* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide boscalid, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only boscalid, 3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro[1,1′-biphenyl]-2-yl), in or on the following commodities:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage, except alfalfa	1.0
Animal feed, nongrass, group 18, hay, except alfalfa	2.0

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0279; FRL–8828–6]

Prothioconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of prothioconazole and prothioconazole-desthio, calculated as parent in or on grain, cereal, group 15 (except sweet corn, sorghum, and rice), and grain, cereal, forage, fodder and straw, group 16 (except sweet corn, sorghum, and rice) and sweet corn. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 28, 2010. Objections and requests for hearings must be received on or before July 27, 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–2009–0279. 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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8050; e-mail address: *maignan.tawanda@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 *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. 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–2009–0279 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 27, 2010. 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 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–2009–0279, 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 August 19, 2009 (74 FR 41898) (FRL–8426–7), 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 8F7485) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.626 be amended by establishing tolerances for residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, in or on grain, cereal, group 15, except sweet corn, sorghum and rice at 0.35 parts per million (ppm); forage, cereal, group 16, except sweet corn, sorghum and rice at 8.0 ppm; stover, cereal, group 16, except sweet corn, sorghum and rice at 10 ppm; hay, cereal, group 16, except sweet corn, sorghum and rice at 7.0 ppm; straw, cereal, group 16, except sweet corn, sorghum and rice at 5.0 ppm; corn, sweet, forage at 7.0 ppm; corn, sweet, stover at 8.0 ppm; and corn, sweet, kernel plus cob with husks removed at 0.02 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has established and increased the proposed tolerance of 0.02 ppm for combined residues in/on sweet corn to a higher tolerance of 0.04 ppm. Further, EPA has modified crop group terminology and established tolerances for grain, cereal, group 15, except sweet corn, sorghum, and rice at 0.35 ppm; grain, cereal, group 16, except sorghum and rice; forage at 8.0 ppm; grain, cereal, group 16, except sorghum and rice; stover at 10 ppm; grain, cereal, group 16, except sorghum and rice; hay at 7.0 ppm; grain, cereal, group 16, except sorghum and rice; straw at 5.0 ppm. With the establishment of the above tolerances, EPA has revoked the following tolerances: barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. EPA is also not establishing the proposed tolerances for sweet corn forage at 7 ppm and sweet corn stover at 8 ppm because the commodities will be covered under grain, cereal, group 16; forage and stover. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 prothioconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prothioconazole 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. Prothioconazole has low acute toxicity by oral, dermal, and inhalation routes. It is not a dermal sensitizer, or a skin or eye irritant. Prothioconazole's metabolite, prothioconazole-desthio, also has low acute toxicity by oral, dermal, and inhalation routes. It is not a dermal sensitizer, or a skin irritant, but it is a slight eye irritant. The subchronic and chronic studies show that the target organs at the lowest observable adverse effects level (LOAEL) include the liver, kidney, urinary bladder, thyroid and blood. In addition, the chronic studies showed body weight and food consumption changes. Prothioconazole and its metabolites may be primary developmental toxicants, producing effects including malformations in the conceptus at levels equal to or below maternally toxic levels in some studies, particularly those studies conducted using prothioconazole-desthio. Reproduction studies in the rat with prothioconazole and prothioconazole-desthio suggest that these chemicals may not be primary reproductive toxicants. Acute and subchronic neurotoxicity studies were conducted in the rat using prothioconazole. A developmental neurotoxicity study was conducted in the rat using prothioconazole-desthio.

The available data show that the prothioconazole-desthio metabolite produces toxicity at lower dose levels in subchronic, developmental, reproductive, and neurotoxicity studies as compared with prothioconazole and the two additional metabolites that were tested.

The available carcinogenicity and/or chronic studies in the mouse and rat, using both prothioconazole and prothioconazole-desthio, show no increase in tumor incidence. Therefore, EPA has concluded that prothioconazole and its metabolites are not carcinogenic, and are classified as "Not likely to be Carcinogenic to Humans" according to the 2005 Cancer Guidelines.

Specific information on the studies received and the nature of the adverse effects caused by prothioconazole 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 "Prothioconazole. Human Health Risk Assessment for Proposed Section 3 Uses on Crop Group 15 and 16 (Cereal Grains and Forage, Fodder and Straw of the Cereal Grains Group Except Sweet Corn, Sorghum and Rice) and Sweet Corn," pages 14 to 17 in docket ID number EPA–HQ–OPP–2009–0279.

