

Commodity	Parts per million
Banana .....	0.3
Beet, sugar, dried pulp ...	1.0
Beet, sugar, molasses ....	0.4
Beet, sugar, roots .....	0.3
Beet, sugar, tops .....	9.0
Bushberry subgroup 13B	0.3
Cattle, meat byproducts	0.05
Citrus, dried pulp .....	5.0
Citrus, oil .....	40.0
Cranberry .....	0.5
Fruit, citrus, group 10 ....	1.0
Fruit, stone, group 12 ....	1.0
Goat, meat byproducts ...	0.05
Grain, aspirated fractions	6.0
Grape <sup>1</sup> .....	1.0
Horse, meat byproducts	0.05
Peanut .....	0.1
Pecan .....	0.05
Sheep, meat byproducts	0.05
Wheat, forage .....	4.0
Wheat, grain .....	0.1
Wheat, hay .....	8.0
Wheat, straw .....	8.0

<sup>1</sup>There are no United States registrations for grape as of August 2006.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0347; FRL-8092-1]

**Propiconazole; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes or revises tolerances for combined residues of propiconazole and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent compound in or on various commodities; and inadvertent residues in or on alfalfa, forage and alfalfa, hay. Syngenta Crop Protection, Inc. and Interregional Research Project No. 4 (IR-4), requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0347. All documents in the

docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Mary Waller, Registration Division (7505P), 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:

- 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?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0347 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 November 21, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0347, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of May 3, 2006 (71 FR 26084) (FRL-8060-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) 2F6371 and 5F4498 by Syngenta Crop Protection, Inc., and PP 6E4788, 7E4860, and 8E4931 by Interregional Research Project No. 4 (IR-4). The petitions requested that 40 CFR 180.434 be amended by 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 compound in or on leafy vegetables (Subgroup 4B) at 5.0 parts per million (ppm) (PP 6E4788); cranberry at 1.0 ppm (PP 7E4860); Mint at 3.0 ppm (PP 8E4931); and under PP 2F6371, almond, hulls and onion, green at 8.0 ppm; berries (Group 13) and legume vegetables (Group 6) at 1.0 ppm; foliage of legume vegetables (Group 7)/sorghum/soybean, forage and sugar beet, tops at 10.0 ppm; carrot, roots/pistachios/nuts, tree (Group 14) at 0.2 ppm; foliage of legume vegetable (Group 7)/soybean, hay at 32.0 ppm; onion, dry bulb/corn, grain/sugar beet, roots at 0.3 ppm; sorghum, grain/grain cereal group (except corn, rice, and sorghum), bran at 2.5 ppm; sorghum, stover at 15.0 ppm; soybean, seed/grain, cereal group (except corn, rice, and sorghum), hay/sugar beet, dried pulp at 2.0 ppm; strawberry at 1.5 ppm; grain, cereal group (except corn, rice, and sorghum) (Group 15), forage/sugar beet, molasses at 3.0 ppm; grain, cereal group (except corn, rice, and sorghum), straw at 13.0 ppm; grain, cereal group (except corn, rice, and sorghum)/corn, oil at 0.5 ppm; rice, bran and hulls at 28.0 ppm; and aspirated grain fraction at 17.0 ppm. Further, the petition requested existing tolerances be amended for corn, forage at 4.0 ppm; corn, stover at 25.0 ppm; rice, grain at 7.0 ppm; and rice, straw at 18.0 ppm. Additionally, PP 5F4498, requested inadvertent residues for alfalfa, forage and hay at 0.1 ppm. That 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.

