 20, 2010.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.474 is amended by revising the introductory text of paragraphs (a)(1), (a)(2), and (c) and alphabetically add the commodity "vegetable, fruiting, group 8" to the table in paragraph (a)(1) to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol), in or on the commodity.

Commodity	Parts per million
* *	* * *
Vegetable, fruiting, group 8	1.3
* *	* * *

(2) Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) and its diol metabolite (1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol), calculated as the stoichiometric equivalent of tebuconzole, in or on the commodity.

* * * * *

(c) *Tolerances with Regional Registrations.* Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on the commodity.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0139; FRL–8820–4]

Spirodiclofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spirodiclofen per se (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate) in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 5, 2010. Objections and requests for hearings must be received on or before July 6, 2010, 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–2009–0139. 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: Rita Kumar, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200