

underlying final rule (68 FR 32172, May 29, 2003).

### *J. 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. The EPA will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The direct final rule is not a "major rule" as defined by 5 U.S.C. 804 (2).

### List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: July 29, 2004.

**Michael O. Leavitt**,  
Administrator.

■ For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

### **PART 63—[AMENDED]**

■ 1. The authority citation for part 63 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

### **Subpart 0000—[Amended]**

■ 2. Section 63.4281 is amended by revising paragraph (d)(3) to read as follows:

#### **§ 63.4281 Am I subject to this subpart?**

\* \* \* \* \*

(d) \* \* \*

(3) Coating, slashing, dyeing, or finishing operations at a synthetic fiber manufacturing facility where the fibers are the final product of the facility.

\* \* \* \* \*

[FR Doc. 04-17778 Filed 8-3-04; 8:45 am]

**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

[OPP-2004-0086; FRL-7352-1]

### **Propiconazole; Time-Limited Pesticide Tolerances**

**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 compound in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, sweet, kernel plus cob with husks removed; peanut; peanut, hay; pineapple; and pineapple, fodder. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire on November 30, 2008.

**DATES:** This regulation is effective August 4, 2004. Objections and requests for hearings must be received on or before October 4, 2004.

**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 ID number OPP-2004-0086. 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 South 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:** Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: [waller.mary@epa.gov](mailto:waller.mary@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:

- 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 February 27, 2004 (69 FR 9315) (FRL-7346-7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8F3654 and 8F3674) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419-8300. This notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the

registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.434 be amended by establishing tolerances 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 compound in or on corn, field, forage at 12 parts per million (ppm); corn, field, grain at 0.1 ppm; corn, field, stover at 12 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; peanut at 0.2 ppm; peanut, hay at 20 ppm (8F3654); pineapple at 0.1 ppm; and pineapple, fodder at 0.1 ppm (8F3674).

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...."

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).

### III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of propiconazole on corn, field, forage at 12 ppm; corn, field, grain at 0.1

ppm; corn, field stover at 12 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; peanut at 0.2 ppm; peanut, hay at 20 ppm; pineapple at 0.1 ppm; and pineapple, fodder at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by propiconazole are discussed in this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

1. Acute toxicity data were as follows: Acute oral lethal dose (LD)<sub>50</sub> = 1,517 milligrams/kilogram (mg/kg) (toxicity category III); acute dermal LD<sub>50</sub> > 4,000 mg/kg (toxicity category III); acute inhalation lethal concentration (LC)<sub>50</sub> 1.26 mg/liter (L); primary eye irritation - clear by 72 hours (toxicity category III); primary skin irritation - slight irritation (toxicity category IV); and dermal sensitization - negative.

2. A developmental toxicity study with rats which were gavaged with doses of 0, 30, 90 or 360/300 mg/kg/day. The developmental NOAEL was 30 mg/kg/day. Evidence of developmental toxicity observed at the 90 mg/kg/day level LOAEL included increased incidence of unossified sternebrae, rudimentary ribs, shortened or absent renal papillae, and increased cleft palate. The maternal NOAEL was 90 mg/kg/day and the maternal LOAEL was 300 mg/kg/day based on severe clinical toxicity.

3. A development toxicity study with rabbits which were gavaged with doses of 0, 30, 90, or 180 mg/kg/day with no evidence of maternal or developmental toxicity observed under the conditions of the study.

4. A developmental toxicity study with rabbits which were gavaged with doses of 0, 100, 250, or 400 mg/kg/day on gestation days 7 through 19 with no developmental toxicity observed under the conditions of the study. The maternal NOAEL was 100 mg/kg/day and the maternal LOAEL was 250 mg/kg/day based on decreased food consumption, weight gain, and an increase in the number of resorptions at the higher dose levels. The

developmental NOAEL was 250 mg/kg/day. The developmental LOAEL was 400 mg/kg/day based on increased incidence of fetuses/litters with 13<sup>th</sup> rib and increased abortions.

