understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, and Department of Homeland Security Management Directive 5100.1, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (32)(e), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); § 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. Revise § 117.323 to read as follows:

§ 117.323 Outer Clam Bay

The drawspan of the Outer Clam Bay Boardwalk Drawbridge shall open on signal if at least 30 minutes advance notice is given.

Dated: March 2, 2007.

D.W. Kunkel,

Rear Admiral, U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. E7–4590 Filed 3–13–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0312; FRL–8113–6]

Prothioconazole; Pesticide Tolerance

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 barley, grain/hay/straw; grain, aspirated grain fractions; pea and bean, dried shelled, except soybeans, subgroup 6C; peanut; peanut hay; rapeseed, seed; wheat, grain/forage/hay/straw; and for combined residues of prothioconazole, prothioconazole-desthio and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent in or on cattle, meat/meat byproducts/fat/milk; poultry, liver; goat, fat/meat/meat byproducts; hog, meat byproducts; horse, fat/meat/meat byproducts; sheep, fat/meat/meat byproducts. Bayer CropScience requested tolerances 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 14, 2007. Objections and requests for hearings must be received on or before May 14, 2007, 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–2005–0312. 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: Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9443; e-mail address: *kish.tony@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:

- 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 provides 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 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, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2005–0312 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 on or before May 14, 2007.

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 your copies, identified by docket ID number EPA–HQ–OPP–2005–0312, 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. Background and Statutory Findings

In the **Federal Register** of November 30, 2005 (70 FR 71831) (FRL–7747–6), 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 4F6830) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for 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, in or on barley, grain at 0.2 parts per million (ppm); barley, hay at 7.0 ppm; barley, straw at 2.0 ppm; barley, pearled at 0.2 ppm; barley, bran at 0.4 ppm; black mustard, seed at

0.1 ppm; borage, seed at 0.1 ppm; canola, seed at 0.1 ppm; crambe, seed at 0.1 ppm; field mustard, seed at 0.1 ppm; flax, seed at 0.1 ppm; grain, aspirated fractions at 13.0 ppm; Indian mustard, seed at 0.1 ppm; Indian rapeseed 0.1 ppm; pea and bean, dried shelled (except soybeans) at 0.8; peanut, nutmeat at 0.02 ppm; peanut, hay at 5.0 ppm; peanut, meal at 0.3 ppm; rapeseed, seed at 0.1 ppm; rice, grain at 0.25 ppm; rice, straw at 1.5 ppm; rice, hulls at 1.0 ppm; wheat, grain at 0.06 ppm; wheat, bran at 1.5 ppm; wheat, forage at 7.0 ppm; wheat, germ at 0.15 ppm; wheat, hay at 4.0 ppm; wheat, straw at 2.3 ppm and for combined residues of prothioconazole, its desthio and 4-hydroxy metabolites, and conjugates of each in cattle, meat at 0.01 ppm; cattle, meat byproducts at 1.2 ppm; cattle, fat at 0.1 ppm; and milk at 0.006 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

For the reasons stated in Unit V., EPA is not establishing at this time the following petitioned-for tolerances: Rice; black mustard; borage; flax; Indian mustard; barley, pearled barley; barley, bran; canola; crambe; field mustard; Indian rapeseed; peanut, meal; wheat, bran; and wheat, germ.

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/oppfead1/trac/science*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of prothioconazole and prothioconazole-desthio, calculated as parent in or on barley, grain at 0.35 ppm; barley, hay at 7.0 ppm; barley, straw at 4.0 ppm; grain, aspirated grain fractions at 11.0 ppm; pea and bean, dried shelled, except soybeans, subgroup 6C at 0.9; peanut at 0.02 ppm; peanut, hay at 6.0 ppm; rapeseed, seed at 0.15 ppm; wheat, grain at 0.07 ppm; wheat, forage at 6.0 ppm; wheat, hay at 4.5 ppm; wheat, straw at 5.0 ppm and for combined residues of prothioconazole, prothioconazole-desthio, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent in or on cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.2 ppm; cattle, fat at 0.1 ppm; goat, fat at 0.1 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.2 ppm; hog, meat byproducts at 0.05 ppm; horse, fat at 0.1 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.2 ppm; milk at 0.02 ppm; poultry, liver at 0.02 ppm; sheep, fat at 0.1 ppm; sheep, meat at 0.02 ppm and sheep, meat byproducts at 0.2 ppm.

