August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

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, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

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

Dated: May 3, 2011.

**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 180.649 is amended as follows:

■ a. Revise the table in paragraph (a)(1).

■ b. In the table in paragraph (a)(2), revise the entries for cattle, liver; cattle, meat byproducts, except liver; goat, liver; goat, meat byproducts, except liver; horse, liver; horse, meat byproducts, except liver; sheep, liver; and sheep, meat byproducts, except liver.

The revised texts read as follows:

**§ 180.649 Saflufenacil; tolerances for residues.**

(a) * * * (1) * * *

| Commodity | Parts per million |
|---|---|
| Almond, hulls | 0.10 |
| Cotton, gin byproducts | 0.45 |
| Cottonseed subgroup 20C | 0.20 |
| Fruit, citrus, group 10 | 0.03 |
| Fruit, pome, group 11 | 0.03 |
| Fruit, stone, group 12 | 0.03 |
| Grain, aspirated fractions | 10 |
| Grain, cereal, forage, fodder and straw group 16 | 0.10 |
| Grain, cereal, group 15 | 0.03 |
| Grape | 0.03 |
| Nut, tree, group 14 | 0.03 |
| Pea and bean, dried shelled, except soybean, subgroup 6C | 0.30 |
| Pea and bean, succulent shelled, subgroup 6B | 0.03 |
| Pea, hay | 17 |
| Pistachio | 0.03 |
| Rapeseed subgroup 20A | 0.45 |
| Sunflower subgroup 20B | 1.0 |
| Soybean, hulls | 0.50 |
| Soybean, seed | 0.10 |
| Vegetable, foliage of legume, group 7 (except pea, hay) | 0.10 |
| Vegetable, legume, edible podded, subgroup 6A | 0.03 |

(2) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Cattle, liver | 2.5 |
| * * * * * | |
| Cattle, meat byproducts, except liver | 0.05 |
| * * * * * | |
| Goat, liver | 2.5 |
| * * * * * | |
| Goat, meat byproducts, except liver | 0.05 |
| * * * * * | |
| Horse, liver | 2.5 |
| * * * * * | |
| Horse, meat byproducts, except liver | 0.05 |
| * * * * * | |
| Sheep, liver | 2.5 |
| * * * * * | |
| Sheep, meat byproducts, except liver | 0.05 |
| * * * * * | |

[FR Doc. 2011–11553 Filed 5–10–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2009–1009; FRL–8873–2]**

### Propiconazole; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of propiconazole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action establishes a time-limited tolerance for residues of propiconazole in or on avocado, in response to the approval of a quarantine exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use to control the disease, laurel wilt (caused by *Raffaelea lauricola*) in the state of Florida. This regulation establishes a maximum permissible level of residues of propiconazole in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2013.

**DATES:** This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 2011, 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–2009–1009. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.),

2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2009–1009 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 11, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–1009, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 19, 2010 (75 FR 13277) (FRL–8813–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7659) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.434 be amended by establishing tolerances for 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 onion, bulb, subgroup 3–07A at 0.2 parts per million (ppm); onion, green, subgroup 3–07B at 9.0 ppm; caneberry subgroup 13–07A at 1.0 ppm; bushberry subgroup 13–07B at 1.0 ppm; and low growing berry subgroup 13–07G, except cranberry at 1.3 ppm. The petition also proposed to amend the tolerances in 40 CFR 180.434 by increasing the tolerances in or on peppermint, tops and spearmint, tops from 3.5 ppm to 10 ppm; and by removing the tolerances for berry group 13 at 1.0 ppm; onion, bulb at 0.2 ppm; onion, green at 9.0 ppm and strawberry at 1.3 ppm. That notice referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

EPA is also establishing a time-limited tolerance for residues of propiconazole in or on avocado at 10 ppm. This tolerance expires and is revoked on December 31, 2013. The Agency is establishing this time-limited tolerance in response to a quarantine exemption request under FIFRA section 18 on behalf of the Florida Department of Agriculture and Consumer Services for emergency use of propiconazole to control the disease, laurel wilt, in avocado.

According to the applicant, an emergency situation exists due to the introduction of laurel wilt, a disease affecting avocado trees caused by the pathogenic fungus *Raffaelea lauricola.* This fungus is vectored by the redbay ambrosia beetle, a newly introduced species, native to Asia, which has moved rapidly toward the avocado production area since its initial discovery in Georgia in 2002. Avocado tree death from laurel wilt has been documented and research has demonstrated that the redbay ambrosia beetle attacks healthy avocado trees from all 22 cultivars tested so far. Control of the vector, the redbay ambrosia beetle, is problematic since inoculation of a tree requires only 1 beetle, the beetle is capable of flight to escape insecticide treatments, and the two currently registered insecticides will not provide the necessary year-round control due to limits in residual activity and number of applications allowed. Once a tree is infected with the disease, there is no cure and the tree will die. For these reasons, the applicant states that the potential impact of this disease on avocado growing and production could be devastating. The applicant states that the avocado producing areas are under severe threat from laurel wilt, and control through a suitable fungicide, such as the requested material, is essential to protecting

