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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0695; FRL-9955-74]

Tetraconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tetraconazole in or on vegetable, fruiting (Crop Group 8-10) at 0.30 parts per million (ppm) and vegetable, cucurbit (Crop Group 9) at 0.15 ppm and revises the tolerance for residues on beet, sugar, root; beet, sugar, dried pulp; and beet, sugar molasses. Isagro S.P.A. (d/b/a Isagro USA, 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-2015-0695, 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: Michael Goodis, 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-2015-0695 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-2015-0695, 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., 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.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 March 16, 2016 (81 FR 14030) (FRL-9942-86), 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 5F8400) by Isagro S.P.A. (d/b/a Isagro USA, Inc.), 430 Davis Drive, Suite 240, Morrisville, NC 27560. That document provided notice that the petition requested that 40 CFR 180.557 be amended by establishing tolerances for residues of the fungicide tetraconazole, in or on Vegetable, Fruiting (Crop Group 8-10) at 0.30 parts per million (ppm) and Vegetable, Cucurbit (Crop Group 9) at 0.15 ppm. In the **Federal Register** of August 29, 2016 (81 FR 59165) (FRL-9950-22), EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the remainder of that petition requesting revision of the existing tolerances for tetraconazole residues on beet, sugar, root to 0.15 ppm; beet, sugar, dried pulp to 0.20 ppm; and beet, sugar molasses to 0.25 ppm. Those documents referenced a summary of the petition prepared by Isagro S.P.A. (d/b/a Isagro USA, Inc.), the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to these notices of filing.

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 tetraconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tetraconazole 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 liver and kidney are the primary target organs of tetraconazole in all species in oral toxicity studies of sub-chronic and chronic durations. Following long-term oral exposure, tetraconazole caused liver tumors in mice in both sexes. In the acute neurotoxicity study, loss of motor activity in both sexes, and clinical signs including hunched posture, decreased defecation, and/or red or yellow material on various body surfaces were observed in females. There was no evidence of immunotoxicity or neurotoxicity following sub-chronic exposure. There were no systemic effects observed in the 21-day dermal toxicity study up to the highest dose tested. Tetraconazole did not show evidence of mutagenicity in *in vitro* or *in vivo* studies.

Oral rat and rabbit developmental toxicity studies showed no increased susceptibility of fetuses to tetraconazole. Maternal toxicity (decreased body weight gain and food consumption, increased water intake and increased liver and kidney weights) and developmental toxicity (increased incidence of small fetuses, supernumerary ribs and hydroureter and hydronephrosis) occurred at the same dose level in the rat study. No developmental toxicity was seen in the rabbit study, whereas maternal toxicity (decreased body weight gain) was noted at the highest dose tested. Similarly, there was no evidence of increased susceptibility of offspring in the 2-generation rat reproduction study.

In contrast to the oral studies where the most sensitive effects were in the liver and kidney, inhalation exposure of tetraconazole to rats resulted in portal-of-entry effects including; squamous cell metaplasia of the laryngeal mucous, mono-nuclear cell infiltration, goblet cell hyperplasia, hypertrophy of the nasal cavity and nasopharyngeal duct, and follicular hypertrophy of the thyroid in males. At the highest concentration tested, there were treatment-related increases in absolute lung weights in both sexes.

Since the last risk assessment, a 28-day *in vivo* cancer mode-of-action study in mice was submitted and reviewed leading to the re-evaluation of tetraconazole's cancer potential and classification. EPA has now classified tetraconazole as "Not likely to be carcinogenic to humans at levels that do not cause increased cell proliferation in the liver." Quantification of carcinogenic potential is not required.

Specific information on the studies received and the nature of the adverse effects caused by tetraconazole 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 document "Human Health Risk Assessment for the Section 3 Registration for Application to Fruiting Vegetables (Crop Group 8) and Cucurbit Vegetables (Crop Group 9) and Amending the Sugar Beet Application Scenario and Tolerance" in docket ID number EPA-HQ-OPP-2015-0695.