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. Specific information on the studies received and the nature of the toxic 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*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, and estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at:

1. *http://www.epa.gov/oppfead1/trac/science*.

2. *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

3. *http://www.epa.gov/pesticides/trac/science/aggregate/pdf*.

Both prothioconazole and prothioconazole-desthio have low acute toxicities by oral, dermal, and inhalation routes. Neither compound is a dermal sensitizer, nor a skin or eye irritant.

Subchronic toxicity studies show that the target organs at the LOAEL include the liver, kidney, urinary bladder, thyroid, and blood. NOAEL/LOAEL values across the family of chemicals (i.e., prothioconazole, and metabolites prothioconazole-desthio, and prothioconazole sulfonic acid potassium salt) in the toxicity database indicate that prothioconazole-desthio is a more toxic chemical.

The profile of chronic toxicity is similar to that of subchronic toxicity, and also includes body weight and food consumption changes, and toxicity to the lymphatic and gastrointestintal (GI) systems. The relative potency of prothioconazole-desthio is greater than prothioconazole.

The data from developmental toxicity studies indicate that prothioconazole and the three metabolites evaluated (i.e., prothioconazole-desthio, prothioconazole sulfonic acid potassium salt, and prothioconazole-deschloro) variously produce prenatal developmental effects at levels equal to or below maternally toxic levels. 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. Prothioconazole-desthio is the most toxic orally or dermally, with LOAELs significantly below that of the other chemicals.

In reproduction studies in the rat, conducted using prothioconazole and prothioconazole-desthio, reproductive and offspring toxicities are observed only in the presence of parental toxicity. 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 include decreases in reproductive indices such as those that indicate pup survival and growth. Offspring toxicity is manifested by decreased pup weights and malformations such as cleft palate. The data show that prothioconazole-desthio is more toxic by an order of magnitude.

Acute and subchronic neurotoxicity studies were conducted in the rat using prothioconazole. The acute neurotoxicity study produced reduced motor and locomotor activity at a relatively high dose level, while no neurotoxicity was observed in the subchronic neurotoxicity study. As mentioned in the discussion of developmental toxicity, a developmental neurotoxicity study was conducted in the rat using prothioconazole-desthio, and neurotoxic effects were at the high dose level only were included in the report. Judging from these three neurotoxicity studies, prothioconazole-desthio is the more potent neurotoxicant, which is consistent with its relative potency in other areas of toxicity.

A battery of mutagenicity studies was conducted using both prothioconazole and its desthio metabolite. In addition, carcinogenicity studies were conducted in rats and mice using these two chemicals. The available data indicate that neither of these compounds is mutagenic or carcinogenic in the species tested, which mitigates against concern for carcinogenicity in humans.

A summary of the toxicological endpoints for prothioconazole used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PROTHIOCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Dose used in risk assessment, interspecies and intraspecies and any traditional UF	FQPA safety factor (SF) and level of concern for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age)	NOAEL = 2.0 milligram/kilogram/day (mg/kg/day) UF = 100 X acute reference dose (RfD) = 0.002 mg/kg/day	FQPA SF = 10X acute population adjusted dose (aPAD) = acute RfD/Special FQPA SF = 0.002 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 = 100 X chronic RfD = 0.001 mg/kg/day	FQPA SF = 10X chronic population adjusted dose (cPAD) = chronic RfD/FQPA SF = 0.001 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))
Cancer (Oral, dermal, inhalation)	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

