during the consolidation process, and the new consolidated regulation does not affect the general public. Similar requirements concerning the use of off-road vehicles on Army land are now provided by 32 CFR 650, Environmental Protection and Enhancement (AR 200–1) and 32 CFR 651, Environmental Analysis Of Army Actions (AR 200–2) which when taken into combination provided greater and wider protection on installation than did 32 CFR Part 656 or AR 385–55.

List of Subjects in 32 CFR Part 656

Environmental protection, Federal buildings and facilities, Traffic regulations.

PART 656—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority 10 U.S.C. 3012, 32 CFR Part 656, Installations, Use of Off-Road Vehicles on Army Land, is removed in its entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–9599 Filed 12–8–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0654; FRL–8093–4]

Cyproconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of cyproconazole ((2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H -1,2,4- triazole-1-yl)butan-2-ol) in or on soybean seed. This action is associated with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of cyproconazole in this food commodity. The tolerance will expire and be revoked on December 31, 2009.

DATES: This regulation is effective December 8, 2006. Objections and requests for hearings must be received on or before February 6, 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–2006–0654. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive Arlington, VA 22202–3553. The hours of operation of this Docket Facility are 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: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax: (703) 308–8041; e-mail address: *rodia.carmen@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather 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 the FFDCA, as amended by the 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–2006–0654 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 February 6, 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–2006–0654, 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 Avenue, NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA 22202–3553. 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and 346a(l)(6), is establishing a tolerance for residues of the fungicide cyproconazole, in or on soybean seed at 0.10 parts per million (ppm). This tolerance will expire and be revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of the section 408 safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Cyproconazole on Soybeans and FFDCA Tolerances

Australasian soybean rust (SBR) is a plant disease caused by two fungal species, *Phakopsora pachyrhizi* and *P. meibomiae*, and is spread primarily by windborne spores that can be transported over long distances. SBR models suggest that most of the soybean acreage in the U.S. could be compromised by an SBR epidemic. In accordance with the 2002 Agricultural Bioterrorism Protection Act, SBR was identified by USDA as a select biological agent with the potential to pose a severe threat to the soybean industry and livestock production, in general. As such, USDA has invested in extensive readiness and outreach activities among soybean producers. The states of Minnesota and South Dakota petitioned EPA to allow under FIFRA section 18, the use of cyproconazole on soybeans for control of Australasian soybean rust in Minnesota and South Dakota. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cyproconazole in or on soybeans. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance expires and is revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybean seed after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether cyproconazole meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of cyproconazole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for growers in any State other than those in which State lead agencies have obtained an exemption to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cyproconazole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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 the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of the 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 cyproconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of cyproconazole in or on soybean seed at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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 endpoint. 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. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences), the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyproconazole used for human risk assessment is shown in the following Table:

SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYPROCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (U.S. general population including infants and children)	Not applicable	None	An endpoint of concern (effect) attributable to a single exposure (dose) for the U.S. General Population was not identified in the oral toxicity studies reviewed.
Acute Dietary (Females 13-49 years of age)	LOAEL = 2.0 mg/kg/day UF = 300 Acute RfD = 2.0 mg/kg/day/300 = 0.01 mg/kg/day	FQPA SF = 1x aPAD = acute RfD ÷ FQPA SF = 0.01 mg/kg/day	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Chronic Dietary (All populations)	NOAEL = 1.0 mg/kg/day UF = 100 Chronic RfD = 1.0 mg/kg/day/100 = 0.01 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD÷FQPA SF = 0.01 mg/kg/day	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Short-Term Incidental Oral (1 to 30 days) Intermediate-Term Incidental Oral (1 to 6 months)	NOAEL = 1.5 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day oral toxicity - rat; LOAEL = 27.3 mg/kg/day based on decreased body weight gain in males and increased liver weight in females.
Short-Term Dermal (1 to 30 days) Intermediate-Term Dermal (1 to 6 months)	NOAEL = 2.0 mg/kg/day (dermal absorption rate = 11%)	Residential LOC for MOE = 300 Occupational LOC for MOE = 300	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Long-Term Dermal (>6 months)	NOAEL = 1.0 mg/kg/day (dermal absorption rate = 11%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Short-Term Inhalation (1 to 30 days) Intermediate-Term Inhalation (1 to 6 months)	NOAEL = 2.0 mg/kg/day (inhalation-absorption rate = 100% oral equivalent)	Residential LOC for MOE = 300 Occupational LOC for MOE = 300	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Long-Term Inhalation (>6 months)	NOAEL = 1.0 mg/kg/day (inhalation-absorption rate = 100% oral equivalent)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Cancer (oral, dermal, inhalation)	Cyproconazole has been classified as a Group B2, probable human carcinogen; Q1* is 1.58 x 10^{-1} $(mg/kg/day)^{-1}$ in human equivalents, based on male mouse liver adenoma and/or carcinoma combined tumor rates.		