5. A 2-generation reproduction study with rats fed diets containing 0, 100, 500, or 2,500 ppm showed no reproductive effects under the conditions of the study. The offspring NOAEL was 500 ppm (equivalent to 43-52 mg/kg/day), and the offspring LOAEL was 2,500 ppm (equivalent to 192-263 mg/kg/day) based on decreased offspring survival, body weight depression, and increased incidence of hepatic lesions in rats. The parental NOAEL was 100 ppm (equivalent to 8 mg/kg/day) and the parental LOAEL was 500 ppm (equivalent to 42 mg/kg/day) based on increased incidence of hepatic cell change.

6. A 1-year feeding study with dogs fed diets containing 0, 5, 50, or 250 ppm with a NOAEL of 50 ppm (equivalent to 1.25 mg/kg/day). The LOAEL was 250 ppm (equivalent to 6.25 mg/kg/day) based on mild irritation of stomach mucosa.

7. A 2-year chronic feeding/carcinogenicity study with rats fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 500 ppm (equivalent to 18 mg/kg/day) based on liver lesions and reduced body weight gain at the 2,500 ppm level (96 mg/kg/day). There were no carcinogenic effects observed under the conditions of the study.

8. A 2-year chronic feeding/carcinogenicity study with mice fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 100 ppm (equivalent to 10 mg/kg/day) based on increased liver lesions and liver weight in males. There was a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at the 2,500 ppm level (equivalent to 340 mg/kg/day).

9. An 18-month oncogenicity study with male mice fed diets containing 0, 100, 500, or 850 ppm with a NOAEL of 100 ppm (11 mg/kg/day) based on hepatotoxicity and body weight gain effects at the LOAEL of 500 ppm (59 mg/kg/day). There was a treatment related increase in the incidence of hepatocellular (liver) adenoma and combined liver adenomas and carcinomas at the 850 ppm level when compared to controls.

10. A battery of mutagenicity studies to determine the potential of propiconazole to induce gene mutation, chromosomal aberrations, and other genotoxic effects were all negative.

### B. 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 level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. The Agency retained a 3X database uncertainty factor for acute (single dose) and short-term exposure scenarios to account for the lack of an acute neurotoxicity study. These missing data are not expected to have an impact on longer duration exposure scenarios.

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 Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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) =  $NOAEL / \text{exposure}$ ) 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  $1 \times 10^{-6}$  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 ( $MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$ ) is calculated. A summary of the toxicological endpoints for propiconazole used for human risk assessment is shown in Table 1 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 30 mg/kg/day UF = 300 Acute RfD = 0.1 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 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 including infants and children)	NOAEL = 90 mg/kg/day UF = 300 Acute RfD = 0.3 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.3 mg/kg/day	Developmental Toxicity Study - Rats LOAEL = 300 mg/kg/day based on 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	Special FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 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 increases in liver lesions (masses/raised areas/swellings/nodular areas mainly
Short-Term - Incidental Oral (1–30 days) (Residential)	Maternal NOAEL = 90 mg/kg/day	LOC for MOE = 300 (Residential)	Developmental Toxicity Study LOAEL = 300 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/day (dermal absorption rate = 1%)	LOC for MOE = 300	Developmental Toxicity Study - Rats LOAEL = 90 mg/kg/day based on developmental toxicity: Increased incidence of rudimentary ribs, unossified sternebrae, shortened and absent renal papillae, and cleft palate
Cancer	N/A	N/A	Group C - possible human carcinogen, non-quantifiable

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

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.434) for the combined residues of propiconazole, in or on a variety of raw agricultural commodities. The commodities and/or crops are as follows: Bananas; barley; celery; corn; cranberry; dry beans; stone fruits; mint; mushrooms; oats; peanuts; pecans; pineapples; rice; rye; sorghum; wheat; wild rice; eggs, kidney, liver and meat and meat by products of poultry; and milk, meat, fat, kidney, liver, meat and meat by products of cattle, goats, hogs, horses and sheep. 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 (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues were used for all food commodities and it was assumed that 100% of all crops were treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) 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 following assumptions were made for the chronic exposure assessments: Tolerance level residues were used for all food commodities and it was assumed that 100% of all crops were treated.

iii. *Cancer.* A quantitative risk assessment using a cancer endpoint was not performed. The chronic risk assessment is adequately protective for cancer risk as well as other chronic effects.

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 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. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to propiconazole they are further discussed in the aggregate risk sections in unit III.