Note: The toxicity endpoints for prothioconazole-desthio were used for the prothioconazole risk assessment because they were slightly more conservative than those for prothioconazole *per se*.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have not been previously established for the combined residues of prothioconazole and prothioconazole-desthio, calculated as parent, in or on a variety of raw agricultural commodities and combined residues of prothioconazole and prothioconazole-desthio and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent, in or on milk and edible animal products. Risk assessments were conducted by EPA to assess 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 conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, version 2.03), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A moderately refined acute dietary exposure assessment was conducted for prothioconazole. Empirical processing factors (PFs) and livestock maximum residues were incorporated, and 100 percent crop treated (PCT) was assumed for the acute assessment. Average residue levels were also used, since all of the plant commodities included in this assessment are blended food forms.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used DEEM-FCID™, version 2.03, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A moderately refined chronic dietary exposure

assessment was performed. Empirical PFs, average residues, and livestock maximum residues were incorporated into the chronic assessment and 100 PCT was assumed.

iii. *Cancer*. The Agency classified prothioconazole and/or its metabolites as ''Not likely to be Carcinogenic to Humans'' according to the 2005 Cancer Guidelines, based on available studies in the mouse and rat that showed no increase in tumor incidence. Accordingly, no exposure assessment is necessary for assessing cancer risk.

iv. *Anticipated residue and PCT information*. For assessment of acute dietary risk, empirical PFs and livestock maximum residues were incorporated, and 100 PCT was assumed for the acute assessment. Average residue levels were also used, since all of the plant commodities included in this assessment are blended food forms. Likewise for the assessment of chronic dietary risk, empirical PFs, average residues, and livestock maximum residues were incorporated into the chronic assessment and 100 PCT was also assumed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure 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 physical 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 Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of prothioconazole for acute exposures are estimated to be 22 parts per billion (ppb) for surface water. The EDWCs for chronic exposures are estimated to be 11 ppb for surface water. EPA used the EDWCs for surface water in assessing the risk from prothioconazole because the EWDCs for ground water 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. 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, 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 UFs) 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 SF for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, docket ID number EPA–HQ–OPP–2005–0497.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 SF value based on the use of traditional UFs and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity*—i. *Prenatal*. Available evidence from rat developmental toxicity studies with prothioconazole (oral) and its desthio (oral and dermal) and sufonic 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, indicate 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.

ii. *Postnatal*. 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 missing data on brain morphometry at lower does from the developmental neurotoxicity study. 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

To assess aggregate risk, drinking water estimates were incorporated directly into the dietary analysis, rather than using back-calculated drinking water levels of comparison (DWLOCs). To better evaluate aggregate risk associated with exposure through food and drinking water, EPA is no longer comparing EDWCs generated by water quality models with DWLOCs. Instead, EPA is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentration into our aggregate assessments relies on actual CSFII-reported drinking water consumptions and more appropriately reflects the full distribution of drinking water concentrations.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to prothioconazole will occupy 11% of the aPAD for females 13 years and older, the only population subgroup of concern. In addition, there is potential for acute dietary exposure to prothioconazole in drinking water. The acute dietary exposure from food plus water to prothioconazole will occupy 60% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to prothioconazole from food will utilize 12% of the cPAD for the U.S. population, 17% of the cPAD for all infants (< 1 year old), and 48% of the cPAD for children 1–2 years old, the subpopulation at greatest exposure. There are no residential uses for prothioconazole that result in chronic residential exposure to prothioconazole. In addition, there is potential for chronic dietary exposure to prothioconazole in drinking water. The chronic dietary exposure for food plus water will occupy 86% of the cPAD for all infants (< 1 year old). All other population subgroups are lower.

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 toxicology studies in the mouse and rat showed no increase in tumor incidence, and therefore the Agency concluded that prothioconazole or its metabolites are not carcinogenic, and 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, and to infants and children from aggregate exposure to prothioconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies high performance liquid chromatography/tandem mass spectrometry (HPLC-MS/MS) and liquid chromatography (with electrospray ionization) and tandem mass spectrometry (LC-MS/MS)) is 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

There are currently no U.S., Canadian, Mexican, or international Codex tolerances established for prothioconazole. There are no maximum residue limits (MRLs) established for prothioconazole in Codex or in Mexico. Maximum residue limits have been established in Canada as a result of this Joint Review.

C. Response to Comments

A private citizen responded to PP 4F6830. Comments were received on November 30, 2005, objecting to sale and use of this product. The comments further stated that there are not enough long-term testing, short-term testing is useless and unreliable and that research is not exhaustive enough to support use.

