Commodity	Parts per million
Vegetable, brassica, leafy greens, subgroup 5B	12
Vegetable, cucurbit, group 9	0.10
Vegetable, fruiting, group 8	0.30
Vegetable, leafy greens, subgroup 4A	12
Vegetable, tuberous and corm, subgroup 1C	0.02

(2) Tolerances are established for the combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), and its metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties, calculated as the parent compound equivalents in the following livestock commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat byproducts	0.05
Goat, fat	0.05
Goat, meat byproducts	0.05
Horse, fat	0.05
Horse, meat byproducts	0.05
Milk, fat	0.10
Sheep, fat	0.05
Sheep, meat byproducts	0.05

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for the inadvertent or indirect combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1- oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in the following rotational crop commodities:

Commodity	Parts per million
Alfalfa, forage	1.5
Alfalfa, hay	3.0
Barley, grain	0.03
Barley, hay	0.25
Barley, straw	0.15
Beet, sugar, roots	0.03
Beet, sugar, tops	0.20
Wheat, forage	0.20
Wheat, grain	0.03
Wheat, hay	0.15
Wheat, straw	0.25

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0196; FRL–7727–1]

Propiconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propiconazole 1-[[2-2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent in or on soybean, soybean forage, and soybean hay. This action is in response to 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 maximum permissible levels for residues of propiconazole in these food commodities. The tolerances will expire and are revoked on December 31, 2009.

DATES: This regulation is effective July 27, 2005. Objections and requests for hearings must be received on or before September 26, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0196. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703) 308–9367; e-mail address: *Sec-18-Mailbox@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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

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, is establishing a tolerance for combined residues of the fungicide propiconazole 1-[[2-2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-

dichlorobenzoic acid and expressed as parent, in or on soybean at 2.0 parts per million (ppm); soybean, forage at 10 ppm; and soybean, hay at 25 ppm. These tolerances will expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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 section 408 of the FFDCA and the new 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.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Propiconazole on Soybeans and FFDCA Tolerances

The States of Minnesota and South Dakota, as lead state agencies in what is essentially a national section 18 request for all soybean growing states, have petitioned the Agency requesting an Emergency Exemption for propiconazole to control soybean rust under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). On November 10, 2004, U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) confirmed the presence of *Phakopsora pachyrhizi*, the pathogen that causes soybean rust, on soybean leaf samples taken from two plots associated with a Louisiana State University research farm. Soybean rust has been designated as a biosecurity threat and therefore it is important that control measures be available for the disease. EPA has authorized under FIFRA section 18 the use of propiconazole on soybeans for control of soybean rust in Minnesota, South Dakota, and all the other states that have requested an exemption for this use. 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 propiconazole in or on soybean, soybean forage, and soybean hay. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances 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 safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are 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 tolerances remaining in or on soybean, soybean forage, and soybean hay 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 were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether propiconazole meets EPA's registration requirements for use on soybeans or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of propiconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than those which have been granted exemptions as part of the soybean rust section 18 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 propiconazole, 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 the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 propiconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of propiconazole 1-[[2-2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent in or on soybean at 2.0 ppm; soybean forage at 10 ppm; and soybean hay at 25 ppm.