Based on the FIRST and SCI-GROW models the estimated 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 currently registered for use on the following residential non-dietary site: Residential lawns. The risk assessment was conducted using the following residential exposure assumptions: For adults treating residential lawns, it was assumed there was a possibility of short-term dermal exposure, and for infants and small children playing on treated lawns, it was assumed there was a possibility of incidental oral and dermal exposure.

4. *Cumulative exposure to 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.”

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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 its level of concern. 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 and are expected to be submitted to the Agency in late 2004. Upon completion of the review of these data, EPA will prepare a more sophisticated assessment based on the revised toxicological and exposure databases.

i. *Toxicology.* The toxicological database for 1,2,4-triazole is incomplete. Preliminary summary data presented by the USTTF to EPA indicate that the most conservative endpoint currently available for use in a risk assessment for 1,2,4-triazole is a LOAEL of 15 mg/kg/day, based on body weight decreases in male rats in the reproductive toxicity study (currently underway). This endpoint, with an uncertainty factor of 1,000 was used for both acute and chronic dietary risk, resulting in an RfD of 0.015 mg/kg/day. The uncertainty factor of 1,000 addresses aspects of the toxicology of 1,2,4-triazole related to potential enhanced susceptibility of infants and children. The resulting PAD is 0.015 mg/kg/day.

ii. *Dietary exposure.* The USTTF conducted an acute dietary exposure assessment based on the highest triazole-derivative fungicide tolerance level combined with worst-case molecular weight and plant/livestock metabolic conversion factors. This approach provides a conservative estimate of all sources for 1,2,4-triazole except the *in vivo* conversion of parent compounds to free-triazole following dietary exposure. The degree of animal *in vivo* conversion is dependent on the identity of the parent fungicide. In rats, this conversion ranges from 0 to 77%—the *in vivo* conversion for propiconazole is 5%. For purposes of this interim assessment, EPA used the dietary exposure estimates provided by the USTTF adjusted based on the highest rate of conversion observed for any of the parent triazole-derivative fungicides to account for this metabolic conversion. The assessment includes residue estimates for all food commodities with either existing or pending triazole-derivative fungicide registrations. The resulting acute dietary exposure estimates are extremely conservative and range from 0.0032 mg/kg/day for males 20+ years old to 0.014 mg/kg/day for children 1 to 6 years old. Estimated risks range from 22 to 93% of the PAD. In order to estimate chronic exposures via food, EPA used the 70<sup>th</sup> percentile of exposures from the acute assessment. Estimated risks range from 10 to 47% of the PAD. The dietary assessment does not include potential

exposure via residues in water. It is emphasized that the use of both highest-tolerance-level residues and the highest *in vivo* conversion factor results in dietary risk estimates that far exceed the likely actual risk.

iii. *Non-dietary exposure.* Triazole-derivative fungicides are registered for use on turf, resulting in the potential for residues of free triazole in grass and/or soil. Thus, dermal and incidental oral exposures to children may occur. It is believed that residues of free triazole occur within the plant matrices and are not available as surface residues. Therefore, direct dermal exposure to 1,2,4-triazole due to contact with plants is not likely to occur. However, dermal exposure to parent fungicide and subsequent *in vivo* conversion to 1,2,4-triazole may occur. In order to account for this indirect exposure to free triazole, EPA used a conversion factor of 10%, which is the highest rate of *in vivo* conversion observed in rats for any of the triazole-derivative fungicides with registrations on turf. Incidental oral exposure may occur by direct and indirect routes. To assess direct exposure, EPA used a conversion factor of 17%, which is the highest rate of conversion to free triazole observed in any of the plant metabolism studies. As with indirect dermal exposure, EPA used a conversion factor of 10% in its assessment of indirect oral exposure. Based on residential exposure values estimated for propiconazole (0.0005 mg/kg/day via the dermal route and 0.03 mg/kg/day via the oral route) and the conversion factors described in Unit III.C.4.ii., combined direct and indirect dermal exposures are estimated to be less than 0.0001 mg/kg/day and combined oral exposures are estimated to be less than 0.0019 mg/kg/day. The overall residential exposure is likely to be less than 0.0020 mg/kg/day. Relative to the 15 mg/kg/day point of departure, this gives an MOE of approximately 7,500 for children. Based on the current set of uncertainty factors, the target MOE is 1,000, indicating that the risk associated with residential exposure to 1,2,4-triazole for children is below EPA's level of concern. The adult dermal exposure estimate is slightly less than that of children. Incidental oral exposure is not expected to occur with adults.

