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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0300; FRL-9999-58]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenbuconazole in or on tea. Dow Agrosciences, LLC 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-2018-0300, 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-2018-0300 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-2018-0300, 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 8E8678) by Dow Agrosciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.480 be amended by establishing tolerances for residues of the fungicide fenbuconazole, in or on the raw agricultural commodities tea, dried at 10 parts per million (ppm); and tea, instant at 10 ppm. That document referenced a summary of the petition prepared by Dow Agrosciences, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

After the publication of the notice of filing in the Federal Register, Dow Agrosciences, LLC requested that its requested tolerance for residues on tea be established at 30 ppm in/on tea, dried and tea, instant based on additional magnitude of the residue studies conducted in 2016 and 2017.

Based upon the data reviewed by the Food Safety Commission of Japan, EPA is establishing tolerances for tea, dried and tea, instant at 30 ppm. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

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

Subchronic and chronic feeding studies were conducted in the rat, mouse, and dog. The liver was the main target of toxicity in all three species. At lower dose levels in the subchronic studies, there were changes in liver histopathology, predominantly hepatocellular hypertrophy, along with increased liver weight. In the absence of other findings, these effects appeared to be adaptive liver changes, but at higher dose levels, increased levels of enzymes indicative of liver damage were observed (alkaline phosphatase or ALK; serum glutamic-pyruvic transaminase or SGPT; and serum glutamic-oxaloacetic transaminase or SGOT). Increased hepatocellular

vacuolization was observed at the higher dose levels as well, and in mice after subchronic exposure, hepatocellular necrosis was observed with a low incidence at the highest dose. In the rat after subchronic exposure, the thyroid was a secondary target organ with increased follicular cell size. In the chronic studies, liver effects were observed (including hepatocellular hypertrophy and vacuolization, changes in liver enzymes, and increased liver weights), as well as decreased body weight gains in all three species. Again, in the chronic rat study, the thyroid was a secondary target with increased thyroid and parathyroid weights and thyroid follicular cell hypertrophy. In addition, thyroid hormones were affected, with increased mean T4 (thyroxine) and decreased TSH (thyroid stimulating hormone) being observed in the high-dose rats near the end of the study. In the chronic dog study, kidney and adrenal weights were also increased.

In the rat and rabbit developmental toxicity studies and the rat two-generation study, all effects in the pups occurred in the presence of maternal toxicity, including changes in body weight in rats and decreased food consumption and clinical signs in rabbits. Developmental effects included increased post-implantation loss and decreased fetuses per dam in the rat developmental study; increased early resorptions in the rabbit developmental study; and decreased mean pup body weight, increased number of stillborn pups, decreased number of total offspring delivered, and decreased viability index of pups in the two-generation study in rats. No increased qualitative or quantitative susceptibility was observed in any of the studies. There was no evidence of neurotoxicity in any of the studies available in the toxicology database.

Fenbuconazole is classified as a “Group C,” or possible human carcinogen, based on an increased incidence of liver tumors in male and female mice and thyroid tumors in male rats. A cancer potency factor has been used to estimate potential cancer risk associated with fenbuconazole uses.

Specific information on the studies received and referenced in this section and the nature of the adverse effects caused by fenbuconazole, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in the document titled "Fenbuconazole: Human Health Risk Assessment for Proposed Use on Imported Tea," on pages 23-30 in docket ID number EPA-HQ-OPP-2018-0300.

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 are observed, 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 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 fenbuconazole used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Fenbuconazole for Use in

Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 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 Toxicity (Rat)** Developmental LOAEL = 75 mg/kg/day based on increased resorption and decreased live fetuses per dam
Acute dietary (General population including infants and children)	An endpoint for acute dietary (general population) exposures was not selected. An appropriate dose and endpoint were not identified for this population group		
Chronic dietary (All populations)	NOAEL = 3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day cPAD = 0.03 mg/kg/day	**Combined Chronic Toxicity/Carcinogenicity (Rat)** LOAEL = 30.6 mg/kg/day based on decreased body weight gain, increased thyroid weight, and histopathogical lesions in the liver and thyroid gland
Cancer (Oral, dermal, inhalation)	**Classification: Group C, possible human carcinogen.** This classification is based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice and thyroid follicular adenomas and combined adenomas/carcinomas in male rats. Quantification of risk was derived using combined hepatocellular adenomas/carcinomas in female mice. The upper bound estimate of unit risk, Q_1* $(mg/kg/day)^{-1}$ is 3.59×10^{-3} in human equivalents. (TXR #0011894; CPRC; 4/15/1996)		

FQPA SF = Food Quality Protection Act Safety Factor. LOC = level of concern. mg/kg/day = milligram/kilogram/day. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). 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 fenbuconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing fenbuconazole tolerances in 40 CFR 180.480. EPA assessed dietary exposures from fenbuconazole 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.

Although no endpoints of concern were identified for the general population including infants and children, such effects were identified for fenbuconazole for females 13-49 years old. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The acute dietary exposure analysis used tolerance-level residue estimates and assumed 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue estimates in food, EPA conducted a partially refined chronic dietary (food and drinking water) exposure assessment for all established food uses of fenbuconazole. Average residues from field trials and 100 PCT were used. Empirical and default processing factors were used, as available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fenbuconazole should be classified as "a possible human carcinogen" and a linear approach has been used to quantify cancer risk. The cancer dietary exposure analysis used average field trial residue estimates and average PCT values. Empirical and default processing factors were used, as available.

iv. *Anticipated residue and PCT information*. Average residue values were used in the Agency's chronic and cancer assessment of fenbuconazole. Average percent crop treated estimates were used in the Agency's cancer assessment of fenbuconazole.