Upon completing review of the current propiconazole database, the

Agency concluded that the appropriate tolerance levels for propiconazole residues in or on pending crops and livestock commodities should be established as follow: On grain, aspirated fractions at 30 ppm; almond, hulls at 7.0 ppm; barley, grain at 0.3 ppm; barley, hay at 1.4 ppm; barley, straw at 10 ppm; barley, bran at 0.6 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts, except liver and kidney at 0.05 ppm; leafy petioles, subgroup 4B at 5.0 ppm; Berry group 13 at 1.0 ppm; carrot, roots at 0.25 ppm; corn, field, forage at 12 ppm; corn, sweet, forage at 6.0 ppm; corn, field, grain at 0.2 ppm; corn, pop, grain at 0.2 ppm; corn, field, stover at 30 ppm; corn, pop, stover at 30 ppm; corn, sweet, stover at 30 ppm; goat, fat at 0.05 ppm; goat, meat at 0.05 ppm; goat, meat byproducts, except liver and kidney at 0.05 ppm; hog, kidney at 0.2 ppm; hog, liver at 0.2 ppm; horse, fat at 0.05 ppm; horse, meat at 0.05 ppm; horse, meat byproducts, except liver and kidney at 0.05 ppm; spearmint, tops at 3.5 ppm; peppermint, tops at 3.5 ppm; oat, forage at 1.7 ppm; oat, grain at 0.3 ppm; oat, hay at 1.4 ppm; oat, straw at 10 ppm; onion, bulb at 0.2 ppm; onion, green at 9.0 ppm; pistachio at 0.1 ppm; rice, bran at 15 ppm; rice, grain at 7.0 ppm; rice, hulls at 20 ppm; rice, straw at 18 ppm; rye, grain at 0.3 ppm; rye, forage at 1.7 ppm; rye, straw at 10 ppm; rye, bran at 0.6 ppm; sorghum, grain, forage at 12 ppm; sorghum, grain, grain at 3.5 ppm; sorghum, grain, stover at 15 ppm; sheep, fat at 0.05 ppm; sheep, meat at 0.05 ppm; sheep, meat byproducts, except liver and kidney at 0.05 ppm; soybean, forage at 11 ppm; soybean, hay at 30 ppm; soybean, seed at 2.0 ppm; strawberry at 1.3 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 10 ppm; beet, sugar, molasses at 1.5 ppm; nut, tree, group 14 at 0.1 ppm; wheat, bran at 0.6 ppm; wheat, forage at 1.7 ppm; wheat, grain at 0.3 ppm; wheat, hay at 1.4 ppm; wheat, straw at 10 ppm; cranberry at 1.0 ppm; and inadvertent residues in or on alfalfa, forage at 0.1 ppm and alfalfa, hay at 0.1 ppm. The Agency concluded that there are insufficient data to establish tolerances legume vegetables (Group 6); foliage of legume vegetables (Group 7); cereal group (except corn, rice, and sorghum) (Group 15). For additional information refer to [www.regulations.gov](http://www.regulations.gov) Docket No. EPA-HQ-OPP-2006-0347-0008.

EPA is also deleting several established tolerances in 40 CFR 180.434(a), (b), and (c) that are no longer needed as a result of this action.

The revisions to 180.434(a) are as follows:

- Delete celery at 5.0 ppm. Replaced with leafy petioles, subgroup 4B at 5.0 ppm.
- Delete pecans at 0.1 ppm. Replaced with nut, tree, group 14 at 0.1 ppm.

The revisions to 180.434(b) are as follows:

- Delete the time-limited tolerance for blueberry at 1.0 ppm. Replaced with Berry group 13 at 1.0 ppm, under 40 CFR 180.434(a).
- Delete the time-limited tolerance for cranberry; grain, aspirated fractions; sorghum, grain, grain; sorghum, grain, stover; soybean; soybean, forage; and soybean, hay. All are being replaced by permanent tolerances.
- Delete time-limited tolerance for dry bean; dry bean forage; and dry bean hay since these tolerances have expired.

The revisions to 180.434(c) are as follows:

- Delete mint, tops (leaves and stems) at 0.3 ppm. Replaced with spearmint, tops at 3.5 ppm and peppermint, tops at 3.5 ppm under 40 CFR 180.434(a).