B. Toxicological Points of Departure and 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 prothioconazole used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROTHIOCONAZOLE 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 (Females 13–49 years of age)	NOAEL = 2.0milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.02 mg/kg/day aPAD = 0.02 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL = 10 mg/kg/day based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and multiple malformations.
Chronic dietary (All populations)	NOAEL = 1.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Chronic/Oncogenicity Study in Rats LOAEL = 8.0 mg/kg/day based on liver histopathology (hepatocellular vacuolation and fatty change (single cell, centrilobular, and periportal)).

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to prothioconazole and its metabolites and/or degradates, EPA considered exposure under the petitioned-for tolerances as well as all existing prothioconazole tolerances in 40 CFR 180.626. EPA assessed dietary exposures from prothioconazole 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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a moderately refined acute dietary exposure assessment. Average field trial values (because all of the crops included in this assessment are blended food forms, except sweet corn), empirical processing factors, and livestock maximum residues were incorporated into the refined acute assessment. The assessment also assumed 100% crop treated (CT). Since no observed effects would be attributable to a single dose exposure for the general U.S. population, females 13 to 49 years of age was the only population subgroup included in the acute assessment.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted a moderately refined chronic dietary exposure assessment. Empirical processing factors, average field trial residues, and livestock commodity residues derived from feeding studies and a reasonably balanced dietary burden (RBDB) were incorporated into the chronic assessment; 100% crop treated was assumed.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight-of-the-evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized.

Based on the data summarized in Unit III.A., EPA has concluded that prothioconazole is classified as "Not Likely to be Carcinogenic to Humans." Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. 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 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. Average residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prothioconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prothioconazole. 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 prothioconazole for the acute dietary risk assessment, the water concentration value of 94.7 parts per billion (ppb) was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration value of 84.3 ppb was used to assess the contribution to drinking water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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).

Prothioconazole is not registered for any specific use patterns that would result in residential exposure.

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."

Prothioconazole is a member of the triazole-containing class of pesticides, often referred to as the triazoles. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. The conazole pesticides, as a whole, tend to exhibit carcinogenic, developmental, reproductive, and/or neurological effects in mammals. Additionally, all the members of this class of compounds are capable of forming, via environmental and metabolic activities, 1,2,4-triazole, triazolylalanine and/or triazolylacetic acid. These metabolites have also been shown to cause developmental, reproductive, and/or neurological effects. That these compounds, however, have structural similarities and share some common effects does not alone show 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. A number of potential events could contribute to the toxicity of conazoles (e.g., altered cholesterol levels, stress responses, altered DNA methylation). At this time, there is not sufficient evidence to determine whether conazoles share common mechanisms of toxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding for the diverse range of effects found. Investigations into the conazoles are currently being undertaken by the EPA's Office of Research and Development. When the results of this research are available, the Agency will make a determination of whether there is a common mechanism of toxicity and, therefore, a basis for assessing cumulative risk. 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*.

To support existing tolerances and to establish new tolerances for conazole pesticides, including prothioconazole, EPA conducted human health risk assessments for exposure to 1,2 4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of triazole-containing pesticides (as of 9/1/05). The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with the common metabolites (e.g., use of maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high-end estimates of both dietary and non-dietary exposures). Acute and chronic aggregate risk estimates associated with these compounds are below the Agency's level of concern for all durations of exposure and for all population subgroups, including those of infants and children. The Agency's risk assessment for these common metabolites is available in the propiconazole reregistration docket 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*. There is evidence of increased susceptibility following prenatal/or postnatal exposure in:

i. Rat developmental toxicity studies with prothioconazole as well as its prothioconazole-desthio and sulfonic acid K salt metabolites.

ii. Rabbit developmental toxicity studies with prothioconazole-desthio.

iii. A rat developmental neurotoxicity study with prothioconazole-desthio; and

iv. Multi-generation reproduction studies in the rat with prothioconazole-desthio. Effects include skeletal structural abnormalities, such as cleft palate, deviated snout, malocclusion, extra ribs, and developmental delays. Available data also show that the skeletal effects such as extra ribs are not completely reversible after birth in the rat, but persist as development continues.

