ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0094; FRL–10001–27]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes certain established tebuconazole tolerances that are superseded by new tolerances established in this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 12, 2019. Objections and requests for hearings must be received on or before January 13, 2020, 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–2018–0094, 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 Publishing 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–2018–0094 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 January 13, 2020. 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–2018–0094, 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 July 24, 2018 (83 FR 34968) (FRL–9980–31), 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 7E8648) by IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road, East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, including its metabolites and degradates, determined by measuring only alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on *Brassica,* leafy greens, subgroup 4–16B, except watercress at 2.5 parts per million (ppm); Cottonseed, subgroup 20C at 2.0 ppm; Fruit, pome, group 11–10 at 1.0 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 6.0 ppm; Fruit, stone, group 12–12, except cherry at 1.0 ppm; Nut, tree, group 14–12 at 0.05 ppm; Sunflower, subgroup 20B at 0.1 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 1.6 ppm; and Watercress at 9.0 ppm.

Upon establishment of the above tolerances, the petitioner requested that the following established tolerances be removed from 40 CFR 180.474: *Brassica,* leafy greens, subgroup 5B at 2.5 ppm; Cotton, undelinted seed at 2.0 ppm; Fruit, pome, group 11 at 0.05 ppm; Fruit, stone, group 12, except cherry at 1.0 ppm; Grape at 5.0 ppm; Lychee at 1.6 ppm; Nut, tree, group 14 at 0.05 ppm; Peach at 1.0 ppm; Pistachio at 0.05 ppm; Plum, pre- and post-harvest at 1.0 ppm; and Sunflower, seed at 0.05 ppm, as they are superseded by this regulation. That document referenced a summary of the petition prepared by Makhteshim Agan of North America (''ADAMA''), 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 is establishing tolerances that vary slightly from what was requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tebuconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tebuconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity database 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.

A summary of the toxicological profile for tebuconazole can be found in the final rule published in the **Federal Register** on November 15, 2013 (78 FR 68741) (FRL–9392–1). Specific information on the studies received and the nature of the adverse effects caused by tebuconazole 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, ''Tebuconazole: Human Health Aggregate Risk Assessment for Establishment of Registrations and a Permanent Tolerance for Residues in/on Watercress, Add Greenhouse Tomato to Label and Crop Group Conversions/Expansions to *Brassica* Leafy Greens, Subgroup 4–16B, Except Watercress; Cottonseed, Subgroup 20C; Pome Fruit, Group 11–10, Stone Fruit, Group 12–12, Except Cherry; Small Vine Climbing Fruit, Except Fuzzy Kiwifruit, Subgroup 13–07F; Tropical and Subtropical Small Fruit, Inedible Peel, Subgroup 24A, Tree Nut, Group 14–12 and Sunflower, Subgroup 20B'' at pages 45–48 in docket ID number EPA–HQ–OPP–2018–0094.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for tebuconazole used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of November 15, 2013 (78 FR 68741) (FRL–9392–1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tebuconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tebuconazole tolerances in 40 CFR 180.474. EPA assessed dietary exposures from tebuconazole 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 tebuconazole. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, a partially refined acute probabilistic dietary exposure assessment was conducted for all existing and proposed uses of tebuconazole. For the acute assessment, anticipated residues for grapes, grape juice, tree nuts, pome fruits, fruiting vegetables, cucurbit vegetables, banana, plantain, asparagus, hops, bulb onion and green onion subgroups, lychee, *Brassica* leafy green subgroup, mango, livestock commodities, and stone fruit were used. Data for peach, grapes, and oranges were derived using the latest USDA Pesticide Data Program (PDP) monitoring data. Anticipated residues for all other registered and proposed food commodities were based on field trial data or feeding studies. Anticipated residues for all current uses were further refined using percent crop treated (PCT) data where available. Percentage of imported orange juice and oranges were also provided. DEEM 2018 default and some empirical processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM–FCID, Version 3.16, which uses the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, estimates from PDP data (mean residue levels) and average residues from field trials were used. Mean residue levels from PDP were used for apple, arugula, asparagus, snap bean, black bean, broad been, cowpea, great northern bean, kidney bean, lima bean, mung bean, navy bean, pinto bean, cantaloupe, cherry, chickpea, chives, fresh leaves, crabapple, garden and upland cress, cucumber, garden beet roots, goji berry, grape, raisin, grape juice, guar seed,

honeydew melon, leeks, lentil seed, loquat, milk, nectarine, mustard greens, oats, oat bran, green onion, oranges, orange juice, orange peel, peach, peach baby food, canned peach, peanut, peanut butter, pear, bell peppers, non-bell peppers, plum, rape greens, shallot bulb, shallot fresh leaves, soybean, summer squash, winter squash, tomatillo, tomato, tree tomato, watermelon, wheat grain and flour. In some cases, data were translated from representative commodities of their crop group.

