ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 93

Determining Conformity of Federal Actions to State or Federal Implementation Plans

CFR Correction

■ In Title 40 of the Code of Federal Regulations, parts 87 to 95, revised as of July 1, 2011, on page 579, in § 93.118, paragraph (e)(2) is corrected to read as follows:

§ 93.118 Criteria and procedures: Motor vehicle emissions budget.

* * * * *

(e) * * *

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(2) If EPA has not declared an implementation plan submission's motor vehicle emissions budget(s) adequate for transportation conformity purposes, the budget(s) shall not be used to satisfy the requirements of this section. Consistency with the previously established motor vehicle emissions budget(s) must be demonstrated. If there are no previously approved implementation plans or implementation plan submissions with adequate motor vehicle emissions budgets, the interim emissions tests required by § 93.119 must be satisfied.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0397; FRL–9350–9]

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. This regulation additionally removes an established tolerance on stone fruit crop group 12, as it will be superseded by the new tolerance for stone fruit crop group 12, except plum. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 27, 2012. Objections and requests for hearings must be received on or before August 27, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0397, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email 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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2011–0397 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 August 27, 2012. 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–2011–0397, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket,

along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL–8880–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7855) 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]-1*H*-1,2,4-triazole and its metabolites determined as 2,4,-dichlorobenzoic acid (DCBA) and expressed as parent compound, in or on bean, snap at 0.8 ppm; bean, succulent shelled at 0.15 ppm; bean, dry seed at 0.3 ppm; legume, foliage at 25 ppm; tomato at 2.5 ppm; fruit, citrus, group 10–10 at 8.0 ppm; fruit, stone, group 12, except plum at 7.0 ppm; and plum at 1.0 ppm. The petition also requested that the existing tolerance for stone fruit group 12 at 1.0 ppm be removed upon establishment of the requested tolerances. That notice referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being set for various commodities as well as some commodity definitions. The reason for these changes is explained in Unit IV.C.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 maternally toxic dose, while in rats, developmental toxicity occurred at lower doses than the maternally 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 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 parentally 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 or to female mice. The Agency classified propiconazole as a 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, indicates 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; 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–2011–0397 on pages 43–49 of the document titled ''Propiconazole Human Health Risk Assessment for a Section 3 Registration on Snap beans, Succulent shelled beans, Dry Beans, and Post-harvest use on Tomato, Citrus Fruit, and Stone fruit.''

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 discussed in Unit B of the final rule published in the **Federal Register** of Wednesday, May 11, 2011 (76 FR 27261) (FRL–8873–2).

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 United States 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 nonlinear 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 percent crop treated (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 from post-application dermal exposure. 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 conazole 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, 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–2011–0397, in the document titled ''Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address The Amended Propiconazole Section 3 Registration to Add Uses on Snap beans, succulent shelled beans, dry beans, tomato (post-harvest, citrus (post-harvest), and stone fruit (post-harvest), Difenoconazole, and Flutriafol.''

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 Safety Factor (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.* 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. 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/day, but no evidence of neuropathology from propiconazole administration. Although there was quantitative evidence of increased susceptibility of the young following exposure to propiconazole in the developmental rat study, the Agency determined there is a low degree of concern for this finding and no residual uncertainties because the increased susceptibility was 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.

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. Further, 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. 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.

iii. Although an apparent increased quantitative susceptibility was observed in fetuses and offspring, for the reasons noted in this Unit 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 PAD (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 77% 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 63% 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 130 for toddlers (children 1 to 2 years old), between 110 and 1700 for adults from handler activities and 290 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 74 for toddlers (children 1 to 2 years old). The aggregate MOE is 74, which is less than the target MOE of 100. However, this aggregate MOE is based on 100 PCT and tolerance-level residues concerning food exposure, conservative (protective) assumptions in the ground and surface water modeling, and similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. Additional refinements incorporating average field trial and/or percent crop treated information would result in MOEs well above the target MOE of 100. Therefore, this scenario is 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, a high performance liquid chromatography with ultraviolet detection method (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; email 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 United Nations 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 an MRL for propiconazole for any of the subject commodities in this document.

C. Revisions to Petitioned-For Tolerances

Based on the Agency's evaluation of the residue data submitted with the petition, for all proposed commodities, with the exception of the level for the citrus fruit group 10–10 (8.0 ppm), the Agency has modified the levels for which tolerances are being established. The proposed tolerances for snap bean, succulent shelled beans, stone fruit group 12 except plum, and plum are being reduced to 0.70 ppm, 0.10 ppm, 4.0 ppm, and 0.60 ppm, respectively. The proposed tolerances for foliage of legume foliage, dry bean seed, and tomato are being increased to 30 ppm, 0.40 ppm, and 3.0 ppm, respectively, and the commodity definition for legume foliage is being changed to ''vegetable, foliage of legume, group 7.'' Lastly, a tolerance for citrus oil is being established at 1000 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data

using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.*

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, in or on bean, snap at 0.70 ppm; bean, succulent shelled at 0.10 ppm; vegetable, foliage of legume, group 7 at 30 ppm; bean, dry seed at 0.40 ppm; tomato at 3.0 ppm; fruit, citrus, group 10–10 at 8.0 ppm; fruit, stone, group 12, except plum at 4.0 ppm; plum at 0.60 ppm; and citrus, oil at 1000 ppm. Additionally, the established tolerance is removed for fruit, stone, group 12 at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 (PRA), 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 FFDCA section 408(d), 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.

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 FFDCA section 408(n)(4). 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 (UMRA) (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 (NTTAA), 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: June 8, 2012.

Lois Rossi,

Director, Registration Division.

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. In § 180.434, the table in paragraph (a) is amended as follows:
■ i. Remove the entry ''fruit, stone, group 12'' and
■ ii. Add, alphabetically, the following commodities to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Bean, dry seed	0.40
Bean, snap	0.70
Bean, succulent shelled	0.10
* * * * *	
Citrus, oil	1000
* * * * *	
Fruit, citrus, group 10–10	8.0
Fruit, stone, group 12, except plum	4.0
* * * * *	
Plum	0.60
* * * * *	
Tomato	3.0
* * * * *	
Vegetable, foliage of legume, group 7	30
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0029; FRL–9352–5]

Cyflufenamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyflufenamid in or on multiple commodities which are identified and discussed later in this document. Nippon Soda Co., Ltd., c/o Nisso America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 27, 2012. Objections and requests for