6,9,10,11,12,13,14,16a,16b-hexadecahydro 14-methyl-, (2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR); XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9, 10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aR,5aS,5bS, 9S,13S,14R,16aS,16bS); ND-J: (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-9-ethyl-14-methyl-13-[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b, 6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d] oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranoside; and NF-J: (2R,3S,6S)-6-[[(2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranosyl) oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a, 16b-octadecahydro-1H-as-indaceno[3,2-d] oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide.''

III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because this final rule corrects a technical error and does not otherwise change the original requirements of the final rule. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

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

This final rule corrects a technical error and does not otherwise change the requirements in the final rule. As a technical correction, this action is not subject to the statutory and Executive Order review requirements. For information about the statutory and Executive Order review requirements as they related to the final rule, see Unit VI. in the **Federal Register** of October 10, 2007.

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 4, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 is corrected as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.635, the introductory text for paragraph (a) is revised to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide spinetoram, expressed as a combination of XDE-175-J: 1-H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b, 6,9,10,11,12,13,14,16a,16b-hexadecahydro 14-methyl-, (2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR); XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino) tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9, 10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aR,5aS,5bS, 9S,13S,14R,16aS,16bS); ND-J: (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR) -9-ethyl-14-methyl-13-[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14, 15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranoside; and NF-J: (2R,3S,6S)-6-[[(2R,3aR,5aR,5bS,9S, 13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranosyl) oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9, 10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d] oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide, in or on the following raw agricultural commodities:

* * * * *

[FR Doc. E8–5402 Filed 3–18–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0178; FRL–8353–2]

Prothioconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of prothioconzole and prothioconazole-desthio, calculated as parent, in or on soybean, forage; soybean, seed; soybean, hay; and sugar beet, roots. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 19, 2008. Objections and requests for hearings must be received on or before May 19, 2008, 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–2007–0178. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

•Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

•Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0178 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 May 19, 2008.

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–2007–0178, 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'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 27, 2007 (72 FR 35237) (FRL–8133–4), and in the **Federal Register** of July 12, 2006 (71 FR 39313) (FRL–8074–9), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (6F7134 and 6F7073, respectively) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle. These petitions requested that 40 CFR 180.626 be amended by establishing a tolerance for combined residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, and prothioconazole-desthio, in or onsoybean, forage at 5 parts per million (ppm); soybean, seed at 0.15 ppm; soybean, hay at 22 ppm; and sugar beet, roots at 0.25 ppm and sugar beet, tops at 9 ppm. Those notices 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 filings.

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of

and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of prothioconazole, and prothioconazole-desthio, calculated as parent, in or on soybean, forage at 4.5 ppm; soybean, seed at 0.15 ppm; soybean, hay at 17 ppm; sugar beet, roots at 0.25 ppm. Sugar beet, tops do not need a tolerance because they are not a human food commodity. EPA's assessment of exposures and risks associated with establishing the tolerance 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-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. Subchronic studies show that the target organs at the LOAEL include the liver, kidney, urinary bladder, thyroid and blood. Significant clinical chemistry findings were also made. NOAEL/LOAEL values across the family of chemicals (i.e., prothioconazole, and prothioconazole-desthio and prothioconazole sulfonic acid potassium salt metabolites) in the toxicity database indicate that prothioconazole-desthio is a most toxic chemical. In addition to the target organs and effects observed in the subchronic studies (i.e., liver, kidney, urinary bladder, thyroid, hematology and clinical chemistry), chronic toxicity at the LOAEL also included body weight and food consumption changes, and toxicity to the lymphatic and GI systems. The relative potency of prothioconazole-desthio was greater than prothioconazole.

Studies in the rat and mouse, using both prothioconazole and prothioconazole-desthio, showed no evidence of carcinogenicity. The data show that dosing was adequate, except in the rat cancer study using prothioconazole, where the dosing was considered too high.

The data indicate that prothioconazole and the three metabolites evaluated (i.e., prothioconazole-desthio, prothioconazole sulfonic acid potassium salt, and prothioconazole-deschloro) variously produce pre-natal developmental effects at levels equal to or below maternally toxic levels. Prothioconazole-desthio is the most toxic orally and dermally, with LOAELs significantly below that of the other chemicals. The rabbit is the more sensitive species. Lastly, prothioconazole-desthio is a developmental neurotoxicant, producing changes in brain morphometrics and increases in the occurrence of peripheral nerve lesions in the neonate. A NOAEL was not determined, since these observations were looked for only at the high dose level. Reproduction studies in the rat, conducted using prothioconazole and prothioconazole-desthio, suggested that these chemicals may not be primary reproductive toxicants. Reproductive and offspring toxicities were observed only in the presence of parental toxicity. Indeed, the parental LOAELs are lower. The data show that prothioconazole-desthio is more toxic by an order of magnitude. The nature of parental toxicity is similar to what was observed in the subchronic studies, such as body weight and food consumption changes, liver effects, etc. Reproductive effects included decreases in reproductive indices such as those that indicate pup survival and growth. Offspring toxicity was manifested by decreased pup weights and malformations such as cleft palate.