Although increased susceptibility was seen in these studies, the Agency concluded that there is a low concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of prothioconazole because:

- Developmental toxicity NOAELs and LOAELs from prenatal exposure are well characterized after oral and dermal exposure;
- The off-spring toxicity NOAELs and LOAELs from postnatal exposures are well characterized; and
- The NOAEL for the fetal effect, malformed vertebral body and ribs, is used for assessing acute risk of females 13 years and older and, because it is lower than the NOAELs in other developmental studies, is protective of all potential developmental effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for prothioconazole is considered complete, with the exception of required functional immunotoxicity testing. The Agency began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Although an immunotoxicity study in the mouse is part of the existing prothioconazole toxicity database, this study as reported does not satisfy the current guideline requirements for an immunotoxicity study (OPPTS 870.7800). As such, EPA is requiring that an immunotoxicity study be submitted which meets guideline requirements. EPA has evaluated the available prothioconazole toxicity database (including the non-guideline study in the mouse) to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. In one chronic study in the rat (but not in the mouse or dog), blood leukocyte counts were significantly elevated at the high dose level (750 mg/kg/day) along with increased thrombocyte counts and decreased hemoglobin. However, this finding is made in the presence of toxicity to a broad range of organ systems such as the liver, urinary bladder, kidney, thyroid, and decreased body weight gains. In a chronic dog study, splenic effects (increased spleen weight with pigmentation and/or fibrosiderotic plaques) were seen at 40 mg/kg/day and above, but these effects are not considered to be indicative of immunotoxicity, and occurred in the presence of toxicity to the liver, kidney, thyroid, and decreased body weights. Furthermore, no signs of immunotoxicity, such as changes in leukocyte counts and albumin/globulin ratio, changes in thymus and spleen weights, or histopathological changes in lymphoid tissues, were observed at dose levels up to 400 mg/kg/day in the non-guideline immunotoxicity study in the mouse. There appears to be no basis for concern for immunotoxicity, particularly at the Points of Departure (POD) for prothioconazole and its metabolites which, at 2.0 and 1.1 mg/kg/day (Acute and Chronic Reference Dose (aRfD and cRfD), respectively) are two orders of magnitude lower than the 400 and 750 mg/kg/day dose levels mentioned in this Unit. This finding, along with the absence of immunotoxicity observed in the subchronic and chronic studies with prothioconazole and its metabolites supports the reduction of the FQPA factor to 1X in the interim, pending receipt of an acceptable guideline immunotoxicity study.

ii. There is an acceptable battery of neurotoxicity studies including a developmental neurotoxicity study. Although offspring neurotoxicity was found, characterized by peripheral nerve lesions in the developmental neurotoxicity studies on prothioconazole-desthio, the increase was seen only in the highest dose group at 105 mg/kg/day, was not considered treatment related, and a clear NOAEL was established for this study.

iii. Although increased susceptibility was seen in the developmental and reproduction studies, the Agency concluded that there is a low concern and no residual uncertainties for prenatal and/or postnatal toxicity effects of prothioconazole for the reasons explained in Unit III.D.2.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment utilized empirical processing factors, 100% crop treated, average crop field trial residue levels, and livestock maximum residues. Results from ruminant feeding studies and poultry metabolism studies were used to determine the maximum residue levels for livestock commodities. The crop field trials were performed using maximum application rates and minimum pre-harvest intervals. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prothioconazole in drinking water. These assessments will not underestimate the exposure and risks posed by prothioconazole.

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.

Based on the proposed and existing crop uses for prothioconazole, dietary aggregate exposures (i.e., food plus drinking water) are anticipated. There are no residential uses for prothioconazole and, therefore, no residential exposures are anticipated. Consequently, only dietary (food plus drinking water) exposures were aggregated for this assessment.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prothioconazole will occupy 38% of the aPAD for females 13 to 49 years of age, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prothioconazole from food and water will utilize 21% of the cPAD for the general U.S. population and 62% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. There are no residential uses for prothioconazole.

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). Because there is no residential exposure, prothioconazole is not expected to pose a short-term 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). Because there is no residential exposure, prothioconazole is not expected to pose an intermediate-term risk.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate liquid chromatography methods with tandem mass spectrometry detection (LC/MS/MS) are available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with

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

The Codex has established MRLs for residues of desthio-prothioconazole in barley at 0.2 ppm (04/2010), and in oats, rye, and wheat at 0.05 ppm each and in the fodder (dry) of cereal grains at 4 ppm and in the straw (dry) of cereal grains at 5 ppm. There are currently no established Mexican MRLs for prothioconazole. Canadian MRLs have been established for prothioconazole *per se* in/on several commodities, including barley (0.35 ppm), wheat (0.07 ppm), meat byproducts of cattle, goats, horses and sheep (0.2 ppm), meat byproducts of hogs (0.05 ppm), liver of poultry (0.02 ppm), meat of cattle, goats, horses, and sheep (0.02 ppm), and milk (0.02 ppm). Harmonization of the proposed tolerances with the existing Codex for prothioconazole is not possible at this time because of differences in tolerance expression and use patterns. The MRL expression for Codex is prothioconazole-desthio and is thus not compatible with the U.S. tolerance definition, the sum of prothiocoanzole and prothioconazole-desthio. Much of the Codex cereal grain supervised field trial data is from Europe, where the use pattern is different resulting in lower measured residues. The straw numerical value (5 ppm) is matched between the U.S. and Codex.