iii. *Cancer.* Based on the data cited in Unit III.A. of the previously referenced document, **Federal Register**, November 15, 2013 (78 FR 68741) (FRL–9392–1), EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to tebuconazole. The chronic risk assessment or RfD approach is considered to be protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required.

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.

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, and 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.

For the acute dietary risk assessment, the Agency used the maximum PCT estimates for the following crops that are currently registered for tebuconazole: almonds 15%; apples 2.5%; apricots 20%; asparagus 30%; barley 2.5%; beans, green 2.5%; cantaloupes 10%; cherries 45%; corn 2.5%; cotton 2.5%; cucumbers 2.5%; dry beans/peas 5%; garlic 95%; grapes 40%; nectarines 30%; oats 2.5%; onions 5%; peaches 25%; peanuts 65%; pears 5%; pecans 25%; pistachios 15%; plums/prunes 5%; pumpkins 10%; soybeans 2.5%; squash 5%; sweet corn 5%; walnut 5%, and wheat 20%.

In the chronic dietary risk assessment, EPA used the average percent crop treated estimates for the following crops that are currently registered for tebuconazole: almonds 5%; apples 2.5%; apricots 10%; asparagus 5%; barley 2.5%; beans, green 1%; cantaloupes 2.5%; cherries 25%; corn 1%; cotton 1%; cucumbers 1%; dry beans/peas 2.5%; garlic 65%; grapes 25%; nectarines 20%; oats 2.5%; onions 5%; peaches 10%; peanuts 45%; pears 5%; pecans 10%; pistachios 5%; plums/prunes 2.5%; pumpkins 2.5%; soybeans 1%; squash 2.5%; sweet corn 2.5%; walnuts 2.5%; watermelons 15%; and wheat 15%.

The following estimated percent import estimates for the import oranges were used: For acute risk, orange 16%; and orange juice 58%; and for chronic risk: orange 12%; orange juice 46%. For all other crops not listed above, EPA assumed 100 PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% 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 tebuconazole 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 tebuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tebuconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the EDWCs of tebuconazole for acute exposures are estimated to be 87.7 parts per billion (ppb) for surface water and 1.56 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 68.8 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, a

distribution of 30-year daily surface water concentration was estimated for the EDWCs of tebuconazole. For chronic dietary risk assessment, the water concentration of value 68.8 ppb was used to assess the contribution to drinking water. The Agency is relying on the drinking water residues used in the dietary risk assessment previously provided, ''Drinking water and ecological risk for new use of tebuconazole/fluoxastrobin combination for turf and ornamental use'', which can be found at *http://regulations.gov,* under docket ID number EPA–HQ–OPP–2013–0653–0007.

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).

Tebuconazole is currently registered for the following uses that could result in residential exposures: Golf course turf, flower gardens, trees and ornamentals, and pressure treated wood that were assessed previously. No new residential uses of tebuconazole are associated with this petition.

EPA assessed residential exposure using the following assumptions: For residential handlers, exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. For post-application exposures, the Agency assessed residential dermal and incidental oral post-application exposure for adults and children golfing, working in gardens, and performing physical activities on pressure-treated wood after application of tebuconazole as scenarios where homeowners may receive exposure to tebuconazole residues. Post-application exposure is expected to be short-term in duration. For assessment of both handler and post-application exposures, dermal and inhalation exposures were combined since the same endpoint and point of departure (POD) are used for both routes of exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticide science-and-assessing-pesticide-risks/standard-operating-procedures residential-pesticide.*

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tebuconazole and any other substances. Previously, HED concluded that there are no conclusive data that the conazoles share a common mechanism of toxicity; however, EPA is in the process of re-examining these data as part of registration review. Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole and its acid-conjugated metabolites do not contribute to the toxicity of the parent conazole fungicides (triazoles). Tebuconazole does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that tebuconazole has a common mechanism of toxicity with other substances. 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. The most recent assessment is dated August 8, 2018, titled, ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations for Use of Prothioconazole and Tebuconazole.'' EPA concluded that the current uses of tebuconazole do not significantly change the results of that aggregate human health risk assessment. Therefore, the aggregate exposure to the triazole metabolites remains below EPA's level of concern.