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 $x10^{-6}$ 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 propiconazole used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PROPICONAZOLE 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 (Females 13-50)	NOAEL = 30 mg/kg/day UF =300 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1X aPAD =acute RfD = 0.1 mg/kg/day	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity manifested by increased incidence of rudimentary ribs, cleft palate malformations (0.3%) unossified sternebrae, as well as increased incidence of shortened and absent renal papillae.
Acute Dietary (General Population)	NOAEL = 90 mg/kg/day UF =300 Acute RfD = 0.3 mg/kg/day	FQPA SF = 1X aPAD =acute RfD = 0.3 mg/kg/day	Developmental Toxicity Study - Rats. LOAEL = 300 mg/kg/day based on developmental toxicity manifested by severe maternal toxicity: ataxia, coma, lethargy, prostration, audible and labored respiration, salivation and lacrimation
Chronic Dietary (All populations)	NOAEL= 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1X cPAD =chronic RfD = 0.1 mg/kg/day	24 Month Oncogenicity Study - Mice. LOAEL = 50 mg/kg/day based on liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/ swellings/ nodular areas mainly)
Short Term (1-30 days) Incidental Oral	Maternal NOAEL = 90 mg ai/kg/day	Residential MOE =300	Developmental Toxicity Study - Rats. LOAEL = 360 mg/kg/day based on severe clinical signs
Short Term (1-30 days) Dermal (Females 13-50 years old)	Oral Developmental NOAEL = 30 mg ai/kg/dayDermal absorption rate1 = 1%	Residential MOE = 300	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity: increased incidence of rudimentary ribs, unossified sternebrae, and shortened and absent renal papillae.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short Term (1-30 days) Dermal (General Populations, including infants and children)	Oral Maternal NOAEL = 90 mg ai/kg/dayDermal absorption rate1 = 1%)	Residential MOE = 300	Developmental Toxicity Study - Rats. LOAEL = 300 mg/kg/day based on severe maternal clin-ical toxicity (ataxia, coma, lethargy, prostration, audible and labored respiration, salivation and lacrimation)
Short Term (1-30 Days) Inhalation	Oral Developmental NOAEL = 30 mg/kg/day(Inhalation absorption rate = 100%)	Residential MOE = 300	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity manifested by increased incidence of rudimentary ribs, unossified sternebrae, as well as increased incidence of shortened and absent renal papillae.
Cancer	Group C - possible human carcinogen, non-quantifiable		

B. Exposure Assessment

1. *Dietary exposure from food and drinking water.* Tolerances are established for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in/on various plant and animal commodities. The established permanent tolerances for plant and animal commodities range from 0.05 ppm (milk) to 40 ppm (grass hay). Time-limited tolerances are established for cranberry, dry bean forage, dry bean hay, and dry beans. In addition, time-limited tolerances are established for aspirated grain fractions (20 ppm), sorghum grain, and stover. Tolerances with regional registration are also established for mint at 0.3 ppm and wild rice at 0.5 ppm. No tolerances are established for rotational crops.

In conducting the acute and chronic dietary risk assessments, EPA used the Dietary Exposure Evaluation Model (DEEM^{T}) software. Modeled estimates of drinking water concentrations were directly entered into the exposure model to assess the contribution from drinking water. Risk assessments were conducted by EPA to assess dietary exposures from [propiconazole] 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™) 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 following assumptions were made for the acute exposure assessments: A Tier I assessment was conducted using tolerance-level residues, 100% crop treated (CT) information for all commodities, and default processing factors from DEEM were used for processed commodities when available. EPA estimated exposure based on the 95th percentile value in this Tier I assessment. Aggregate acute food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the acute water concentration (264 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

ii. *Chronic exposure.* The chronic dietary exposure assessment also used tolerance level residues and the chronic analysis module of the DEEM-FCID™ software. As with the acute assessment, default DEEM processing factors were used, and no adjustments were made for percent crop treated. Aggregate chronic food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the chronic water concentration (80 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

iii. *Cancer.* Propiconazole has been classified as a Group C possible human carcinogen, non-quantifiable. Consequently, the standard chronic dietary exposure analysis (as discussed above) and risk assessment using the cPAD serves as the assessment for cancer.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for propiconazole 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 propiconazole.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will generally use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index

reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of propiconazole for acute exposures are estimated to be 264 parts per billion (ppb) for surface water and 1.5 ppb for ground water. The EECs for chronic exposures are estimated to be 80 ppb for surface water and 1.5 ppb for ground 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).

Propiconazole is a fungicide that can be used to control turfgrass diseases on residential lawns, sod farms and golf courses. There is potential, therefore, for dermal exposures to propiconazole residues on treated turf. The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of propiconazole (food and drinking water) and non-occupational exposures (turf). Postapplication exposures from the use on turf is considered short-term. Therefore, a short-term aggregate risk assessment was conducted, using children with combined dermal and oral exposures from the turf use as a worst case.

The assessment is considered conservative because it assumes reentry immediately after the application of propiconazole at the highest recommended rate of 1.79 pounds ai per acre and that it was estimated that all of the propiconazole available for the consumer market is applied to lawns. Therefore, aggregate exposure is considered to be an overestimate of potential exposure and risk.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to propiconazole and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propiconazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/.*

However, the Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid, metabolites common to most of the triazole fungicides. To support the extension of existing parent triazole-derivative fungicide tolerances, EPA conducted an interim human health assessment for aggregate exposure to 1,2,4-triazole. The exposure and risk estimates presented in this assessment are overestimates of actual likely exposures and therefore, should be considered to be highly conservative. Based on this assessment EPA concluded that for all exposure durations and population subgroups, aggregate exposures to 1,2,4-triazole are not expected to exceed EPA's level of concern. This assessment is presented in the final rule published in the **Federal Register** on April 22, 2005 (70 FR 20821) (FRL–7702–4) for another triazole fungicide, tetraconazole. This assessment should be considered interim due to the ongoing series of studies being conducted by the U.S. Triazole Task Force (USTTF). Those studies are designed to provide the Agency with more complete toxicological and residue information for free triazole. Upon completion of the review of these data, EPA will prepare a more sophisticated assessment based on the revised toxicological and exposure databases.