iv. *Drinking water.* Modeled estimates of 1,2,4-triazole residues in surface and ground water, as reported by the USTTF, and the DWLOC approach were used to address exposure to free triazole in drinking water. EECs of free triazole in groundwater were obtained from the SCI-GROW model and range from 0.0 to 0.026 ppb, with the higher

concentrations associated with uses on turf. Surface water EECs were obtained using the FIRST model. Acute surface water EECs ranged from 0.29 to 4.64 ppb for agricultural uses and up to 32.1 ppb from use on golf course turf. EPA notes that ground water monitoring studies in New Jersey and California showed maximum residues of 16.7 and 0.46 ppb, respectively, which exceed the SCI-GROW estimates significantly. Contrariwise, preliminary monitoring data from USDA's Pesticide Data Program for 2004 show no detectable residues of 1,2,4-triazole in any drinking water samples, either treated or untreated (maximum limit of detection (LOD) = 0.73 ppb, n=40 each).

v. *Aggregate exposure.* In estimating aggregate exposure, EPA combined potential dietary and non-dietary sources of 1,2,4-triazole. To account for the drinking water component of dietary exposure, EPA used the DWLOC approach, as noted in Unit III.C.2. The DWLOC represents a maximum concentration of a chemical in drinking water at or below which aggregate exposure will not exceed EPA's level of concern. In considering non-dietary exposure, EPA used the residential exposure estimate for children and applied it to all population subgroups. As previously noted, this estimate is considered to be highly conservative for children. Since adults are not expected to have non-dietary oral exposure to 1,2,4-triazole and that pathway makes up the majority of the residential exposure estimate for children, application of that exposure estimate to adults is considered to be extremely conservative. Residential exposure is expected to occur for short- and/or intermediate-term durations, and therefore is not a component in the acute or chronic aggregate exposure assessment. In order to assess aggregate short- and intermediate-term exposure, EPA combined the residential exposure estimate and the chronic dietary exposure estimate. The chronic dietary exposure estimate serves as a background level of exposure to free triazole via food. Less than 1% of lawns in the U.S. are expected to be treated with triazole fungicides, so the likelihood of co-occurring dietary and residential exposures is very low.

With the exception of the acute DWLOCs for infants and children 1–6, all DWLOCs are greater than the largest EEC (surface water estimate from use on turf), indicating that aggregate exposures are not likely to exceed EPA's level of concern. Although the acute DWLOCs for infants and children 1–6 indicate that aggregate exposure may exceed 0.015 mg/kg/day, EPA does not believe

this to be the case due to the extremely conservative nature of the overall assessment (highest-tolerance level residues, 100% crop treated, 77% *in vivo* conversion factor). Furthermore, the drinking water monitoring data from the Pesticide Data Program found no detectable residues of either free triazole or parent triazole-derivative fungicide in its preliminary 2004 dataset, indicating that neither parent compounds nor 1,2,4-triazole are likely to occur in drinking water. For all exposure durations and population subgroups, EPA does not expect aggregate exposures to 1,2,4-triazole to exceed its level of concern.

The Agency is planning to conduct a more sophisticated human health assessment in early 2005 following submission and review of the ongoing toxicology and residue chemistry studies for 1,2,4-triazole.

#### D. 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 database 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 sternbrae, 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:

- 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.

- 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 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, which is discussed in Unit III.D.2. This FQPA safety factor of 3X will be applied in the form of a database uncertainty factor and thus used in deriving the aRfD.

As noted previously, an additional FQPA safety factor of 10X is being used in assessing the risk of 1,2,4-triazole.