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this

action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of propiconazole and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent compound on grain, aspirated fractions at 30 ppm; almond, hulls at 7.0 ppm; barley, grain at 0.3 ppm; barley, hay at 1.4 ppm; barley, straw at 10 ppm; barley, bran at 0.6 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts, except liver and kidney at 0.05 ppm; leafy petioles, subgroup 4B at 5.0 ppm; Berry group 13 at 1.0 ppm; carrot, roots at 0.25 ppm; corn, field, forage at 12 ppm; corn, sweet, forage at 6.0 ppm; corn, field, grain at 0.2 ppm; corn, pop, grain at 0.2 ppm; corn, field, stover at 30 ppm; corn, pop, stover at 30 ppm; corn, sweet, stover at 30 ppm; goat, fat at 0.05 ppm; goat, meat at 0.05 ppm; goat, meat byproducts, except liver and kidney at 0.05 ppm; hog, kidney at 0.2 ppm; hog, liver at 0.2 ppm; horse, fat at 0.05 ppm; horse, meat at 0.05 ppm; horse, meat byproducts, except liver and kidney at 0.05 ppm; spearmint, tops at 3.5 ppm; peppermint, tops at 3.5 ppm; oat, forage at 1.7 ppm; oat, grain at 0.3 ppm; oat, hay at 1.4 ppm; oat, straw at 10 ppm; onion, bulb at 0.2 ppm; onion, green at 9.0 ppm; pistachio at 0.1 ppm; rice, bran at 15 ppm; rice, grain at 7.0 ppm; rice, hulls at 20 ppm; rice, straw at 18 ppm; rye, grain at 0.3 ppm; rye, forage at 1.7 ppm; rye, straw at 10 ppm; rye, bran at 0.6 ppm; sorghum, grain, forage at 12 ppm; sorghum, grain, grain at 3.5 ppm; sorghum, grain, stover at 15 ppm; sheep, fat at 0.05 ppm; sheep, meat at 0.05 ppm; sheep, meat byproducts, except liver and kidney at 0.05 ppm; soybean, forage at 11 ppm; soybean, hay at 30 ppm; soybean, seed at 2.0 ppm; strawberry at 1.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 10 ppm; beet, sugar, molasses at 1.5 ppm; nut, tree, group 14 at 0.1 ppm; wheat, bran at 0.6 ppm; wheat, forage at 1.7 ppm; wheat, grain at 0.3 ppm; wheat, hay at 1.4 ppm; wheat, straw at 10 ppm; cranberry at 1.0 ppm; and inadvertent residues in or on alfalfa, forage at 0.1 ppm and alfalfa, hay at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by propiconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at [www.regulations.gov](http://www.regulations.gov) Docket No. EPA-HQ-OPP-2006-0347-0005; pages 35-42.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

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

A summary of the toxicological endpoints for propiconazole used for human risk assessment is discussed at [www.regulations.gov](http://www.regulations.gov) Docket No. EPA-HQ-OPP-2006-0347-0004; pages 23-25.

#### 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 and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent compound, in or on a variety of raw agricultural commodities. Tolerances are also established for residues of propiconazole and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent

compound in or on milk as well as fat, meat, kidney, liver and meat by products of cattle, goats, hogs, horse, and sheep. Some of these existing tolerances are being revised as a result of this action. Risk assessments were conducted by EPA to assess dietary exposures from propiconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data 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: Tolerance levels and one hundred percent of the crops were treated for all proposed new uses, revised uses, and existing uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance levels and 100% of the crops were treated for all proposed new uses, revised uses, and existing uses.

iii. *Cancer.* Propiconazole has been classified as a group C (possible human carcinogen). The Agency concluded that the chronic risk assessment, making use of the chronic population adjusted dose (cPAD), is protective of any potential carcinogenic risk.