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

UF = uncertainty factor; FQPA SF = Special FQPA safety factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (a = acute, c = chronic); RfD = reference dose; MOE = margin of exposure; and LOC = level of concern.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* A tolerance has been established (40 CFR 180.485) for residues of cyproconazole in or on the imported agricultural commodity coffee, bean, green. There are no U.S. registrations for cyproconazole on raw agricultural commodities at this time. Risk assessments were conducted by EPA to assess dietary exposures from cyproconazole in food as follows:

i. *Acute exposure*. Acute dietary 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 one day or single exposure. The Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute dietary exposure analysis for cyproconazole is based on Tier 1 assumptions of tolerance-level residues and 100% crop treated (CT).

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment, the DEEM-FCID™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic dietary exposure analysis for cyproconazole is refined in that it incorporates estimates of anticipated residues (AR) for all commodities, 10% CT for soybeans and empirical processing factors (a Tier 3 analysis).

iii. *Cancer*. The Q1* for cyproconazole is 1.58×10^{-1} milligrams/kilograms/day (mg/kg/day) in human equivalents, based on liver tumor data in male mice. The 10% CT (i.e., 7.4 million acres) resulted in an acceptable calculated dietary cancer risk of 1.1×10^{-6}, which is equivalent to the Agency's LOC (generally 1×10^{-6}).

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must, pursuant to 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information for cyproconazole as follows: As stated in Unit IV.B.1. acute and chronic dietary exposure and risk analyses were conducted to determine the exposure and risk estimates resulting from the use of cyproconazole in soybeans to control Australasian soybean rust. The acute analysis is based on Tier 1 assumptions of tolerance-level residues and 100% CT. The chronic analysis is refined in that it incorporates estimates of AR for all commodities, 10% CT for soybeans and empirical processing factors (a Tier 3 analysis).

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described in Unit IV.B.1. and in the preceding paragraph for cyproconazole used on soybeans is reliable and has a valid basis. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyproconazole may be applied in a particular area.

2.—i. *Dietary exposure from drinking water*. The Agency used the Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM/EXAMS) to calculate estimated drinking water concentrations (EDWCs) for the use of cyproconazole in soybeans, using the standard Mississippi soybean scenario. Thus, the estimated exposure concentrations for water are based on the proposed highest use rate. The Agency used the Generic Expected Environmental Concentration model to calculate estimated environmental concentrations (EECs) for the use of cyproconazole in turf. Ground water concentrations were estimated with the Screening Concentration in Groundwater (SCI-GROW) model.

ii. *Ground water and surface water EDWCs*. A Tier 2 drinking water assessment was conducted for the proposed use of cyproconazole in soybeans using the proposed maximum application rate of 0.026 lbs. a.i./acre with 2 applications per year and a 7–day Retreatment interval (RTI). The Preharvest interval (PHI) will be 30 days. The linked PRZM and EXAMS models predicted a peak EDWC of 0.79 parts per billion (ppb) for aerial applications. The PRZM/EXAMS model predicted chronic EDWCs of 0.21 ppb (1-in-10 Year Annual Average) for aerial applications and 0.12 ppb (30–year Annual Average) for ground applications. The SCI-GROW model estimated the concentration of cyproconazole in shallow ground water sources to be 0.027 ppb.

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). Cyproconazole 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 the 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.''

Cyproconazole 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 form substances found to have a common mechanism of toxicity see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

Cyproconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including cyproconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with the common metabolites (e.g., use of maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e, high end estimates of both dietary and non-dietary exposures). 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 population 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–2005–0497–0013.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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/or postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines 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.

2. *Developmental toxicity studies*. There is no evidence of increased susceptibility in either the developmental study in rats or in the 2–generation reproduction study in rats. The concern is low for the increased susceptibility in the New Zealand rabbit study since clear NOAELs/LOAELs were established for maternal and developmental toxicities. Similarly, the concern is low for the increased susceptibility in the Chinchilla rabbit study since the incidences of hydrocephaly were low, there was no dose response, the hydrocephaly was not seen at the same doses in the New Zealand White strain of rabbit and this endpoint of concern is used with a 3x FQPA safety factor for risk assessment.

