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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0685; FRL-9940-01]

Propiconazole on Tea; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of propiconazole in or on tea. The Tea Association of the U.S.A., Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2015-0685, 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), West William Jefferson Clinton 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@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://www.ecfr.gov/cgi-bin/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-2015-0685 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 Confidential Business Information (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-2015-0685, 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 CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., N.W., Washington, DC 2 0460-0001.

• *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.html*.

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 October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8300) by the Tea Association of the U.S.A., Inc., 362 5th Avenue, Suite 801, New York, New York, 10001. The petition requested that 40 CFR 180.434 be amended by establishing a tolerance for residues of the fungicide propiconazole in or on tea at 4.0 parts per million (ppm). That document referenced a summary of the petition prepared by the Tea Association of the U.S.A., Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. No comments concerning this tolerance action were received.

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 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 milligram/kilogram/day (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 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.

The acute neurotoxicity study produced severe clinical signs of toxicity (decreased activity, cold, pale, decreased motor activity, etc.) in rats at the high dose of 300 milligram/kilogram (mg/kg). Limited clinical signs (piloerection, diarrhea, tip toe gait) were observed in the mid-dose animals (100 mg/kg), while no treatment related signs were observed at 30 mg/kg. The current acute dietary assessment for the general population is based on the no-observed-adverse-effect-level (NOAEL) of 30 mg/kg from the acute neurotoxicity study. A subchronic neurotoxicity study in rats did not produce neurotoxic signs at the highest dose tested that was associated with decreased body weight.

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 but 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 NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document, "Propiconazole Human Health Risk Assessment for the New Use of Propiconazole on Imported Tea" at pp. 41-46 in docket ID number EPA-HQ-OPP-2015-0685.

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 the NOAEL and the LOAEL are identified. 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 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 Table 1.

Table 1.--Summary of Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

	Factors		
Acute dietary (Females 13-50 years of age)	NOAEL = 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.3 mg/kg/day aPAD = 0.3 mg/kg/day	Developmental Study - Rat MRID 40425001 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 UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.3 mg/kg/day aPAD = 0.3 mg/kg/day	Acute neurotoxicity study Rat MRID 46604601 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 (Adult Males and Females 50+ yrs)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day cPAD = 0.1 mg/kg/day	24-month carcinogenicity study on CD-1 mice. MRID 00129918 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 short-term (1 to 30 days)	NOAEL= 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF= 1x	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Acute Neurotoxicity Study-Rats MRID 46604601 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 intermediate-term (1 to 6 months)	NOAEL= 10 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF= 1x	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	24 Month carcinogenicity Study - Mice MRID 00129918 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)
Dermal Short Term (1-30 days)	NOAEL= 30 mg/kg/day UF_A= 10x UF_H= 10x	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Acute Neurotoxicity Study-Rats MRID 46604601 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)
Dermal Intermediate Term (1-6 months)	NOAEL= 10 mg/kg/day UF_A= 10x UF_H= 10x	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	24 Month carcinogenicity Study - Mice MRID 00129918 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)	NOAEL= 30 mg/kg/day UF_A = 10x	Occupational LOC for MOE = 100	Acute Neurotoxicity Study-Rats MRID 46604601

	UF_H = 10x		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)
Inhalation Intermediate-Term (1 to 6 months)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x	Occupational LOC for MOE = 100	24 Month carcinogenicity Study - Mice MRID 00129918 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)
Cancer (all routes-oral, dermal, inhalation)	Classification: Group C, possible human carcinogen, RfD approach for risk characterization		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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 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 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 average field trial residues, tolerance levels and 100 PCT for all existing and proposed uses.

iii. *Cancer*. 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*.

The Agency does not expect any additional residues of propiconazole in drinking water as a result of the imported tea use. Therefore, the Agency is relying on the previous drinking water assessment for assessing propiconazole tolerances. The previously assessed turf EDWCs are approximately one order of magnitude higher and more protective than the EDWCs for the new use.

Based on the Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model – Ground Water (PRZM-GW) models, the estimated drinking water concentrations (EDWCs) of propiconazole for acute exposures are estimated to be 35.2 parts per billion (ppb) for surface water and 37.9 ppb for ground water, and for chronic exposures are estimated to be 18.6 ppb for surface water and 35.1 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 37.9 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 35.1 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).