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*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as ''Prothioconazole: Human Health Risk Assessment for Proposed Uses on Soybeans and Sugarbeets'' in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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 the document ''Prothioconazole: Human Health Risk Assessment for Proposed Uses on Soybeans and Sugarbeets'' at page 24 in docket ID number EPA–HQ–OPP–2007–0178.

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). As to residue levels in food, EPA relied

upon average residues and 100% percent crop treated (PCT) information.

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 relied upon anticipated residues, and 100% percent crop treated (PCT) information for all commodities.

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 be Carcinogenic to Humans'' according to the 2005 Cancer Guidelines. Consequently, a quantitative dietary cancer assessment was not performed.

iv. *Anticipated residue 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 pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for prothioconazole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 model. For acute dietary risk assessment, the water concentration value of 29 ppb was used to assess the contribution from drinking water. For chronic dietary risk assessment, the water concentration of value 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 from groundwater are 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 on any sites 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. Although conazoles 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 (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Prothioconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite, 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Available evidence from rat developmental toxicity studies with prothioconazole (oral) and its desthio (oral and dermal) and sulfonic acid K salt (oral) metabolites, rabbit developmental with desthio metabolite (oral), and rat developmental neurotoxicity with desthio metabolite (oral), as well as a multi-generation reproduction study with the desthio metabolite, indicates that there is concern for prenatal toxicity. Effects include skeletal structural abnormalities, such as cleft palate, deviated snout, malocclusion, and extra ribs; developmental delays; other effects include changes in brain morphometry, peripheral nerve lesions, and death.

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. Data from the developmental neurotoxicity study also show that brain morphometry is abnormal postnatally, and there is an increased incidence of lesions of the peripheral nerves postnatally.

3. *Conclusion*. The toxicity database for prothioconazole (and its metabolites) is adequate for endpoint selection for exposure risk assessment scenarios and for FQPA evaluation, with the exception of the lack of data on brain morphometry at the lower and mid doses from the developmental neurotoxicity study. Data on brain morphometry at these doses have now been submitted and is currently in review.

Effects are seen in the 2-generation reproduction studies in rats; developmental studies in rats and rabbits; and a developmental neurotoxicity study in rats which suggest that pups are more susceptible: Pup effects were seen at levels below the LOAELs for maternal toxicity and, in general, were of comparable or greater severity compared to the effects observed in adults. Additionally, there is uncertainty concerning the LOAEL/NOAEL for developmental effects seen in the developmental neurotoxicity study in rats (abnormal brain morphometry at high dose) due to a lack of information on brain morphometry at lower doses. Given that both quantitative and qualitative sensitivity was observed in pups in several studies and in more than one species and in at least one of these studies there is uncertainty concerning identification of the LOAEL/NOAEL for developmental effects, the additional 10X factor for the protection of infants and children is being retained.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC 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 prothioconazole will occupy 76% of the aPAD for the population group (females 13 years and older).

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to prothioconazole from food and water will utilize 94% of the cPAD for the population group (infants less than 1 year old). There are no residential uses for prothioconazole that result in chronic residential exposure to prothioconazole.

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

Prothioconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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

Prothioconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *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 mass spectrometry (LC/MS/MS) for both plant and livestock commodities, using tandem 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. 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

There are no maximum residue limits (MRLs) (tolerances) established for prothioconazole in Codex or in Mexico.

V. Conclusion

Therefore, tolerances are established 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 the following commodities: soybean, forage at 4.5 ppm; soybean, seed at 0.15 ppm; soybean, hay at 17 ppm; sugar beet, roots at 0.25 ppm. A tolerance is not needed for sugar beet tops because it is not a human food commodity.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 6, 2000) do not apply to this rule. In addition, This 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 10, 2008.

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 adding alphabetically entries to the table in paragraph (a)(1) to read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, roots	0.25
* * * * *	
Soybean, forage	4.5
Soybean, hay	17
Soybean, seed	0.15
* * * * *	

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[FR Doc. E8–5290 Filed 3–18–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–8543–9; EPA–HQ–SFUND–2007–0685, EPA–HQ–SFUND–2007–0686, EPA–HQ–SFUND–2007–0687, EPA–HQ–SFUND–2007–0688, EPA–HQ–SFUND–2007–0689, EPA–HQ–SFUND–2006–0242, EPA–HQ–SFUND–2007–0691, EPA–HQ–SFUND–2007–0692, EPA–HQ–SFUND–2007–0693, EPA–HQ–SFUND–2007–0694, EPA–HQ–SFUND–2007–0695, EPA–HQ–SFUND–2007–0696]

RIN 2050–AD75

National Priorities List, Final Rule

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the Agency'') in determining which sites warrant further investigation. These further investigations will allow EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds 12 sites to the General Superfund Section of the NPL.

DATES: *Effective Date:* The effective date for this amendment to the NCP is April 18, 2008.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, ''Availability of Information to the Public'' in the **SUPPLEMENTARY INFORMATION** portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone: (703) 603–8852, e-mail: *jeng.terry@epa.gov*, State, Tribal and Site Identification Branch; Assessment and Remediation Division; Office of Superfund Remediation and Technology Innovation (mail code 5204P); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue, NW.; Washington, DC 20460; or the Superfund Hotline, phone (800) 424–