continued production of avocado in Florida as well as protecting other susceptible tree species in the U.S. EPA has authorized under FIFRA section 18 the use of propiconazole on avocado in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of propiconazole in avocado, as discussed below. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA and EPA decided that the necessary time-limited tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this time-limited tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although, this time-limited tolerance expires and is revoked on December 31, 2013, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on avocado after that date will not be unlawful provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decision about whether propiconazole meets EPA's registration requirements for use on avocado or whether a permanent tolerance for this use would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerance serves as a basis for registration of propiconazole by a State for special local needs under FIFRA section 24(c). Nor does the time-limited tolerance serve as the basis for any State other than Florida to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166.

## III. Aggregate Risk Assessment and Determination of Safety

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. * * *"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for propiconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with propiconazole 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.

Propiconazole has low to moderate toxicity in experimental animals by the oral, dermal and inhalation routes. It is moderately irritating to the eyes, and minimally irritating to the skin. It is a dermal sensitizer. Propiconazole is readily absorbed by the rat skin with 40% absorption within 10 hours of dermal application.

The primary target organ for propiconazole toxicity in animals is the liver. Increased liver weights were seen in mice after subchronic or chronic oral exposures to propiconazole at doses greater than 50 milligrams/kilograms/day (mg/kg/day). Liver lesions such as vacuolation of hepatocytes, ballooned liver cells, foci of enlarged hepatocytes, hypertrophy and necrosis are characteristic of propiconazole toxicity in rats and mice. Mice appear to be more susceptible to its toxicity than rats. Decreased body weight gain in experimental animals was seen in subchronic, chronic, developmental and reproductive studies. Dogs appeared to be more sensitive to the localized toxicity of propiconazole as manifested by stomach irritation at 6 mg/kg/day and above.

In rabbits, developmental toxicity occurred at a higher dose than the maternal toxic dose, while in rats, developmental toxicity occurred at lower doses than maternal toxic doses. Increased incidences of rudimentary ribs occurred in rat and rabbit fetuses. Increased cleft palate malformations were noted in two studies in rats. In one published study in rats developmental effects (incomplete ossification of the skull, caudal vertebrae and digits, extra rib (14th rib) and missing sternebrae, malformations of the lung and kidneys) were reported at doses that were not maternally toxic.

In the 2-generation reproduction study in rats, offspring toxicity occurred at a higher dose than the parental toxic dose suggesting lower susceptibility of the offspring to the toxic doses of propiconazole in this study.

Propiconazole was negative for mutagenicity in the *in vitro* BALB/C 3T3 cell transformation assay, bacterial reverse mutation assay, Chinese hamster bone marrow chromosomal aberration assay, unscheduled DNA synthesis studies in human fibroblasts and primary rat hepatocytes, mitotic gene conversion assay and the dominant lethal assay in mice. Hepatocellular proliferation studies in mice suggest that propiconazole induces cell proliferation followed by treatment-related hypertrophy in a manner similar to the known hypertrophic agent phenobarbital.

Propiconazole was carcinogenic to male mice. Propiconazole was not carcinogenic to rats nor to female mice. The Agency classified propiconazole as Group C possible human carcinogen and recommended that for the purpose of risk characterization the reference dose (RfD) approach be used for quantification of human risk. Propiconazole is not genotoxic and this fact, together with special mechanistic studies, indicate that propiconazole is a threshold carcinogen. Propiconazole produced liver tumors in male mice only at a high dose that was toxic to the liver. At doses below the RfD liver

toxicity is not expected, and therefore tumors are also not expected.

Specific information on the studies received and the nature of the adverse 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 *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2009–1009 on pages 34–40 in the document titled "Revised Propiconazole Human Health Risk Assessment for a Section 3 Registration on Mint, Bulb Vegetables, Caneberry Subgroup 13–07A, Bushberry Subgroup 13–07B, and Low Growing Berry Subgroup 13–07G"

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for propiconazole used for human risk assessment is shown in the following Table:

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROPICONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute dietary (Females 13–50 years of age) .. | NOAEL = 30 milligrams/kilograms/day (mg/kg/day).<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Acute RfD =0.3 mg/kg/day.<br>aPAD = 0.3 mg/kg/day | DNT Study—Rat.<br>LOAEL = 90 mg/kg/day based on increased incidence of rudimentary ribs, un-ossified sternebrae, as well as increased incidence of shortened and absent renal papillae and increased cleft palate. |
| Acute dietary (General population including infants and children). | NOAEL = 30 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Acute RfD = 0.3 mg/kg/day.<br>aPAD = 0.3 mg/kg/day | Acute neurotoxicity study Rat.<br>LOAEL = 100 mg/kg/day based on clinical signs of toxicity (piloerection in one male, diarrhea in one female, tip toe gait in 3 females). |
| Chronic dietary (All populations) ..... | NOAEL= 10 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = 0.1 mg/kg/day.<br>cPAD = 0.1 mg/kg/day | 24-month oncogenicity study on CD–1 mice.<br>LOAEL = 50 mg/kg/day based on non-neoplastic liver effects (increased liver weight in males and increase in liver lesions: masses/raised areas/swellings/nodular areas mainly). |
| Incidental Oral Exposure (Short-Term) and Dermal short-term (1 to 30 days). | Oral study .....<br>NOAEL = 30 mg/kg/day dermal absorption rate = 40% exposures.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 ... | Acute Neurotoxicity Study—Rats.<br>LOAEL = 100 mg/kg/day based on clinical signs of toxicity (piloerection in one male, diarrhea in one female, tip toe gait in 3 females). |
| Incidental Oral Exposure (Intermediate-Term) and Dermal intermediate-term (1 to 6 months). | Oral study .....<br>NOAEL= 10 mg/kg/day dermal absorption rate = 40% for dermal exposures.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 ... | 24 Month Oncogenicity Study—Mice.<br>LOAEL = 50 mg/kg/day based on non-neoplastic liver effects (increased liver weight in males and increase in liver lesions: masses/raised areas/swellings/nodular areas mainly). |
| Inhalation short-term (1 to 30 days) ..... | Inhalation (or oral) study.<br>NOAEL= 30 mg/kg/day (inhalation absorption rate = 100%).<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 ... | Acute Neurotoxicity Study—Rats.<br>LOAEL = 100 mg/kg/day based on clinical signs of toxicity (piloerection in one male, diarrhea in one female, tip toe gait in 3 females). |

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROPICONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Cancer (Oral, dermal, inhalation) ..... | Classification: Group C, possible human carcinogen, RfD approach for risk characterization. | | |

$UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propiconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing propiconazole tolerances in 40 CFR 180.434. EPA assessed 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.

Such effects were identified for propiconazole. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance levels and 100 percent crop treated (PCT) for all existing and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance levels and 100 PCT for all existing and proposed uses.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to propiconazole. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for propiconazole. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for propiconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of propiconazole for acute exposures are estimated to be 55.78 parts per billion (ppb) for surface water and 0.64 ppb for ground water, for chronic exposures for non-cancer assessments are estimated to be 21.61 ppb for surface water and 0.64 ppb for ground water and for chronic exposures for cancer assessments are estimated to be 13.24 ppb for surface water and 0.64 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 55.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 21.6 ppb was used to assess 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 the following uses that could result in residential exposures: Turf, ornamentals and in paint. EPA assessed residential exposure using the following assumptions: Short-term risk to toddlers was assessed for incidental oral and dermal exposure. The highest incidental oral and dermal exposure scenarios are expected from residential use on turf. Short-term risk to adults was assessed for dermal and inhalation residential handler exposure as well as dermal exposure for residential post-application. Adult handlers have some inhalation exposure however, based on the low vapor pressure of propiconazole, negligible post application inhalation exposure is anticipated to occur. The highest post application exposure from residential use on turf was used to assess risk to short term aggregate exposures.

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

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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 their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same,

or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's Web site 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 and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including propiconazole, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.,* use of a maximum combination of 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 Food Quality Protection Act (FQPA) safety factor (SF) for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov,* Docket Identification (ID) Number EPA–HQ–OPP–2005–0497 and an update to assess the addition of the commodities included in this action may be found in docket ID number EPA–HQ–OPP–2009–1009 in the documents titled "Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address The Section 3 Request for Propiconazole on Mint, Bulb Vegetables Subgroups 3–07A and 3–07B, Caneberry Subgroup 13–07A, Bushberry Subgroup 13–07B, and Low growing Berry Subgroup 13–07G" and "Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address The Section 18 Request for Propiconazole on Avocado in Florida."

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is low concern for prenatal and/or postnatal toxicity resulting from exposure to propiconazole. In the developmental toxicity study in rats, fetal effects observed in this study at a dose lower than that evoking maternal toxicity are considered to be quantitative evidence of increased susceptibility of fetuses to *in utero* exposure to propiconazole. In the developmental toxicity study in rabbits, 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 prenatal and/or postnatal exposure to propiconazole was observed in this study. There is no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with propiconazole. In the rat acute neurotoxicity study, there was evidence of mild neurobehavioral effects at 300 mg/kg, but no evidence of neuropathology from propiconazole administration. Since there was 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 and concluded that the degree of concern for the effects observed in this study was low and no residual uncertainties were identified, for the reasons explained in this Unit.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for propiconazole is complete except for the lack of immunotoxicity and subchronic neutotoxicity studies. In the absence of specific immunotoxicity studies, EPA has evaluated the available propiconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system in any propiconazole study. In addition, propiconazole does not belong to a class of chemicals (*e.g.,* the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the considerations in this Unit, EPA does not believe that conducting a special Harmonized Guideline 870.7800 immunotoxicity study will result in a POD less than the NOAEL of 10.0 mg/kg/day used in calculating the cPAD for propiconazole, and therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

In the absence of the subchronic neurotoxicity study, EPA has evaluated the available propiconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential neurotoxicity after repeated exposures. With the exception of the developmental studies in the rat, there were no indications in any of the repeated dose studies that propiconazole is neurotoxic. In the developmental studies in the rat, there were some clinical signs of neurotoxicity at 300 mg/kg/day but not at lower doses. Based on the considerations in this Unit, EPA does not believe that conducting a Harmonized Guideline 870.6200b subchronic neurotoxicity study will result in a POD less than the NOAEL of 10 mg/kg/day used in calculating the cPAD for propiconazole, and therefore, an additional database uncertainty factor is not needed to account for potential neurotoxicity from repeated exposures. There is no indication in the developmental and reproduction studies, or in the acute neurotoxicity

study that a developmental neurotoxicity study should be required.

ii. There is no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with propiconazole. In the rat acute neurotoxicity study, there was evidence of mild neurobehavioral effects at 300 mg/kg, but no evidence of neuropathology from propiconazole administration.

iii. Although an apparent increased quantitative susceptibility was observed in fetuses and offspring based on minimal toxicity at high doses of administration, clear NOAELs and LOAELs have been identified for all effects of concern, and a clear dose-response has been well defined. Since this increased susceptibility is occurring at high doses and a clear dose response has been well defined for all effects of concern, residual uncertainties or concerns for prenatal and/or postnatal toxicity are minimal.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propiconazole in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by propiconazole.

*E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 17% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to propiconazole from food and water will utilize 18% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of propiconazole is not expected.

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

Propiconazole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to propiconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 160 for toddlers (children 1 to 2 years old), between 120 and 4,400 for adults from handler activities, and 330 for adults from post-application activities. Because EPA's level of concern for propiconazole is a MOE of 100 or below, these MOEs are not of concern.

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

Propiconazole is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to propiconazole.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 120 for toddlers (children 1 to 2 years old). Because EPA's level of concern for propiconazole is a MOE of 100 or below, these MOEs are not of concern.

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.

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, or to infants and children from aggregate exposure to propiconazole residues.

## IV. Other Considerations

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (HPLC/UV Method AG–671A) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

*B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for propiconazole for any of the subject crops in this document.

*C. Response to Comments*

A comment was received from a private citizen objecting to establishment of tolerances stating that residues should be zero. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686, June 30, 2005; 70 FR 1354, January 7, 2005; 69 FR 63096, October 29, 2004 for the Agency's response to these objections.

## V. Conclusion

Therefore, tolerances are established for residues of propiconazole, (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole) and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound as set forth in the regulatory text. In addition this regulation establishes a time-limited tolerance for residues of propiconazole in or on avocado at 10 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* 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).

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 (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

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, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: May 2, 2011.

**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. Amend § 180.434 as follows:

■ i. In the table to paragraph (a), remove the entries for "berry group 13," "onion, bulb," "onion, green," and "strawberry"; revise the entries for "peppermint, tops" and "spearmint, tops", and add alphabetically entries for "bushberry, subgroup 13–07B," "caneberry, subgroup 13–07A," "low growing berry subgroup 13–07G, except cranberry," "onion, bulb subgroup 3–07A," and "onion, green, subgroup 3–07B."

■ ii. In the table to paragraph (b) add alphabetically and entry for "avocado."

The added and revised text reads as follows:

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

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Bushberry, subgroup 13–07B ... | 1.0 |
| Caneberry, subgroup 13–07A .. | 1.0 |
| * * * * * | |
| Low growing berry subgroup 13–07G, except cranberry .... | 1.3 |
| * * * * * | |
| Onion, bulb subgroup 3–07A ... | 0.2 |
| Onion, green, subgroup 3–07B | 9.0 |
| * * * * * | |
| Peppermint, tops ..... | 10.0 |
| * * * * * | |
| Spearmint, tops ..... | 10.0 |
| * * * * * | |

(b) * * *

| Commodity | Parts per million | Expiration/ revocation date |
|---|---|---|
| Avocado ..... | 10 | 12/31/13 |
| * * * * * | | |

* * * * *

[FR Doc. 2011–11564 Filed 5–10–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2010–0938; FRL–8872–6]**

### Glyphosate; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation increases the established tolerance for residues of glyphosate in or on corn, field, forage. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 2011, 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–