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, 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 used the following average PCT estimates for fenbuconazole for assessing cancer risk: Almonds: 5%; apples: 5%; apricots: 5%; blueberries: 55%; cherries: 15%; grapefruit: 40%; nectarines: 5%; oranges: 5%; peaches: 15%; pecans: 10%; plums/prunes: 1%; sugar beets: 1%; tangelos: 10%; tangerines: 1%.

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 fenbuconazole may be applied in a particular area.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the 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 and cancer dietary risk analyses and a maximum PCT for acute 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 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 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.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fenbuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenbuconazole. 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 (PRZM/EXAMS), the estimated drinking water concentrations (EDWCs) of fenbuconazole for acute exposures are estimated to be 24.1 parts per billion (ppb) for surface water and 0.031 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 16.5 ppb for surface water and 0.031 ppb for ground water. For chronic exposures for cancer assessments are estimated to be 11.7 ppb for surface water and 0.031 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The PRZM/EXAMS 1-in-10-year annual peak surface water value of 24.1 ppb for peppers is greater than the SCI-GROW groundwater value of 0.031 ppb. As a result, the surface water value was used in the acute dietary analysis. The 1-in-10-year annual mean surface water value of 16.5 ppb for cherries is greater than the groundwater value of 0.031 ppb. As a result, the surface water value was used in the chronic dietary analysis. Finally, the 30-year annual mean surface water value of 11.7 ppb for cherries is greater than the groundwater value of 0.031 ppb. As a result, the surface water value was used in the cancer dietary analysis.

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). Fenbuconazole 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."

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 fenbuconazole and any other substances. 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). The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. The use of fenbuconazole on tea is not expected to quantitatively alter the dietary exposure estimates used in the most recent aggregate risk assessment for the common triazole metabolites because tea is not a significant consumption item and other conazoles are already registered for tea. The most recent triazole aggregate risk assessment (*Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations For Use of Difenoconazole and Mefentrifluconazole*; DP451447, dated May 15, 2019) can be found at *https://www.regulations.gov* at docket ID number EPA-HQ-OPP-2018-0002. Fenbuconazole 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 fenbuconazole has a common mechanism of toxicity with other substances.

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 is no indication of quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

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 fenbuconazole is complete.

ii. There is no indication that fenbuconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenbuconazole results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The exposure

assessment was based on field-trial residues and modeled drinking water estimates that will not underestimate dietary exposure and risk. The acute dietary exposure analysis used tolerance-level residues and assumed 100 PCT. The chronic and cancer dietary exposure analyses used average field-trial residue estimates. The chronic (non-cancer) assessment assumed 100 PCT, and the cancer analysis made use of average PCT estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenbuconazole in drinking water. These assessments will not underestimate the exposure and risks posed by fenbuconazole.

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 fenbuconazole will occupy 3.0% of the aPAD at the 95th percentile of exposure for females 13-49 years old, the only population subgroup with a relevant endpoint.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenbuconazole from food and water uses 6.8% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. The chronic risk estimate for the general U.S. population uses 2.5% of the cPAD.

There are no residential uses for fenbuconazole.

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). There are no registered residential uses for fenbuconazole, and therefore aggregate exposure and risk are equivalent to dietary exposure and risk, and these risk estimates are not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no registered residential uses for fenbuconazole, and therefore aggregate exposure and risk are equivalent to dietary exposure and risk, and these risk estimates are not of concern.

5. Aggregate cancer risk for U.S. population. Cancer risk was estimated at 1.8×10^{-6}. The Agency generally considers risks up to 3×10^{-6} to be within the negligible risk range and below the Agency's LOC. In addition, actual cancer risk is likely to be much lower, since the residue inputs were based on field trial data (as opposed to monitoring data) and used upper-bound PCT estimates.

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 fenbuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Tolerance enforcement method 34-90-47R is available for determining residues of fenbuconazole, RH-9129, and RH-9130 in plant commodities through gas chromatography with

a nitrogen phosphorous detector (GC-NPD). The method has undergone successful independent laboratory validation. The GC-NPD method TR 34-94-142 is adequate for collecting data on residues of fenbuconazole, RH-9129, and RH-9130 in livestock commodities.

These methods 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 fenbuconazole in tea.

C. Revisions to Petitioned-For Tolerances

The petitioner initially proposed a tolerance level of 10 ppm for residues in/on tea, dried and tea, instant, based on 1995 magnitude of the residue data reviewed by the Food Safety Commission of Japan. However, based on additional magnitude of the residue studies conducted in 2016 and 2017, the petitioner updated the proposed tolerance to 30 ppm in/on tea, dried and tea, instant. The proposed 30 ppm tolerance is in accordance with the Organization for

Economic Cooperation and Development (OECD) tolerance calculation procedure. Based on the residue data reviewed by the Food Safety Commission of Japan, the Agency concluded that the proposed tolerances of 30 ppm in/on tea, dried and tea, instant are appropriate.

V. Conclusion

Therefore, tolerances are established for residues of fenbuconazole and its lactone metabolites (*trans*- or *cis*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-2(3*H*)-furanone), in or on tea, dried and tea, instant at 30 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 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: September 30, 2019.

Michael Goodis,

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 § 180.480, add alphabetically entries for "tea, dried" and "tea, instant" to the table in paragraph (a) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Tea, dried[2]	30
Tea, instant[2]	30
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[2]There are no U.S. registrations for use of fenbuconazole on tea.

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[FR Doc. 2019-23380 Filed: 10/24/2019 8:45 am; Publication Date: 10/25/2019]