D. Safety Factor for Infants and Children

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.

EPA has determined that reliable data support reducing the FQPA SF to 3X, as that factor will be safe for infants and children. Detailed discussions of the Agency's FQPA SF rationale can be found in the final rule published in the **Federal Register** on May 16, 2018 (83 FR 22995) (FRL9976–62), which also established tolerances for tebuconazole in/on various food commodities, and in the risk assessment document for the subject rulemaking found in docket ID number EPA–HQ–OPP–2018–0094 at *http://www.regulations.gov,* ''Tebuconazole: Human Health Aggregate Risk Assessment for Establishment of Registrations and a Permanent Tolerance for Residues in/on Watercress, Add Greenhouse Tomato to Label and Crop Group Conversions/Expansions to *Brassica* Leafy Greens, Subgroup 4–16B, Except Watercress; Cottonseed, Subgroup 20C; Pome Fruit, Group 11–10, Stone Fruit, Group 12–12, Except Cherry; Small Vine Climbing Fruit, Except Fuzzy Kiwifruit, Subgroup 13–07F; Tropical and Subtropical Small Fruit, Inedible Peel, Subgroup 24A, Tree Nut, Group 14–12 and Sunflower, Subgroup 20B''.

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.* The acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tebuconazole will occupy 94% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* There are no residential use patterns that result in chronic residential exposure to residues of tebuconazole. Dietary (food and water) route of exposure alone is

relevant to chronic aggregate risk. The combined chronic dietary exposure from food and drinking water is estimated to be 5.7% of the cPAD for the general U.S. population and 14% of the cPAD for all infants, the population subgroup with the highest estimated chronic dietary exposure to tebuconazole.

3. *Short- and Intermediate-term risks.* Short- and intermediate-term aggregate exposure take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For short-term aggregate risk assessments, a deterministic approach was used in which point estimates of exposure from each source are added together; and each of the point estimates used are in turn deterministic. Dietary exposure estimates use point estimates for food and drinking water residues (anticipated residues based on PDP data, field trial data, tolerance level residues, and PCT) and the residential scenarios also employ point estimates (central to high-end values considered protective). Exposures are assumed to occur over the same time frame, and no use frequency data are considered. There is the potential for residential exposure to co-occur with background dietary exposure over the short-term (1–30 days), whereas co-occurring intermediate exposures (1–6 months) are less likely. However, since the POD employed for both durations are the same, the aggregate assessments address both exposure durations.

EPA reassessed residential post-application exposure from registered golf course use and the impact on aggregate risk using the TTR study. Using data from the TTR study for non-irrigated and irrigated plots, EPA calculated residential post-application exposure and risk estimates for population subgroups including; adults, youths 11 to <16 years old, and children 6 to <11 years old. For these age groups, the activity of golfing results in MOEs for irrigated turf ranging from 2,100 in youth 6 to less than 11 years old to 2,500 in adults. For non-irrigated turf, for the same population subgroups, MOEs range from 560 to 660. Under the golfing scenario for both irrigated and non-irrigated turf and for each population subgroup, resulting MOEs were all greater than the level of concern (LOC) of 300. Residential exposures and risk estimates from gardens, trees, ornamentals, and pressure treated wood were unchanged from the most recent previous assessments which reported MOEs greater than EPA's LOC of 300.

4. *Aggregate cancer risk for U.S. population.* Based on the Agency's determination that the chronic risk assessment will be protective of any cancer effects, a separate quantitative cancer risk assessment was not conducted. Because there is no chronic risk of concern from aggregate exposure to tebuconazole, the Agency concludes that aggregate exposure to tebuconazole will not result in cancer risks of concern.

5. *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 tebuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate gas chromatographic methods with nitrogen/phosphorus detection (GC/NPD) methods are available for enforcing tolerances in plant and livestock commodities. These methods have undergone an independent laboratory validation and a petition method validation (PMV). The methods are available in the residue analytical method index on EPA's website and may also 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. Tolerances established in this rulemaking are harmonized with established Codex MRLs, except for apricot. The Codex MRL for apricot is 2 ppm. EPA is establishing a tolerance of 1 ppm for plum subgroup 12–12C, which harmonizes with the Codex MRLs for eight commodities in that subgroup other than apricot.