A 3x safety factor (as opposed to a 10x) for the lack of a NOAEL in this critical study is adequate because the magnitude of the response was low (low incidences without dose response) and the effect of concern was seen in an unusual strain (Chinchilla) of rabbits and not in the New Zealand strain commonly used in developmental toxicity studies. The Agency evaluated the quality of the hazard and exposure data for cyproconazole and determined that the FQPA safety factor can be reduced to 1x. Therefore, there is no residual uncertainty for prenatal and/or postnatal exposure to cyproconazole.

3. *Reproductive toxicity study*. There was no evidence of reproductive toxicity in the 2–generation reproduction study in rats. In this study, cyproconazole was administered to rats at dose levels of 0, 0.4, 1.7 and 10.6 mg/kg/day. The parental systemic NOAEL is 1.7 mg/kg/day and LOAEL of 10.6 mg/kg/day, based on liver effects. The reproductive toxicity NOAEL is 10.6 mg/kg/day. Although gestation length was slightly increased and litter size decreased, these changes were not considered to be treatment-related.

4. *Prenatal and postnatal sensitivity*. Please refer to the explanation provided above in Unit IV.C.2. for a detailed discussion regarding ''prenatal and/or postnatal sensitivity.''

5. *Conclusion*. The Agency evaluated the quality of the hazard and exposure data and determined that, based on the hazard and exposure data, the special FQPA SF is reduced to 1x. In terms of hazard, there are low concerns and no residual uncertainties with regard to prenatal and/or postnatal toxicity.

D. Aggregate Risks and Determination of Safety

EPA conducted human health risk assessments for acute, chronic and cancer dietary exposures (food + drinking water only) for existing and proposed uses. Because there are no uses of cyproconazole that are expected to result in residential exposures, this aggregate risk assessment takes into consideration dietary food + drinking water exposure only; therefore, the acute and chronic aggregate estimates would be the same as the dietary exposure results.

1. *Acute risk*. Using the exposure assumptions discussed in this unit, the acute dietary exposure from food to cyproconazole will occupy 1.3% of the aPAD for females 13-49 years old. Given existing and proposed uses, the Agency has no risk concern for exposure to cyproconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyproconazole from

food will utilize 1% of the cPAD for all infants less than a year old. There are no residential uses for cyproconazole that will result in chronic residential exposure to cyproconazole. Given existing and proposed uses, the Agency has no risk concern for exposure to cyproconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Cyproconazole 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 drinking water, which were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Cyproconazole 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 drinking water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. When relying on the exposure assumptions described in this notice, EPA calculated an acceptable cancer risk of 1.1 x 10^{-6}, which is equivalent to the Agency's LOC (generally 1.0 x 10^{-6}).

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

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No CODEX, Canadian or Mexican MRLs or tolerances have been established for cyproconazole on soybeans. Therefore, international harmonization is not an issue at this time.

C. Conditions

EPA has concluded that the toxicological, residue chemistry, dietary exposure and occupational/residential exposure assessments are adequate to support a time-limited tolerance of 0.10 ppm for residues of cyproconazole per se in/on soybean, seed.

VI. Conclusion

Therefore, the tolerance is established for residues of cyproconazole per se, in or on soybean, seed at 0.10 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the 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 the 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.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 24, 2006.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—AMENDED

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

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

■ 2. Section 180.485 is amended by adding text and table to paragraph (b) to read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide cyproconazole per se ((2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H -1,2,4- triazole-1-yl)butan-2-ol) in or on soybean seed in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance will expire and be revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Soybean, seed	0.10	12/31/09

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2005–0033; FRL–8103–2]

RIN 2070–AD16

Revocation of TSCA Section 4 Testing Requirements for Coke-Oven Light Oil (Coal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is amending the test rule entitled Testing of Certain High Production Volume Chemicals promulgated under section 4 of the Toxic Substances Control Act (TSCA). This amendment removes coke-oven light oil (coal) (CAS No. 65996–78–3) from the list of chemicals subject to the test rule. EPA is basing its decision on information it received after publication of the test rule. Also, upon the effective date of the revocation of the TSCA section 4 testing requirements for coke–oven light oil (coal), persons who export or intend to export coke–oven light oil (coal) are no longer subject to the TSCA section 12(b) export notification requirements to the extent that they were triggered by the testing requirements being revoked by this action.

DATES: This direct final rule is effective on February 6, 2007 without further notice, unless EPA receives adverse comment in writing, or a request to present comments orally, by January 8, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2005–0033, by one of the following methods:

Federal eRulemaking Portal: *http://www.regulation.gov*. Follow the on-line instructions for submitting comments.

Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

Hand Delivery: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2005–0033. The DCO is open from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2005–0033. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/docket.htm*.

Docket: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket, EPA Docket Center (EPA/DC). The EPA/DC suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Room Number 3334) in EPA West, located at 1301 Constitution Ave., NW., Washington,