contrary to the intention of the changes as discussed in the proposed rule. Notice and comment are unnecessary to correct an erroneous deletion of a tolerance that was neither intended nor discussed in rulemaking. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

The discussion in Unit IV. of the September 12, 2007 final rule also applies to this action.

V. 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: March 18, 2009.

Debra Edwards,

Director, 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), 346(a) and 371.

■ 2. Section 180.185, is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.185 DCPA; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * *	* *
Onion, green	1.0
* * *	* *

* * * * *

[FR Doc. E9–7040 Filed 3–31–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0327; FRL– 8403–9]

Prothioconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases a tolerance for combined residues of prothioconzole and prothioconazole-desthio, calculated as parent in or on, wheat, forage. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 1, 2009. Objections and requests for hearings must be received on or before June 1, 2009 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–2008–0327. 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: Bryant Crowe, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: *crowe.bryant@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also 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*.

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–2008–0327 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 June 1, 2009.

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–2008–0327, 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 June 4, 2008 (73 FR 31863) (FRL–8365–3), 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 7F7279) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.626 be amended by increasing a tolerance for combined residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and prothioconazole-desthio, in or on, wheat, forage from 6.0 to 8.0 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.

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 combined residues of prothioconazole, and prothioconazole-desthio, calculated as parent, in or on wheat, forage at 8.0 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. 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-observed-adverse effect level (the LOAEL) include the liver, kidney, urinary bladder, thyroid and blood. In addition, the chronic studies showed body weight and food consumption changes, and toxicity to the lymphatic and GI systems. 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 conducted using prothioconazole-desthio. Reproduction studies in the rat with prothioconazole and prothioconazole-desthio suggested 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 the lowest dose levels in the areas of subchronic, developmental, reproductive, and neurotoxic toxicities 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 prothioconazole or its metabolites are not carcinogenic, and are classified ''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 LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document *Prothioconazole; Pesticide Tolerance* pages 14714–14719 in docket ID number EPA–HQ–OPP–2007–0178.

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 LOAEL 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-term, intermediate-term, 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/oppfead1/trac/science; http://www.epa.gov/pesticides/factsheets/riskassess.htm*; and *http://www.epa.gov/pesticides/trac/science/aggregate.pdf*.

A summary of the toxicological endpoints for prothioconazole used for human risk assessment can be found at *http://www.regulations.gov* in document *Prothioconazole: Human Health Risk Assessment for Proposed Section 3 Seed treatment Use on Wheat, Barley, and Triticale, Plus Increase Tolerance on Forage of Wheat, Barley, and Triticale* pages 20–21 in docket ID number EPA–HQ–OPP–2008–0327.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to prothioconazole, 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 residues 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). A moderately refined acute dietary exposure (food and drinking water) assessment was conducted for prothioconazole. Average field trial values, empirical processing factors, and livestock maximum residues were incorporated into the refined acute assessment. The assessment also assumed 100 percent of crops covered by the existing tolerances, as well as the changed tolerance on wheat forage, are treated with prothioconazole.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. A moderately refined chronic dietary exposure (food and drinking water) assessment was conducted for prothioconazole. Average field trial values, empirical processing factors, and livestock maximum residues were incorporated into the refined acute assessment. The assessment also assumed 100 percent of crops covered by the existing tolerances, as well as the changed tolerance on wheat forage, are treated with prothioconazole.

iii. *Cancer*. The available toxicology studies in the mouse and rat showed no increase in tumor incidence, and therefore the Agency has concluded that neither prothioconazole, nor its metabolites are carcinogenic. Thus classified, by the Agency, as ''Not Likely to Carcinogenic to Humans'' according to the 2005 Cancer Guidelines. Consequently, a quantitative dietary cancer assessment was not performed.