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. Further information regarding EPA drinking water models used in pesticide exposure assessment

can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

A registrant drinking water monitoring study showed very few detections among a total of 38 selected community water systems in 12 states. The Agency concluded that the sampling scheduling of this monitoring study is not rigorous enough to be used for water assessment. Since the monitoring studies did not provide good quality data, this drinking water assessment is based on the model predicted drinking water concentrations.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of propiconazole for acute exposures are estimated to be 55.8 parts per billion (ppb) for surface water and 0.64 ppb for ground water. The EECs for chronic exposures are estimated to be 21.6 ppb for surface water and 0.64 ppb for ground water.

To estimate surface water for each specific use, the maximum allowable label rate was input into PRZM/EXAMS. The output concentrations were without percent cropped area (PCA) consideration. The final estimated drinking water concentrations were then adjusted with the proper PCA. Except the uses of soybean (0.41 ppb) and wheat (0.56 ppb), other uses assume the default PCA of 0.87 ppb. Among these modeling results, turf use gives the highest acute concentration of 55.78 ppb (Microgram/liter ( $\mu\text{g/L}$ )). For the chronic exposure, turf use has the highest concentration of 21.61 ppb ( $\mu\text{g/L}$ ).

The EECs in ground water were calculated using the Tier I SCI-GROW model. SCI-GROW is neither scenario- nor crop-specific. The only input requirements are application rate, number of applications,  $K_{oc}$ , and aerobic soil metabolism half-life. The higher estimated concentrations are associated with the higher rate. Turf use has the highest concentration of 0.64  $\mu\text{g/L}$  (ppb). Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID<sup>TM</sup>). For acute dietary risk assessment, the peak water concentration value of 55.8 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 21.6 ppb was used to access the contribution to drinking 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 sites: Ground covers; turf and ornamentals in lawns and golf courses; ornamentals trees (injection); shade trees (outdoor spray); herbaceous plants; ornamental woody shrubs and vines and antimicrobial uses in paint and wood protection treatment. The risk assessment was conducted using the following residential exposure assumptions:

Homeowners can be exposed to propiconazole through dermal and inhalation routes while applying home use products. All risk calculations were conducted using the maximum turf application rate (1.8 lb ai/acre). The anticipated use patterns and current labeling indicate three major residential exposure scenarios based on the types of equipment and techniques that can potentially be used to make propiconazole applications. The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

- Mixer/Loader/applying liquids and wettable powder in water soluble packets via low pressure handwand.
- Mixer/Loader/applying liquids and wettable powder in water soluble packets via hose-end sprayer.
- Applying treated paint using airless sprayer and hose-end spray.

Residential handler exposure scenarios are considered to be short-term only due to the infrequent uses associated with homeowner products.

The existing residential use patterns result in post application dermal exposures to adults, and dermal and oral exposures to infants and children. These exposure scenarios are considered short term only, due to the fact that:

- i. Post-application exposures were calculated using propiconazole as the parent compound;
- ii. Compound specific turf transferable residue (TTR) data indicate that at the Indiana, California, and Pennsylvania test sites, average total propiconazole residues declined to below the minimum quantifiable limit (MQL) by 14, 10 and 8 days after treatment, respectively. These dissipation rates, combined with label specific use rates and frequency of use specifications, reinforce the hand to mouth short-term exposure scenario;
- iii. For short term exposure to children 1–2 years old, the driving factors for this risk assessment are hand to mouth, object to mouth, and dermal

exposure. Soil ingestion is insignificant (margin of exposure (MOE) >300,000) compared to these factors, indicating that the post application scenario should be short term only. Although both residential and antimicrobial uses result in incidental oral and dermal exposure to children, the highest incidental oral and dermal exposure scenarios are from residential use on turf, which were used in the short term aggregate risk assessment.

In addition to using the EPA's Standard Operational Procedure (SOP) for residential assessment, the study specific turf transferable residue (TTR) was used to estimate exposures. The EPA combined exposures resulting from separate post-application exposure scenarios when it is likely they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population. The assumptions used for each of the scenarios separately are considered to account for potential high levels of exposure (i.e., time spent outdoors, dislodgeable residues) therefore, combining all these activities together is considered a very high end estimate of exposure. Propiconazole is classified as a non-volatile chemical; therefore a residential inhalation post-application assessment was not assessed.