#### E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs 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 the pesticide 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 residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to propiconazole will occupy 2% of the aPAD for the U.S. population, 4% of the aPAD for females 13 years and older, 4% of the aPAD for

all infants < 1 year old and 4% of the aPAD for children 1–2 years old. In addition, there is potential for acute dietary exposure to propiconazole in

drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, 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)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.3	2	264	1.5	10,000
All infants (< 1 year old)	0.3	4	264	1.5	2,900
Children 1–2 years old	0.3	4	264	1.5	2,900
Females 13–49 years old	0.1	4	264	1.5	2,900

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propiconazole from food will utilize 2% of the cPAD for the U.S. population, 4% of the cPAD for all infants (< 1 year old) and 6% of the

cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of propiconazole is not expected. In addition, there is potential for chronic dietary exposure to propiconazole in drinking water. After calculating DWLOCs and comparing

them to the EECs for surface and ground water, 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 (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. population	0.1	2	80	1.5	3,400
All infants (< 1 year old)	0.1	4	80	1.5	960
Children 1–2 years old	0.1	6	80	1.5	940

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 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. Using the exposure assumptions described in this unit for short-term

exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 2,400 for food, incidental oral and dermal exposure for infants and small children. Only infants and small children were assessed as they represent the worst case scenario because they have higher food exposure plus two routes of exposure to turf residues. In addition, the MOE's for adults exposed to turf residues are high (13,000 - lowest MOE calculated from data from three

locations. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of propiconazole in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Infants and small children	2,400	300	264	1.5	2,600

4. *Aggregate cancer risk for U.S. population.* EPA classified propiconazole as a Group C, possible human carcinogen. Risk concerns for carcinogenicity due to long-term consumption of propiconazole residues

are adequately addressed by the aggregate chronic exposure analysis using the chronic PAD. Therefore, EPA concludes that there is reasonable certainty that no harm will result from

aggregate exposure to propiconazole residues.

5. *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.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography) 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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

International CODEX maximum residue limits are established for almond, animal products, bananas, barley, coffee, eggs, grapes, mango, meat, milk, oat, peanut-whole, peanut grains, pecans, rape, rye, stone fruit, sugar cane, sugar beets, sugar beet tops, and wheat. The U.S. residue definition includes both propiconazole and metabolites determined as 2,4 dichlorobenzoic acid (DCBA), and the CODEX definition is for propiconazole, per se, i.e. parent only. This difference results in unique tolerance expressions with the U.S. definition resulting in the higher tolerance levels (0.2 ppm versus CODEX 0.1 ppm for peanuts). EPA includes the metabolites in its assessment because they also raise hazard concerns.

##### C. Conditions

An acute neurotoxicity study will be required. The requirement for a developmental neurotoxicity study will be held in reserve pending receipt and review of the acute neurotoxicity study.

#### V. Conclusion

Therefore, the tolerance is established 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 compound in or on corn, field, forage at 12 ppm; corn, field, grain at 0.1 ppm; corn, field stover at 12 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; peanut at 0.2 ppm; peanut, hay at 20 ppm; pineapple at 0.1 ppm; and pineapple, fodder at 0.1 ppm.

#### VI. 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), 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-2004-0086 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 October 4, 2004.

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 issues(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 14<sup>th</sup> 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 VI.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 docket ID number OPP-2004-0086, 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](mailto: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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any

enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of 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 in 40 CFR Part 180**

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

Dated: July 26, 2004.

**Lois Rossi,**  
*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 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 as follows:

- a. By revising the expiration date for several commodities in the table in paragraph (a).
- b. By removing the commodity Corn, stover in the table in paragraph (a).
- c. By removing the commodity Raspberry in the table in paragraph (b).

**§ 180.434 Propiconazole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million	Expiration Date
* * *	* * *	* * *
Corn, field, forage .....	12	11/30/08
Corn, field, grain	0.1	11/30/08
Corn, field, stover .....	12	11/30/08
Corn, sweet, kernel plus cob with husks removed .....	0.1	11/30/08
* * *	* * *	* * *
Peanut .....	0.2	11/30/08
Peanut, hay .....	20	11/30/08
* * *	* * *	* * *
Pineapple .....	0.1	11/30/08
Pineapple, fodder .....	0.1	11/30/08
* * *	* * *	* * *

\* \* \* \* \*  
[FR Doc. 04-17509 Filed 8-3-04; 8:45 am]  
**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0100; FRL-7368-8]

**Propamocarb hydrochloride; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of propamocarb hydrochloride in or on lettuce, leaf; lettuce, head; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; and tomato paste. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective August 4, 2004. Objections and requests for hearings must be received on or before October 4, 2004.