Although there are no proposed residential uses associated with the imported tea use, propiconazole is currently registered for the following uses that could result in residential exposures: Turf, landscapes, ornamentals, and in paint. The highest incidental oral and dermal exposure scenarios are expected from residential use on turf. EPA assessed short-term risk to toddlers from incidental oral and dermal exposure as well as from post-application dermal exposure. 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 wood treatment, which the Agency assumes may result in dermal and incidental oral post-application exposures to children. 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 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 rand 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 efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Propiconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole 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). The Agency retained a 3X for the LOAEL to NOAEL safety factor when the reproduction study was used. In addition, the Agency retained a 10X for the lack of studies including a DNT. 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 ID Number EPA-HQ-OPP-2005-0497.

An updated aggregate human health risk assessment for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was completed on April 9, 2015, in association with the registration requests for several triazole fungicides (propiconazole, difenoconazole, and flutriafol). That analysis concluded that risk estimates were below the Agency's level of concern for all population groups. This assessment may be found on *http://www.regulations.gov* by searching for the following title and docket ID number: "Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations For Use of Propiconazole on Tea, Dill, Mustard Greens, Radish, and Watercress; Use of Difenoconazole on Globe Artichoke, Ginseng and Greenhouse Grown Cucumbers and Conversion of the Established Foliar Uses/Tolerances for Stone Fruit and Tree Nut Crop Groups to Fruit, Stone, Group 12-12 and the Nut, Tree, Group 14-12.; and Use of Flutriafol on Hops" located under docket ID number EPA-HQ-OPP-2015-0685.

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 Food Quality Protection Act Safety Factor (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.* 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. Neither quantitative nor qualitative evidence of increased susceptibility was observed *in utero* or post-natally in either the rabbit developmental or 2-generation reproduction rat 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 clinical toxicity at the high dose of 300 mg/kg, 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.

ii. Other than the mild effects seen at 300 mg/kg in the acute neurotoxicity study, neurotoxicity and neurobehavioral effects were not seen in the propiconazole toxicity database. The liver, not the nervous system, is the primary target organ of propiconazole toxicity.

iii. Although an apparent increased quantitative susceptibility was observed in fetuses and offspring, for 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 acute dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues, while the chronic used a combination of tolerance-level residues and reliable data on average field trial residues and 100 PCT. 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 post-application exposure of children as well as incidental oral exposure of toddlers. A turf transferable residue study is unavailable but being requested from the registrant for registration review of propiconazole. In all probability this study will reduce exposure estimates for both the incidental oral and post-application exposure to children. 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 85% 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 24% 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 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 from post-application activities (the highest exposure scenario) of 200 for adults and 96 for children 1-2 years old. This assessment is considered conservative since the short-term endpoints are based on a conservative LOAEL that is 3x higher than the NOAEL. Therefore, the true NOAEL is likely higher and would result in MOEs greater than 100. Further, the assessment is based on a combination of tolerance-level residues and reliable data on average field-trial residues and 100 PCT, conservative assumptions in the ground and surface water modeling, and conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. Additionally, the assessment could be further refined by using PCT

estimates and anticipated residues for all crops. Although dietary (food and water) is not the aggregate exposure driver, incorporating PCT would likely increase the aggregate MOE further above 100. For example, the Agency's latest PCT figures indicate that the highest average PCT reported for propiconazole residues on crops is 55%, which is much less than the 100 PCT the Agency used for all commodities in its assessment. Accordingly, even though this MOE for children 1-2 years old is slightly below the target MOE of 100, the difference is small and is more than offset by the conservative exposure assumptions and therefore 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 aggregate MOEs of 110 for children 1-2 years old. Because EPA's level of concern for propiconazole is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the discussion in Unit III.A., EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk. As there is no chronic risk of concern, EPA does not expect any cancer risk to the U.S. population from aggregate exposure to propiconazole.

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 on tea.

V. Conclusion

Therefore, tolerances are established for residues of propiconazole, including its metabolites and degradates, in or on tea at 4.0 ppm. As there are currently no U.S. registrations for propiconazole for use on tea, EPA is adding a footnote to the regulation to clarify that fact.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action 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. 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 (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 16, 2015.

Susan Lewis,

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. In § 180.434:

a. Redesignate paragraph (a) as paragraph (a)(1).

b. Add a new paragraph (a)(2).

The amendments read as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for 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 propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, in or on the commodity.

Commodity	Parts per million
Tea[1]	4.0

[1] There are no United States registrations for use of propiconazole on tea as of [insert date of publication in the **Federal Register**].

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[FR Doc. 2015-32328 Filed: 12/23/2015 8:45 am; Publication Date: 12/24/2015]