The only residential use scenario that will result in potential intermediate term exposure to propiconazole is post application exposure to children from wood treatment (antimicrobial use) from incidental oral and dermal contact activities.

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."

Propiconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between this pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some

induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Propiconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including propiconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at [www.regulations.gov](http://www.regulations.gov), Docket ID number EPA-HQ-OPP-2005-0497-0013.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are

incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is low concern for pre- and/or postnatal toxicity resulting from exposure to propiconazole. In the developmental toxicity study in rats, the EPA considered the fetal effects observed in this study at a dose lower than that evoking maternal toxicity to be quantitative evidence of increased susceptibility of fetuses to *in utero* exposure to propiconazole. In the developmental toxicity study in rabbits, the Agency determined that neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to propiconazole was observed in this study. In the 2-generation reproduction study in rats, neither quantitative nor qualitative evidence of increased susceptibility of neonates (as compared to adults) to pre- and/or postnatal exposure to propiconazole was observed in the study. Since there is quantitative evidence of increased susceptibility of the young following exposure to propiconazole in the developmental rat study, the Agency performed a Degree of Concern Analysis to:

- i. Determine the LOC for the effects observed when considered in the context of all available toxicity data; and
- ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of this chemical. If residual uncertainties are identified, then EPA examines whether these residual uncertainties can be addressed by a special FQPA safety factor and, if so, the size of the factor needed. In the developmental rat study, quantitative susceptibility was evidenced as 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 EPA characterized the degree of concern for the effects

observed in this study as low, noting that there is a clear no observed adverse effect level (NOAEL) and well-characterized dose response for the developmental effects observed. No residual uncertainties were identified. The NOAEL for developmental effects in this study (30 mg/kg/day) is used as the basis for the acute Reference dose (aRfD) for the female 13–50 population subgroup as well as for short-term incidental oral, dermal and inhalation endpoints. For all other toxicity endpoints established for propiconazole, a NOAEL lower than this developmental NOAEL is used.

3. *Conclusion.* There is a complete toxicity data base for propiconazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is low concern for pre- and/or postnatal toxicity resulting from exposure to propiconazole. In the developmental toxicity study in rats the fetal effects observed were seen at a dose lower than that evoking maternal toxicity. These effects were considered to be quantitative evidence of increased susceptibility of fetuses to *in utero* exposure to propiconazole. Therefore, as discussed above a Degree of Concern Analysis was conducted and the EPA concluded that the degree of concern for the effects observed in this study was low and no residual uncertainties were identified. EPA determined that the 10X SF to protect infants and children should be removed.

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

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 6% of the acute Population Adjusted Dose (aPAD) for the U.S. population, 5% of the aPAD for females 13 years and older, 14% of the aPAD for all infants (<1 year old), the subpopulation at greatest exposure, and 13% of the aPAD for children 1–2 years old. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propiconazole from food and water will utilize 6% of the chronic Population Adjusted Dose (cPAD) for the U.S. population, 14% of the cPAD for all infants (<1 year old), and 14% of the cPAD for children 1–2 years old, the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of propiconazole is not expected.

Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and 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, water and residential exposures aggregated result in aggregate MOEs for children 1–2 years old of 1,100 for hand to mouth activity on turf; 4,500 for object to mouth activity on turf; 330,000 for soil ingestion; 210 for high contact turf activities; and 410 from the antimicrobial use of propiconazole in treated wood. The food, water and residential exposures aggregated for children 1–2 years old following post-application of propiconazole result in an aggregate MOE of 160 for high contact activities. The corresponding aggregate MOE for adults following post-application exposure is 330. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC.

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

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water and residential exposures aggregated result in an aggregate MOE of 120 for combined exposures from incidental oral and dermal contact activities for children 1–2 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses. Therefore, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment,

making use of the cPAD, to be protective of any aggregate cancer risk. See Unit III.E.2.