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 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), 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 this tolerance. 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 acute exposures are estimated to be 29 parts per billion (ppb) for surface water and 0.67 ppb for ground water. The EDWCs for chronic exposures are estimated to be 13 ppb for surface water and 0.67 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure models. For acute dietary risk assessment, the water concentration value of 29 ppb was used to assess the contribution from drinking water. For the chronic dietary risk assessment, the water concentration value of 13 ppb was used to assess the contribution from drinking water. EPA used the EDWCs from surface water only in assessing the risk from prothioconazole because the EDWCs for ground water source are less than 1 ppb, and considered minimal in comparison to surface water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Prothioconazole is not registered for 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 conazoles. 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. Structural similarities and sharing a common effect does 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. Hence, the underlying basis of toxicity is the same, or essentially the same for each chemical.'' (EPA, 2002) 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 efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and three triazole conjugates (triazole alanine, triazole acetic acid, and triazolylpyruvic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment included evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's September 1, 2005 risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov* (Docket ID EPA–HQ–OPP–2005–0497). In October and December of 2008, EPA updated the dietary and aggregate risk assessments for exposure to 1,2,4-triazole, triazole alanine, triazole acetic acid, and triazolylpyruvic acid resulting from the use of all current and pending uses of any triazole-derived fungicide to support existing tolerances and to establish new tolerances for new uses of metconazole (canola, corn, cotton, and sugarcane; PP 7F7221, 7F7292, and 08FL03), propiconazole (beets, parsley, and pineapple; PP 7F7300), prothioconazole (wheat and barley; PP 7F7279), and tetraconazole (grapes; PP 7E7273). These updated dietary and aggregate assessments are below the Agency's level of concern. These updated triazole risk assessments can be found in the Rule's docket (EPA–HQ–OPP–2008–0327) and the following associated dockets at *http://www.regulations.gov* (Docket IDs EPA–HQ–OPP–2007–514 and EPA–HQ–OPP–2008–0718).

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 prematal/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 complete, except for immunotoxicity testing. EPA 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 data base, 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 milligrams/kilogram/day (mg/kg/day)) along with increased thrombocyte counts and decrease 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. Furthermore, no signs of immunotoxicity, including evidence of toxicity to the lymphatic system, 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. Previously, because of incomplete data reporting, there were uncertainties regarding dose levels at which neurotoxicities (brain morphometrics and peripheral nerve degeneration) were occurring in the pups. Because of this database uncertainty, the FQPA safety factor was retained at 10X in previous hazard characterizations. Critical data on brain morphometry and peripheral nerve lesions in a rat developmental neurotoxicity study have now been submitted and reviewed. Upon evaluation of these new data, neither the apparent increases in axonal degeneration at the high dose or the brain morphometric changes at the low and mid doses were considered treatment-related. Therefore, these data support the reduction of the FQPA factor to 1X.

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 assessments were performed based on 100 PCT and tolerance-level or anticipated residues derived from reliable residue field trials. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to prothioconazole in drinking water. Residential exposures are not expected. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the Acute Percent Adjusted Dose and Chronic Percent Adjusted Dose (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-term, intermediate-term, 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.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and therefore no acute dietary endpoint was selected for the general population. However, an acute dietary endpoint was selected for the population subgroup females 13 to 49 years of age. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and drinking water to prothioconazole will occupy 8% of the aPAD for (female 13 to 49 years old).

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 22% of the cPAD for (infants less than 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).

Prothioconazole is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to prothioconazole through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Prothioconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to prothioconazole through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Aggregate cancer risk for U.S. population. The available studies in the mouse and rat show no increase in tumor incidence, therefore the Agency has concluded that neither prothioconazole nor its metabolites are carcinogenic, and are classified ''Not likely to be Carcinogenic to Humans'' according to the 2005 Cancer Guidelines. Therefore, prothioconazole is not expected to pose a cancer risk.

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 enforcement methodology are available to enforce the tolerance expression, consisting of liquid chromatography/tandem massspectrometry (LC/MS/MS) for both plant and livestock commodities, usingtandem mass spectrometry electrospray ionization in both the positive and negative modes. Both methods (LC/MS/MS Method RPA JA/03/01 for plants and LC/MS/MS Method Bayer Report No. 200537 for animals) have successfully passed tolerance method validation at ACB/BEAD. Methods 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

There are no maximum residue limits (MRLs) (tolerances) established for prothioconazole in Codex or in Mexico. MRLs have been established in Canada on barley grain at 0.35 ppm and wheat grain at 0.07 ppm.

V. Conclusion

Therefore, a tolerance is being revised for combined residues of prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2- hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and prothioconazole-desthio, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, calculated as parent, in or on wheat, forage, from 6.0 ppm to 8.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under

Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: March 19, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.626 is amended by revising the entry for ''wheat, forage'' in the table in paragraph (a)(1) to read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * * * *	
Wheat, forage	8

* * * * * *

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