C. Revisions to Petitioned-For Tolerances

Instead of establishing a tolerance for Fruit, stone, group 12–12, except cherry, EPA is establishing tolerances for the subgroups in group 12–12 to harmonize with the relevant Codex MRLs. The Codex MRLs for nectarine and peach are 2 ppm, so EPA is establishing a U.S. tolerance for peach, subgroup 12–12B at 2 ppm. EPA is establishing a U.S. tolerance of 1 ppm for plum, subgroup 12–12C, which is harmonized with the Codex MRLs for eight commodities in that subgroup. In addition, several tolerances are being established at different levels than requested to conform with EPA rounding class practice by removing the trailing zero.

V. Conclusion

Therefore, tolerances are established for residues of tebuconazole, including its metabolites and degradates, determined by measuring only alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on *Brassica,* leafy greens, subgroup 4–16B, except watercress at 2.5 ppm; Cottonseed, subgroup 20C at 2 ppm; Fruit, pome, group 11–10 at 1 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 6 ppm; Nut, tree, group 14–12 at 0.05; Peach subgroup 12–12B at 2 ppm; Plum subgroup 12–12C at 1 ppm; Sunflower, subgroup 20B at 0.1 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 1.6 ppm; and Watercress at 9 ppm. In addition, EPA is removing the following tolerances from paragraph (a)(1) because they are superseded by the new tolerances being established in this rulemaking: *Brassica,* leafy greens, subgroup 5B at 2.5 ppm; Cotton, undelinted seed at 2.0 ppm; Fruit, pome, group 11 at 0.05 ppm; Fruit, stone, group 12, except cherry at 1.0 ppm; Grape at 5.0 ppm; Lychee at 1.6 ppm; Nut, tree, group 14 at 0.05 ppm; Peach at 1.0 ppm; Pistachio at 0.05 ppm; Plum, pre- and post-harvest at 1.0 ppm; and Sunflower, seed at 0.05 ppm.

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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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 tolerances 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: October 25, 2019.

Daniel 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 § 180.474, amend the table in paragraph (a)(1) as follows:
■ a. Remove the entry for ''Brassica, leafy greens, subgroup 5B'';
■ b. Add alphabetically the entry for ''*Brassica,* leafy greens, subgroup 4–16B, except watercress'';
■ c. Remove the entry for ''Cotton, undelinted seed'';
■ d. Add alphabetically the entry for ''Cottonseed, subgroup 20C'';
■ e. Remove the entry for ''Fruit, pome, group 11'';
■ f. Add alphabetically the entries for ''Fruit, pome, group 11–10'' and ''Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F'';
■ g. Remove the entries for ''Fruit, stone, group 12, except cherry''; ''Grape''; ''Lychee''; and ''Nut, tree, group 14'';
■ h. Add alphabetically the entry for ''Nut, tree, group 14–12'';
■ i. Remove the entry for ''Peach'';
■ j. Add alphabetically the entry for ''Peach subgroup 12–12B'';
■ k. Remove the entries for ''Pistachio'' and ''Plum, pre- and post-harvest'';
■ l. Add alphabetically the entry for ''Plum subgroup 12–12C'';
■ m. Remove the entry for ''Sunflower, seed''; and
■ n. Add alphabetically the entries for ''Sunflower, subgroup 20B''; ''Tropical and subtropical, small fruit, inedible peel, subgroup 24A''; and ''Watercress''.

The additions read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B, except watercress	2.5
* * * * *	
Cottonseed, subgroup 20C	2
Fruit, pome, group 11–10	1
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	6
* * * * *	
Nut, tree, group 14–12	0.05
* * * * *	
Peach subgroup 12–12B	2
* * * * *	
Plum subgroup 12–12C	1
* * * * *	
Sunflower, subgroup 20B	0.1
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	1.6
* * * * *	
Watercress	9
* * * * *	

* * * * *

[FR Doc. 2019–24267 Filed 11–8–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0283; FRL–10000–50]

Propyzamide; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of propyzamide in or on cranberry. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberry. This regulation establishes a maximum permissible level for residues of propyzamide in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective November 12, 2019. Objections and requests for hearings must be received on or before January 13, 2020 and must be filed in accordance with the