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.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (a gas chromatography (GC) method using electron capture detection (Method AG-454) 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

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for propiconazole in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of propiconazole *per se*. In addition, both Canada and Mexico have established MRLs/tolerances on several commodities which also have U.S. tolerances. The U.S. tolerance expression includes all metabolites determined as 2,4-dichloro-benzoic acid. In conjunction with the reregistration process EPA intends to revise the expression to propiconazole *per se*. To the extent possible, for the present petitions, U.S. tolerances have been numerically harmonized with Codex, Canadian, and Mexican MRLs; however, differences in use patterns and the supporting residue data have precluded reducing many tolerances. A summary of Codex MRLs, Canadian MRLs, and Mexican tolerances and the corresponding U.S. tolerances for propiconazole is discussed at [www.regulations.gov](http://www.regulations.gov) Docket No. EPA–HQ–OPP–2006–0347–0004; pages 53–54.

#### V. Conclusion

Therefore, tolerances are established for combined residues of propiconazole and its metabolites containing the dichlorobenzoic acid (DCBA) moiety expressed as parent compound in or on grain, aspirated fractions at 30 ppm; almond, hulls at 7.0 ppm; barley, grain at 0.3 ppm; barley, hay at 1.4 ppm; barley, straw at 10 ppm; barley, bran at 0.6 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat

byproducts, except liver and kidney at 0.05 ppm; leafy petioles, subgroup 4B at 5.0 ppm; Berry group 13 at 1.0 ppm; carrot, roots at 0.25 ppm; corn, field, forage at 12 ppm; corn, sweet, forage at 6.0 ppm; corn, field, grain at 0.2 ppm; corn, pop, grain at 0.2 ppm; corn, field, stover at 30 ppm; corn, pop, stover at 30 ppm; corn, sweet, stover at 30 ppm; goat, fat at 0.05 ppm; goat, meat at 0.05 ppm; goat, meat byproducts, except liver and kidney at 0.05 ppm; hog, kidney at 0.2 ppm; hog, liver at 0.2 ppm; horse, fat at 0.05 ppm; horse, meat at 0.05 ppm; horse, meat byproducts, except liver and kidney at 0.05 ppm; spearmint, tops at 3.5 ppm; peppermint, tops at 3.5 ppm; oat, forage at 1.7 ppm; oat, grain at 0.3 ppm; oat, hay at 1.4 ppm; oat, straw at 10 ppm; onion, bulb at 0.2 ppm; onion, green at 9.0 ppm; pistachio at 0.1 ppm; rice, bran at 15 ppm; rice, grain at 7.0 ppm; rice, hulls at 20 ppm; rice, straw at 18 ppm; rye, grain at 0.3 ppm; rye, forage at 1.7 ppm; rye, straw at 10 ppm; rye, bran at 0.6 ppm; sorghum, grain, forage at 12 ppm; sorghum, grain, grain at 3.5 ppm; sorghum, grain, stover at 15 ppm; sheep, fat at 0.05 ppm; sheep, meat at 0.05 ppm; sheep, meat byproducts, except liver and kidney at 0.05 ppm; soybean, forage at 11 ppm; soybean, hay at 30 ppm; soybean, seed at 2.0 ppm; strawberry at 1.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 10 ppm; beet, sugar, molasses at 1.5 ppm; nut, tree, group 14 at 0.1 ppm; wheat, bran at 0.6 ppm; wheat, forage at 1.7 ppm; wheat, grain at 0.3 ppm; wheat, hay at 1.4 ppm; wheat, straw at 10 ppm; cranberry at 1.0 ppm; and inadvertent residues in or on alfalfa, forage at 0.1 ppm and alfalfa, hay at 0.1 ppm.

#### VI. Statutory and Executive Order Reviews

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

enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR

67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, 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: September 12, 2006.