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 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. *Prenatal and postnatal sensitivity.* The pre-natal and post-natal toxicology database for propiconazole is complete with respect to current FQPA-relevant toxicological data requirements. Propiconazole is not developmentally toxic in the rabbit. There is evidence that propiconazole is developmentally toxic in the rat. As noted in the developmental toxicity study in rats, quantitative susceptibility was evidenced by increased incidence of rudimentary ribs, unossified sternebrae, as well as increased incidence of shortened and absent renal papillae and increased cleft palate at 90 mg/kg/day, a dose lower than that evoking maternal toxicity (severe clinical toxicity at 300 mg/kg/day).

Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for propiconazole, the Agency characterized the degree of concern for the effects observed in this study as low, noting that there is a clear NOAEL and well-characterized dose response for the developmental effects observed. No residual uncertainties were identified, and no special FQPA safety factor is needed. Although there is no evidence of neurotoxicity, neuropathology, or abnormalities in the development of the fetal nervous system based on available data, neurotoxic effects (ataxia, lethargy, salivation, rales) were noted in pregnant rats administered high doses (360 mg/kg/ day) during the gestation period. Therefore, the Agency has determined that an acute neurotoxicity study is required, and that the need for a developmental neurotoxicity study will be reconsidered upon review of the acute neurotoxicity study.

The Agency has determined that for acute (single dose) and short-term exposure scenarios a 3X database uncertainty factor is adequate to account for the lack of the acute neurotoxicity study based on the following considerations:

i. It is assumed that an acute neurotoxicity study will be conducted at dose levels similar to those used in the rat developmental study wherein neurotoxic effects including ataxia, lethargy, salivation, and rales were observed in pregnant rats at 360 mg/kg/day (the highest dose tested for the first 5 days of dosing in the study). The

NOAEL for the observed neurotoxic effects was 300 mg/kg/day.

ii. The results of the acute neurotoxicity study are not expected to impact the current acute RfD (or endpoints selected for short-term exposure scenarios) by more than 3X since the NOAELs used for the these risk assessment endpoints (e.g., 90 mg/kg/day for acute RfD for the general populations and 30 mg/kg/day for acute females 13- 50 and short-term incidental oral, dermal, and inhalation) are already 3 to 10-fold lower than the NOAEL for neurotoxic effects in the developmental rate study conducted with propiconazole (300 mg/kg/day).

3. *Conclusion*. Although EPA has required that an acute neurotoxicity study be submitted on propiconazole, EPA has concluded that a 3X (acute) and a 1X (chronic) additional safety factor will be sufficient to protect infants and children given the results seen in the existing data bearing on neurotoxicity. This FQPA safety factor of 3X will be applied in the form of a database uncertainty factor and thus used in deriving the aRfD.

D. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated environmental concentrations (EECs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to propiconazole in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of propiconazole on drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. Combining screening level estimates of pesticide residues in drinking water from drinking water models with what may be more realistic values for residues in food is not ideal. Once screening level values are combined with more realistic values it is easy to lose sight of the fact that aggregate exposure estimate is based on a mixture of very conservative and less conservative estimates. Nonetheless, this concern with mixing screening level and more realistic values is outweighed by the advantages of being able to incorporate information on actual body weights and water consumption into the aggregate exposure calculation. This risk assessment for propiconazole was conducted using this approach.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to propiconazole will occupy 7% of the aPAD for the U.S. population, 16% of the aPAD for females 13 years and older, 20% of the aPAD for all infants (<1 year old) and 11% of the aPAD for children 1-2 years old. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PROPICONAZOLE