The tolerance definition for plant commodities in Canada were recently changed (02/10/2010) and is now harmonized with the U.S. residue definition. The barley tolerance of Canada agrees with the recommended U.S. tolerance for cereal grains (except sweet corn, sorghum, and rice) of 0.35 ppm. However, the Canadian tolerance for wheat is lower (0.07 ppm) than the recommended U.S. group tolerance. The 0.07 ppm value is the current U.S. tolerance value for wheat, but will be replaced by the cereal grain group tolerance. Canada does not routinely establish animal feed commodity tolerances, and therefore there are no harmonization issues with forage, stover, hay, and straw.

C. Response to Comments

One comment was received from an anonymous source objecting to establishment of tolerances and stating that the Agency is not protecting human health. The response contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to prothioconazole, including all anticipated dietary exposures and other exposures for which there is reliable information.

D. Revisions to Petitioned-For Tolerances

Prothioconazole tolerances for crop commodities listed in 40 CFR 180.626(a)(1) are expressed in terms of the combined residues of the fungicide prothioconazole and prothioconazole-desthio, calculated as parent. EPA has also revised the tolerance expression to clarify (1) that, as provided in section 408(a)(3) of FFDCA, the tolerance covers metabolites and degradates of prothioconazole not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

Tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, 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 prothioconazole and its metabolite prothioconazole-desthio, or α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, calculated as parent in or on the commodity.

Tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, 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 prothioconazole and its metabolites prothioconazole-desthio, or α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent in or on the commodity.

The proposed tolerance of 0.02 ppm for combined residues in/on sweet corn K+CWHR should be increased to 0.04 ppm (reflecting the combined limit of quantitation of 0.02 ppm each for prothioconazole and prothioconazole-desthio).

The proposed tolerances of 7 ppm for sweet corn forage and 8 ppm for sweet corn stover should be removed. These commodities will be covered by the tolerance for group 16 grain, cereal, forage and group 16, cereal, grain, stover, respectively.

With the establishment of the requested crop group tolerances for group 15 and 16, the established tolerances for the following commodities are no longer necessary and should be removed: barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw.

V. Conclusion

Therefore, tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, including its metabolites and degradates, in or on grain, cereal, group 15, except sweet corn, sorghum, and rice at 0.35 ppm; grain, cereal, group 16, except sorghum and rice; forage at 8.0 ppm; grain, cereal, group 16, except sorghum and rice; stover at 10 ppm; grain, cereal, group 16, except sorghum and rice; hay at 7.0 ppm; grain, cereal, group 16, except sorghum and rice; straw at 5.0 ppm.; corn, sweet, kernel plus cob with husks removed at 0.04 ppm.

Further, the EPA is revoking the following eight existing tolerances because they are no longer needed as a result of this rule: barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. The EPA is also revising the prothioconazole crop and animal tolerance expressions.

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: May 21, 2010.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Amend § 180.626 as follows:

a. Revise the introductory text to paragraph (a)(1).

b. Remove from the table in paragraph (a)(1) existing entries for barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw.

c. Add alphabetically new commodities to the table in paragraph (a)(1).

d. Revise the introductory text to paragraph (a)(2).

The added and revised text read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, 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 prothioconazole and its metabolite prothioconazole-desthio, or α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, calculated as parent in or on the commodity.

Commodity	Parts per million
* * *	* *
Corn, sweet, kernel plus cob with husks removed	0.04
* * *	* *
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; forage	8.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; hay	7.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; stover	10
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; straw	5.0
Grain, cereal, group 15, except sweet corn, sorghum, and rice	0.35
* * *	* *

(2) Tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, 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 prothioconazole and its metabolites prothioconazole-desthio, or α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent in or on the commodity.

* * * * *

[FR Doc. 2010–12922 Filed 5–27–10 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 03–123; WC Docket No. 05–196; FCC 08–275]

Telecommunications Relay Services, Speech–to–Speech Services, E911 Requirements for IP–Enabled Service Providers

AGENCY: Federal Communications Commission

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection requirements associated with the Commission's Telecommunications Relay Services,