**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 revised to read as follows:

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

(a) *General.* Tolerances are established for the combined residues of the fungicide 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 the following commodities:

Commodity	Parts per million
Almond, hulls .....	7.0
Banana .....	0.2
Barley, bran .....	0.6
Barley, grain .....	0.3
Barley, hay .....	1.4
Barley, straw .....	10
Beet, sugar, dried pulp ...	1.0
Beet, sugar, molasses ...	1.5
Beet, sugar, roots .....	0.3
Beet, sugar, tops .....	10
Berry, group 13 .....	1.0
Carrot, roots .....	0.25
Cattle, fat .....	0.05
Cattle, kidney .....	2.0
Cattle, liver .....	2.0
Cattle, meat .....	0.05
Cattle, meat byproducts, except liver and kidney	0.05
Corn, field, forage .....	12
Corn, field, grain .....	0.2
Corn, field, stover .....	30
Corn, pop, grain .....	0.2
Corn, pop, stover .....	30
Corn, sweet, forage .....	6.0
Corn, sweet, kernel plus cob with husks removed .....	0.1
Corn, sweet, stover .....	30
Fruit, stone, group 12 ....	1.0
Goat, fat .....	0.05
Goat, kidney .....	2.0
Goat, liver .....	2.0
Goat, meat .....	0.05
Goat, meat byproducts, except liver and kidney	0.05
Grain, aspirated fractions	30
Grass, forage .....	0.5
Grass, hay .....	0.5
Grass, straw .....	40
Hog, kidney .....	0.2
Hog, liver .....	0.2
Horse, fat .....	0.05
Horse, kidney .....	2.0
Horse, liver .....	2.0
Horse, meat .....	0.05
Horse, meat byproducts, except liver and kidney	0.05
Leaf petioles, subgroup 4B .....	5.0
Milk .....	0.05
Mushroom .....	0.1
Nut, tree, group 14 .....	0.1
Oat, forage .....	1.7
Oat, grain .....	0.3
Oat, hay .....	1.4
Oat, straw .....	10
Onion, bulb .....	0.2
Onion, green .....	9.0
Peanut .....	0.2
Peanut, hay .....	20
Peppermint, tops .....	3.5
Pineapple .....	0.1

Commodity	Parts per million
Pistachio .....	0.1
Rice, bran .....	15
Rice, grain .....	7.0
Rice, hulls .....	20
Rice, straw .....	18
Rye, bran .....	0.6
Rye, forage .....	1.7
Rye, grain .....	0.3
Rye, straw .....	10
Sheep, fat .....	0.05
Sheep, kidney .....	2.0
Sheep, liver .....	2.0
Sheep, meat .....	0.05
Sheep, meat byproducts, except liver and kidney .....	0.05
Sorghum, grain, forage ...	12
Sorghum, grain, grain ....	3.5
Sorghum, grain, stover ...	15
Soybean, forage .....	11
Soybean, hay .....	30
Soybean, seed .....	2.0
Spearmint, tops .....	3.5
Strawberry .....	1.3
Wheat, bran .....	0.6
Wheat, forage .....	1.7
Wheat, grain .....	0.3
Wheat, hay .....	1.4
Wheat, straw .....	10

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. A tolerance with regional registration, as defined in §180.1(m), is established for residues of 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 the following commodities:

Commodity	Parts per million
Cranberry .....	1.0
Rice, wild .....	0.5

(d) Indirect or inadvertent residues. Tolerances are established for the combined residues of the fungicide 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 the following commodities when present therein as a result of application of propiconazole to growing crops in paragraphs (a) and (c) of this section:

Commodity	Parts per million
Alfalfa, forage .....	0.1
Alfalfa, hay .....	0.1

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BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0170; FRL-8092-2]

**Buprofezin; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues or residues of buprofezin in or on almond hulls; cotton, gin byproducts: Cottonseed; and tomato. Nichino America, Inc., Linden Park Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19908 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 September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0170. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kevin Sweeney, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5063; e-mail address: [sweeney.kevin@epa.gov](mailto:sweeney.kevin@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.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the