Population Subgroup	aPAD (mg/kg)	% aPAD (food + water)
General U.S. Population	0.3	7%
All Infants (< 1 year old)	0.3	20%
Children 1-2 years old	0.3	11%
Children 3-5 years old	0.3	10%
Children 6-12 years old	0.3	7%
Youth 13-19 years old	0.3	5%
Adults 20-49 years old	0.3	5%
Adults 50+ years old	0.3	5%
Females 13-49 years old	0.1	16%

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propiconazole from food and water will utilize 5% of the cPAD for the general U.S. population, and 12% of the cPAD for all infants <1 year old (the most highly exposed subgroup). Based on the use pattern, chronic residential exposure to residues of propiconazole is not expected. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPICONAZOLE

Population Subgroup	cPAD (mg/kg/day)	% cPAD
General U.S. Population	0.1	5%
All Infants (< 1 year old)	0.1	12%
Children 1-2 years old	0.1	11%
Children 3-5 years old	0.1	9%

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPICONAZOLE—Continued

Population Subgroup	cPAD (mg/kg/day)	% cPAD
Children 6-12 years old	0.1	6%
Youth 13-19 years old	0.1	4%
Adults 20-49 years old	0.1	4%
Adults 50+ years old	0.1	4%

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPICONAZOLE—Continued

Population Subgroup	cPAD (mg/kg/day)	% cPAD
Females 13-49 years old	0.1	4%

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).

Propiconazole is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for propiconazole.

The short-term aggregate risk assessment takes into account average exposures estimates from dietary consumption of propiconazole (food and drinking water) and non-occupational uses (turf). Postapplication exposures from the use on turf is considered short-term. Therefore, a short-term aggregate risk assessment was conducted, using children with combined dermal and oral exposures from the turf use as a worst case. The MOE from food, water, and non-occupational uses is 2,000. Therefore, short-term aggregate risk does not exceed the Agency's level of concern.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PROPICONAZOLE

Population Group	NOAEL mg/kg/day	Max Exposure[1] mg/kg/day	Average Food + Water Exposure mg/kg/day	Residential Exposure[2], mg/kg/day	Aggregate MOE[3]
All Infants	90	0.3	0.011512	0.033	2,000

[1]Maximum Exposure (mg/kg/day) = NOAEL/Target MOE of 300
[2]Residential Exposure = Combined dermal and incidental oral ingestion for infants. Only infants were assessed since the represent a worst case with their higher food exposure plus incidental oral exposure to treated turf.
[3]Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]

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

There are currently no intermediate-term exposure scenarios for the use of propiconazole, therefore, quantification of intermediate-term risk is not required.

5. *Aggregate cancer risk for U.S. population.* Propiconazole has been classified as a Group C possible human carcinogen, non-quantifiable. Consequently, the standard chronic dietary exposure analysis and risk assessment using the cPAD serves as the assessment for cancer. Since carcinogenic risk for propiconazole is addressed with the cPAD, cancer risk from the proposed use on soybeans is not expected to be of concern.

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 propiconazole residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromotography) 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 no CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for propiconazole on soybeans. Therefore, there are no international harmonization issues associated with this action.

VI. Conclusion

Therefore, the tolerances are established for residues of propiconazole 1-[[2-2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent in or on soybean at 2.0 ppm; soybean forage at 10 ppm; and soybean hay at 25 ppm.

VII. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA,

you must identify docket ID number –OPP–2005–0196 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 September 26, 2005.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number –OPP–2005–0196, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances 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 tolerances 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.

IX. 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 in 40 CFR Part 180

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

Dated: July 15, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.434 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/revocation date
* * *	* *	* *
Soybean	2.0	December 31, 2009
Soybean, forage.	10.0	December 31, 2009
Soybean, hay	25	December 31, 2009

* * * * *

[FR Doc. 05–14599 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0106; FRL–7724–5]

Pymetrozine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pymetrozine in or on asparagus. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 27, 2005. Objections and requests for hearings must be received on or before September 26, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0106. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers, and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers, greenhouse, nursery, and floriculture workers; ranchers, pesticide applicators.
- Pesticide manufacturing (NAICS 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

II. Background and Statutory Findings

In the **Federal Register** of June 9, 2004 (69 FR 32346) (FRL–7360–2), 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 2E6467) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.556 be amended by establishing a tolerance for residues of the insecticide pymetrozine, [4,5-dihydro-6-methyl-4-[(E)-(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one], in or on asparagus at 0.02 parts per million (ppm). The petition was subsequently amended to establish a tolerance of 0.04 ppm. That notice included a summary of the