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 tetraconazole used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 22.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.225 mg/kg/day aPAD = 0.225 mg/kg/day	Developmental toxicity study (rat). Developmental LOAEL = 100 mg/kg/day based on increased incidence of small fetuses, supernumerary ribs, and hydroureter and hydronephrosis.
Acute dietary (General population including infants and children)	NOAEL = 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute neurotoxicity (rat). LOAEL = 200 mg/kg/day due to decreased motor activity on day 0 in both sexes, and clinical signs in females including hunched posture, decreased defecation, and/or red or yellow material on various body surfaces.
Chronic dietary (All populations)	NOAEL= 0.73 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0073 mg/kg/day cPAD = 0.0073 mg/kg/day	Chronic oral toxicity (dog). LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on absolute and relative kidney weights and histopathological changes in the male kidney.
Dermal short-term	No hazard identified and therefore quantification is not required. There ar		

(1to 30 days) and dermal intermediate-term (1 to 6 months)	no developmental concerns via the dermal route and no systemic toxicity was seen following dermal exposure.		
Inhalation short-term (1 to 30 days) and inhalation intermediate-term (1 to 6 months)	*NOAEL not established UF_A = 3x UF_H = 10x UF_L = 10x	LOC= 300	28-Day Inhalation toxicity – rat. LOAEL = 1.3 mg/kg/day (0.0048 mg/kg/L, 0.0548 mg/L (rat)) for males and females, based on squamous cell metaplasia of laryngeal mucous, mononuclear cell infiltration, goblet hyperplasi and hypertrophy of nasal cavity and nasopharyngeal duct and follicular hypertrophy of thyroid i males.
Cancer (Oral, dermal, inhalation)	Classification: **"Not likely to be carcinogenic to humans at levels that do not cause increased cell proliferation in the liver."** Quantification of carcinogenic potential is not required (TXR #0056628, J. Rowland *et al.*, 2-Apr-2013).		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to tetraconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tetraconazole tolerances in 40 CFR 180.557. EPA assessed dietary exposures from tetraconazole 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 tetraconazole. 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 utilized the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID, Version 3.16 default processing factors and tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA dietary survey conducted from 2003 to 2008. As to residue levels in food, EPA utilized residue data from field trials and feeding studies to obtain average residues and assumed the PCT figures provided below. Empirically derived processing factors were used in these assessments when available

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that tetraconazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated Residues 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.

100 PCT were assumed for all food commodities for the acute analysis. The chronic analysis used percent crop treated for new uses (PCTn).

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Sugarbeet, 70%; field corn, 9%; and soybean, 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public

and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tetraconazole may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tetraconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tetraconazole. 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 Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of tetraconazole for acute exposures are estimated to be 11 parts per billion (ppb) for surface water and 120 ppb for ground water. The estimated EDWCs of tetraconazole for chronic exposures for non-cancer assessments are estimated to be 5.5 ppb for surface water and 118 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 120 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration value of 118 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). Tetraconazole is not registered for any specific use patterns that would result in residential exposure.

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."

Tetraconazole 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 the case of 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 tetraconazole shares a common mechanism of toxicity with any other conazole pesticide, and EPA is not following a cumulative risk approach for this tolerance action. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

Tetraconazole 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 tetraconazole, 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 developmental neurotoxicity (DNT) study. 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.

An updated dietary exposure and risk analysis 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 registration requests for several triazole fungicides, propiconazole, difenoconazole, and flutriafol. The requested new uses of tetraconazole did not significantly change the dietary exposure estimates for free triazole or conjugated triazoles. Therefore, an updated dietary exposure analysis was not conducted. The April 9, 2015 update for triazoles may be found in docket ID number EPA-HQ-OPP-2014-0788.

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*. There are no residual uncertainties for pre- and post-natal toxicity. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* exposure to tetraconazole. There is evidence of increased qualitative susceptibility to fetuses in the rat prenatal developmental toxicity study (increased incidences of supernumerary ribs, and hydroureter and hydronephrosis). The LOC is low however because the fetal effects were seen at the same dose as the maternal effects, a clear NOAEL was established, the developmental NOAEL from a study in rats is being used as the POD for the acute dietary endpoint (females 13-49 years of age), and there were no developmental effects in the rabbit study. There is also no evidence of increased quantitative or qualitative susceptibility to offspring in the two-generation reproduction study.