The Agency response is as follows: The Agency considers the database for prothioconazole to be complete and adequate for exposure risk assessment, including several long-term studies. The commenter submitted no scientific information to support the claims.

These comments, as well as related comments regarding animal testing, have been responded to by the Agency on several occasions. For example, 70 FR 1349 (January 7, 2005) (FRL–7691–4) and 69 FR 63083 (October 29, 2004) (FRL–7681–9).

V. Conclusion

Therefore, tolerances are established for combined residues of prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, and prothioconazole-desthio, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol, calculated as parent in or on barley, grain at 0.35 ppm; barley, hay at 7.0 ppm; barley, straw at 4.0 ppm; grain, aspirated grain fractions at 11.0 ppm; pea and bean, dried shelled, except soybeans, subgroup 6C at 0.9; peanut at 0.02 ppm; peanut, hay at 6.0 ppm; rapeseed, seed at 0.15 ppm; wheat, grain at 0.07 ppm; wheat, forage at 6.0 ppm; wheat, hay at 4.5 ppm; wheat, straw at 5.0 ppm and for combined residues of prothioconazole, 2-[2-(1-

chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, and prothioconazole-desthio, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-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 cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.2 ppm; cattle, fat at 0.1 ppm; goat, fat at 0.1 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.2 ppm; hog, meat byproducts at 0.05 ppm; horse, fat at 0.1 ppm, horse, meat at 0.02 ppm; horse, meat byproducts at 0.2 ppm; milk at 0.02 ppm; poultry, liver at 0.02 ppm; sheep, fat at 0.1 ppm; sheep, meat at 0.2 ppm and sheet, meat byproducts at 0.2 ppm.

Using upper bound residues for water derived from the proposed use in rice, acute dietary estimates exceeded the Agency's level of concern for food plus water. Further data is needed to resolve uncertainties regarding residues of prothioconazole in rice application. Therefore, a tolerance for rice is not established at this time.

Additional crop field trial data are needed to support tolerances for black mustard, borage, flax and Indian mustard. Tolerances for these commodities are not established at this time.

Separate tolerances are not needed for barley, pearled barley; barley, bran; peanut, meal; wheat, bran; and wheat, germ. As per 40 CFR 180.1(h), the tolerance for rapeseed will cover the following commodities: Canola seed, crambe seed, field mustard seed, and Indian rapeseed.

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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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 2, 2007.

James Jones,

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 ollows:

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

■ 2. Section 180.626 is added to subpart C to read as follows:

§ 180.626 Prothioconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established 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, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol, calculated as parent in or on the following commodities:

Commodity	Parts per million
Barley, grain	0.35
Barley, hay	7.0
Barley, straw	4.0
Grain, aspirated grain fractions	11
Pea and bean, dried shelled, except soybean, subgroup 6C	0.9
Peanut	0.02
Peanut, hay	6.0
Rapeseed, seed	0.15
Wheat, forage	6.0
Wheat, grain	0.07
Wheat, hay	4.5
Wheat, straw	5.0

(2) Tolerances are established 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, α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-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 following commodities:

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.02
Cattle, meat byproducts	0.2
Goat, fat	0.1
Goat, meat	0.02
Goat, meat byproducts	0.2
Hog, meat byproducts	0.05
Horse, fat	0.1
Horse, meat	0.02
Horse, meat byproducts	0.2
Milk	0.02
Poultry liver	0.02
Sheep, fat	0.1
Sheep, meat	0.02
Sheep, meat byproducts	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E7–4405 Filed 3–13–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0207; FRL–8117–2]

Tribenuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tribenuron methyl in or on corn, field, forage; corn, field, grain; corn, field, stover; rice, grain; rice, straw; sorghum, forage; sorghum, grain, grain; sorghum, grain, stover; soybean, seed; and sunflower, seed. E.I. DuPont de Nemours and Company, Inc. requested these tolerances 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 14, 2007. Objections and requests for hearings must be received on or before May 14, 2007, 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–2006–0207. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-7504; e-mail address: *walters.vickie@epa.gov*.

SUPPLEMENTARY INFORMATION: