VI. Statutory and Executive Order Reviews

This action, which requires the submission of data in support of tolerances in accordance with FFDCA section 408, is in the form of an order and not a rule (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act (APA), orders are expressly excluded from the definition of a rule (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Because this order is not a ''regulatory action'' as that term is defined in Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose additional burdens that require approval by OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The information collection activities associated with the order requesting data from any party interested in supporting certain tolerances are already approved by OMB under OMB Control No. 2070–0174, and are identified by EPA ICR No. 2288.01. Burden is defined at 5 CFR 1320.3(b). Under the PRA, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does 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.

D. Unfunded Mandates Reform Act; Executive Order 13132: Federalism; and Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This order requests data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including 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 (64 FR 43255, August 10, 1999) and Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538).

E. Executive Orders 13045: Protection of Children From Environmental Health Risks and Safety Risks; Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, and Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

As indicated previously, this action is not a ''regulatory action'' as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) and Executive Order 13211 (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

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 (NTTAA), (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.* does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

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

Dated: December 12, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2012–30617 Filed 12–18–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0772; FRL–9369–5]

Propiconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of propiconazole in or on sugarcane, cane. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 19, 2012. Objections and requests for hearings must be received on or before February 19, 2013, 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–2011–0772, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., 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: Erin Malone, Registration Division (7505P),

Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0253; email address: *malone.erin@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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–2011–0772 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 February 19, 2013. 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 (excluding 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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0772, 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), (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 Tolerance

In the **Federal Register** of November 9, 2011 (Volume 76, FR 69690) (FRL–9325–1), 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 1F7892) by Syngenta Crop Protection, LLC, P.O. Box 18300 Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.434 be amended by establishing tolerances for residues of the fungicide propiconazole, 1H-1,2,4-Triazole, 1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-, and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on sugarcane, cane at 1.0 parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, 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 proposed a different tolerance level for the reasons explained in Unit IV.D.

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.

The toxicology database for propiconazole is adequate for evaluating and characterizing toxicity and selecting endpoints for purposes of this risk assessment. 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. 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. Decreased body weight gain was also seen in subchronic, chronic, developmental and reproductive studies in animal studies. Dogs appeared to be more sensitive to the localized toxicity of propiconazole as manifested by stomach irritations 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 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 (malformations of the lung and kidneys, incomplete ossification of the skull, caudal vertebrae and digits, extra rib (14th rib) and missing sternbrae) were reported at doses that were not maternally toxic.

In the two 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.

Propiconazole was negative for mutagenicity in the *in vitro* BALB/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. It caused proliferative changes in the rat liver with or without pretreatment with an initiator, like phenobarbital, a known liver tumor promoter. Liver enzyme induction studies with propiconazole in mice demonstrated that propiconazole is a strong phenobarbital type inducer of xenobiotic metabolizing enzymes. 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 has classified propiconazole as possible human carcinogen used the reference dose (RfD) approach 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.

Propiconazole has low to moderate toxicity in experimental animals by the oral (Category III), dermal (Category III) and inhalation routes (Category IV), is moderately irritating to the eyes (Category III), minimally irritating to the skin (Category IV) and is a dermal sensitizer.

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 the document titled ''Propiconazole Human Health Risk Assessment for an Amended Section 3 Registration on Sugarcane'' on pages 12–18 in docket ID number EPA–HQ–OPP–2011–0772.

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) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA conducted an acute dietary analysis for propiconazole residues of concern using tolerance levels and 100% crop treated 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's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA conducted a chronic dietary analysis for propiconazole residues of concern using tolerance levels for some commodities, average field trial residues for the remaining commodities, and 100% crop treated 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 is 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.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the

levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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) model, 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 EDWCs are 21.61 ppb for surface water and 0.64 ppb for ground water. For chronic exposures for cancer assessment EDWCs are 13.24 ppb for surface water and 0.64 ppb for groundwater.

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).

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 FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *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–2011–0072, 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 Foliar Use on Sugarcane.''

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 neurotoxicity 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 immunotoxicity. 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.

ii. 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 79% of the aPAD for children 1–2 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 21% of the cPAD for children 1–2 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 and 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 exposure result in aggregate MOEs of 200 for children and adults.

4. *Intermediate-term risk.* The only residential use scenario that will result in potential intermediate term exposure to propiconazole is post application exposure to children from wood treatment (antimicrobial use). The aggregate MOE is 120, which is greater than the target MOE of 100. Therefore, this scenario is not of concern.

5. *Aggregate cancer risk for U.S. population.* Propiconazole is classified as a possible human carcinogen with risk quantitated using a reference dose (RfD) approach, this determination is further explained in section III.C.1.iii. As noted in Unit III.E.2., chronic exposure is below the cPAD.

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 established MRLs for propiconazole *per se* in or on sugarcane, cane at 0.02 ppm. These MRLs are different than the tolerances established for propiconazole in the United States. Codex MRLs apply only to applications by seed piece treatment for sugarcane. The Agency considers seed piece treatment to be a non-food use and did not set a tolerance for that use. In the U.S., application to sugarcane is by foliar spray. This results in higher residues in sugarcane, and thus EPA has established a higher tolerance level for propiconazole on sugarcane than the Codex MRL.

C. Response to Comments

No comments received.

D. Revisions to Petitioned-for Tolerances

The petitioned for tolerance level of 1.0 ppm has been revised to 0.40 ppm. The Organization for Economic Cooperation and Development tolerance calculation procedures were utilized in determining the appropriate tolerance level for the requested amended use. Changes in recommended tolerance are based on the use of these calculation procedures. Additionally, the registrant made a calculation error in choosing the tolerance value.

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), in or on sugarcane, cane at 0.40 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: December 10, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.434 is amended by revising paragraph (a), introductory text, and by adding to the table, alphabetically, an entry for ''sugarcane, cane'' to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of propiconazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those propiconazole residues convertible to 2,4-dichlorobenzoic acid (2,4–DCBA), expressed as the stoichiometric equivalent of propiconazole, in or on the commodity in the table below:

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.4
* * * * *	

* * * * *

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 229

[Docket No. FRA–2009–0094, Notice No. 5]

RIN 2130–AC39

Locomotive Safety Standards

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule; response to petitions for reconsideration.

SUMMARY: This document responds to eight petitions for reconsideration received in relation to FRA's final rule, published on April 9, 2012, which revised the existing regulations containing safety standards for locomotives. In response to the petitions, this document amends and clarifies certain sections of the final rule.

DATES: *Effective Date:* The rule is effective December 19, 2012.

FOR FURTHER INFORMATION CONTACT: Charles Bielitz, Office of Safety Assurance and Compliance, Motive Power & Equipment Division, RRS–14, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC, (202) 493–6314 (email *charles.bielitz@dot.gov*), or Michael Masci, Trial Attorney, Office of Chief Counsel, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC, (202) 493–6037 (email *michael.masci@dot.gov*).

SUPPLEMENTARY INFORMATION:

I. Background

On February 22, 2006, FRA presented, and the Railroad Safety Advisory Committee (RSAC) accepted, the task of reviewing existing locomotive safety needs and recommending consideration of specific actions useful to advance the safety of rail operations. The RSAC established the Locomotive Safety Standards Working Group (Working Group) to handle this task. The Working Group met twelve times between October 30, 2006, and April 16, 2009. The Working Group successfully reached consensus on the following locomotive safety issues: locomotive brake maintenance, pilot height, headlight operation, danger markings placement, load meter settings, reorganization of steam generator requirements, and the establishment locomotive electronics requirements based on industry best practices. The full RSAC voted to recommend the consensus issues to FRA on September 10, 2009, which were incorporated into the notice of proposed rulemaking (NPRM) issued in this proceeding on January 12, 2011. *See* 76 FR 2199. The specific regulatory language recommended by the RSAC was amended slightly for clarity and consistency. FRA independently developed proposals related to remote control locomotives, alerters, and locomotive cab temperature, issues that the Working Group discussed, but ultimately did not reach consensus. *Id.* Many comments were submitted to the public docket in response to the NPRM. The comment period closed on March 14, 2011, and after considering the public comments FRA issued a final rule on April 9, 2012. *See* 77 FR 21312.

In accordance with the provisions of Executive Order (E.O.) 13563, the final rule also modified the existing Locomotive Safety Standards based on what was been learned from FRA's retrospective review of the regulation. E.O. 13563 requires agencies to review existing regulations to identify rules that are overly burdensome, and when possible, modify them to reduce the burden. As a result its retrospective review, FRA determined that reductions in the burdens imposed on the industry could be achieved by modifying the regulations related to periodic locomotive inspection and locomotive headlights. FRA continues to believe that the modifications related to periodic locomotive inspection and locomotive headlights that are contained in the final rule do not reduce railroad safety.

Following publication of the final rule, parties filed petitions seeking FRA's reconsideration of some of the final rule's requirements. Petitioners included: The American Association for Justice (AAJ), the Association of American Railroads (AAR), the Central Railway MFG (CRM), D. P. Honold (Honold), David Lombardi (Lombardi), Paul, Reich & Myers, P.C. (PRM), Wabtec Corporation (Wabtec), and the ZTR Equipment Management (ZTR). The petitions filed by these parties principally relate to the following subject areas: locomotive electronics; locomotive alerters; remote control locomotives; periodic inspection of locomotives; preemption of State law; and, locomotive diesel exhaust. In addition to the issues raised in the petitions, FRA has determined that clarification or modification of the final rule is needed with respect to placement of the air flow method (AFM) indicator calibration date on the Form 6180–49A; the duration of the remote control locomotive (RCL) audio indication; and the date by which railroads and vendors must notify FRA regarding electronic locomotive control products that are under development. This document responds to all the issues raised in the petitions for reconsideration and clarifies and amends certain sections of the final rule in response to some of the issues raised in the petitions and clarifies certain other final rule requirements.

II. Issues Raised by Petitions for Reconsideration

In response to the petitions for reconsideration, FRA is modifying the Locomotive Safety Standards final rule related to: § 229.303, Applicability of the Locomotive Electronics; § 229.305, Definition of New or Next-Generation Locomotive; § 229.140(d), Locomotive Alerters; § 229.15(b)(4), RCL Conditioning Run; § 229.15(a)(12)(xii), RCL Audio Indication; and, § 229.23(b)(2) Mechanical Inspection. FRA respectfully refers interested parties to the agency's section-by-section analysis of the final rule and the NPRM for a full discussion of those aspects of the rulemaking that remain unchanged. *See* 76 FR 2199 and 77 FR 21312. The following is a discussion of each of the issues raised in various petitions for reconsideration. These discussions should be read in conjunction with the specific section-by-section analysis that identifies the specific modifications or clarifications being made to the text of the final rule.

A. Locomotive Electronics

Several of the petitions request clarification or revision of certain requirements related to locomotive electronics. FRA's responses to each of the requests that were made in the petitions are provided in this discussion and the specific regulatory changes or modifications are discussed in the section-by-section analysis. For discussion purposes, the responses have been grouped into seven general categories: (1) Responsibility and Applicability, (2) Definitions, (3) Safety Analysis, (4) Appendix F, (5)