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 tetraconazole is complete.

ii. There were effects indicative of neurotoxicity in the acute neurotoxicity study in rats. However, the level of concern (LOC) is low since a clear NOAEL was established

which is being used in endpoint selection. Furthermore, the dose at which these neurotoxic effects were observed is 2 to 100-fold higher than the primary effects seen in the other studies in the database (liver and kidney). After preliminary review, a sub-chronic neurotoxicity study has shown no evidence for neurotoxicity. Finally, there are no other signs of neurotoxicity in any of the other studies in the database. Therefore, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that tetraconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There is evidence of increased qualitative susceptibility to fetuses in the rat prenatal developmental toxicity study (increased incidences of supernumerary ribs, and hydroureter and hydronephrosis). The LOC is low however because:

- the fetal effects were seen at the same dose as the maternal effects,
- a clear NOAEL was established,
- the developmental NOAEL from a study in rats is being used as the POD for the acute dietary endpoint (females 13-49 years of age), and
- there were no developmental effects in the rabbit study. There is also no evidence of increased quantitative or qualitative susceptibility to offspring in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. There are no residual uncertainties identified for pre- and post-natal toxicity in the exposure databases. Tolerance-level residues, 100 PCT, and modeled water estimates

were incorporated into the acute dietary exposure analysis. Therefore, the acute analysis is highly conservative. The chronic and cancer dietary exposure analyses utilized empirical processing factors, average field trial residues, average residues from the feeding studies, percent crop treated estimates, and modeled drinking water estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tetraconazole in drinking water. These assessments will not underestimate the exposure and risks posed by tetraconazole.

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 tetraconazole will occupy 4.6% of the aPAD for all infants (<1 year 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 tetraconazole from food and water will utilize 92% of the cPAD for all infants (<1 year old) the population group receiving the greatest exposure. There are no residential uses for tetraconazole

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). A short-term adverse effect was identified; however, tetraconazole is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for tetraconazole**.**

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). An intermediate-term adverse effect was identified; however**,** tetraconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for tetraconazole**.**

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has concluded that tetraconazole is "Not likely to be carcinogenic to humans at levels that

do not cause increased cell proliferation in the liver." Because the chronic endpoint is protective of cell proliferation in the liver, there is not likely to be a cancer risk from exposure to tetraconazole.

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 tetraconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available to enforce the currently established tetraconazole plant and livestock tolerances (D280006, W. Donovan, 10-Jan-2002, D267481, 12-Oct-2000; D278236, W. Donovan, 22-Oct-2001). Isagro has also submitted adequate method validation and independent laboratory validation (ILV) data which indicates that the QuEChERS multi-residue method L00.00-115 (48135104.der) is capable of quantifying tetraconazole residues in/on a variety of fruit, cereal grain, root, oilseed, and livestock commodities.

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 a MRL for tetraconazole.

C. Revisions to Petitioned-For Tolerances

EPA revised two commodity definitions for vegetable, fruiting, group 8-10 and vegetable, cucurbit, group 9.

V. Conclusion

Therefore, tolerances are established for residues of tetraconazole, in or on vegetable, fruiting, group 8-10 at 0.30 ppm and vegetable, cucurbit, group 9 at 0.15 ppm and revised for beet, sugar, root; beet, sugar, dried pulp; and beet, sugar, molasses.

VI. Statutory and Executive Order Reviews

This action 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 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 14, 2016.

Daniel J. Rosenblatt,

Acting 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 the table in paragraph (a) of § 180.557:

a. Revise the commodities of "Beet, sugar, dried pulp", "Beet, sugar, molasses", and "Beet, sugar, root"; and

b. Add alphabetically the commodities of "Vegetable, cucurbit, group 9" and "Vegetable, fruiting, group 8-10" to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
*******	
Beet, sugar, dried pulp	0.20
Beet, sugar, molasses	0.25
Beet, sugar, root	0.15
*******	
Vegetable, cucurbit, group 9	0.15
Vegetable, fruiting, group 8-10	0.30

* * * * *

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