Kentucky Area to remove the emissions reductions associated with the use of RFG in this area and to demonstrate that the RFG opt-out would not interfere with the area's ability to attain or maintain the 2008 ozone NAAQS and any other NAAQS as required by CAA section 110(l). (*See* 40 CFR 80.72(b)). EPA published a proposed approval of the SIP revision on February 14, 2018 (83 FR 6496) and a final approval of the SIP revision on April 2, 2018 (83 FR 13872). The final approval of the maintenance plan revision was effective upon publication, April 2, 2018. The RFG opt-out regulations provide that the opt-out effective date shall be no less than 90 days from the EPA SIP approval effective date. (*See* 40 CFR 80.72(c)(7)). EPA is unaware of any reason that the effective date should be postponed, and therefore, is establishing an opt-out effective date of July 1, 2018 for the Northern Kentucky Area.

As provided by the RFG Opt-out Rule and the opt-out regulations, EPA will publish a final rule at a later date to remove the three counties in the Northern Kentucky Area from the list of RFG covered areas in 40 CFR 80.70 after the effective date of the opt-out. EPA believes that it is prudent to complete this ministerial exercise to revise the list of covered areas in the Code of Federal Regulations after the effective date of the opt-out.

III. Action

EPA is approving Kentucky's petition because it contained the information required by 40 CFR 80.72, including that Kentucky revised the approved maintenance plan for the 2008 ozone NAAQS for the Northern Kentucky Area to remove the emissions reductions associated with RFG. EPA is also determining the opt-out effective date by applying the criteria in 40 CFR 80.72(c)(7). As discussed in Section II.A. of this document, the opt-out regulations require that if a state included RFG as a control measure in an approved SIP, the state must revise the SIP, reflecting the removal of RFG as a control measure before an opt-out can be effective and the opt-out cannot be effective less than 90 days after the effective date of the approval of the SIP revision. EPA published a final approval of Kentucky's maintenance plan revision and noninterference demonstration on April 2, 2018 (83 FR 13872). The final approval was effective upon publication.

In summary, EPA is today notifying the public that it has applied its regulatory criteria to approve the petition by Kentucky to opt-out of the RFG program for the Northern Kentucky Area of the Cincinnati-Hamilton, OH-KY-IN ozone maintenance area and is thereby removing the prohibition on the sale of conventional gasoline in that area as of July 1, 2018. (*See* 40 CFR 80.72). This opt-out effective date applies to retailers, wholesale purchasers, consumers, refiners, importers, and distributors.

Dated: May 9, 2018.

E. Scott Pruitt,

Administrator.

[FR Doc. 2018–10456 Filed 5–15–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0032; FRL–9976–62]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on ginseng, fresh at 0.15 parts per million (ppm) and ginseng, dried at 0.40 ppm. Bayer CropScience LP, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 16, 2018. Objections and requests for hearings must be received on or before July 16, 2018, 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–2017–0032, 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, Director, 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–2017–0032 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 July 16, 2018. 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–2017–0032, 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 April 10, 2017 (82 FR 17175) (FRL–9959–61), 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 6E8534) by Bayer CropScience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of tebuconazole, α-[2-(4-Chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on ginseng, fresh at 0.15 ppm and ginseng, dried/red at 0.4 ppm. This document referenced a summary of the petition prepared by Bayer CropScience LP, the registrant, which is available in the docket, *http://www.regulations.gov.* No comments were received in response to the notice 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 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 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 toxicological profile remains unchanged from the discussion contained in the final rule published in the **Federal Register** on November 15, 2013 (78 FR 68741) (FRL–9392–1), which is hereby incorporated into this document.

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 *Human Health Aggregate Risk Assessment for Establishment of a Permanent Tolerance Without U.S. Registration for Residues in/on Ginseng* at pages 24–26 in docket ID number EPA–HQ–OPP–2017–0032.

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 can be found in the preamble to the final rule published in the **Federal Register** on November 15, 2013.

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 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 somewhat refined acute probalistic dietary exposure assessment was conducted for all existing and proposed food uses of tebuconazole. For the acute assessment, anticipated residues for grapes, grape juice, and peaches 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. Anticipated residues for all current uses were further refined

using percent crop treated (%CT) data where available. Percentage of imported orange juice and oranges were also provided. Default DEEM (ver. 7.81) and empirical processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 (NHANES/WWEIA). As to residue levels in food, EPA used field trial data, USDA PDP data, assumed PCT data levels and used empirical DEEM (ver. 7.81) default processing factors as described in Unit III.C.iv.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to tebuconazole. The chronic risk assessment or RfD approach is considered to be protective of any cancer effects; therefore, a separate cancer assessment was not conducted.

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, 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 assessment, the Agency estimated the PCT for existing uses as follows: 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%; plums/prunes 5%; soybeans 2.5%; squash 5%; sweet corn 5%; and wheat 25%.

For the chronic assessment, the Agency estimated the PCT for existing uses as follows: 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 5%.

The following estimated percent import estimates for the import oranges were used: *Acute:* Orange 16%; and orange juice 58%; *Chronic:* orange 12%; orange juice 46%. For all other crops not listed above, EPA assumed that 100% of the crop was treated.

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 (DPR) 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 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 2.5% or 1%. In those cases, EPA uses 2.5% or 1%, respectively, as the average PCT value. 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 in those situations in which the maximum PCT is less than 2.5%, in which case, the Agency uses 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 estimated drinking water concentrations (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 and for chronic exposures are estimated to be 68.8 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were previously 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 previously used to assess the

contribution to drinking water. Because the use of tebuconazole on ginseng is not associated with a U.S. registration, there is no impact on drinking water residues. As a result, 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: Turf, flower gardens, trees, ornamentals, and pressure-treated wood.

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 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) is 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.*

Because no new residential uses are being requested at this time, an updated residential exposure assessment would not normally be required. Each of the existing residential use patterns had been previously assessed and the resulting exposures and risk estimates did not exceed the agency's LOC. Since those assessments were conducted, however, a turf transferrable residue (TTR) study required by the Agency in 2013 was submitted to support a reevaluation of the aggregate exposures from the registered use on golf course turf. In addition, the agency updated the residential standard operating procedures and body weights to be used in all human health assessments. Therefore, the existing residential use patterns were reassessed using the updated procedures and data, since the residential exposures can impact the aggregate assessment for tebuconazole. The TTR study is reviewed in a separate HED memorandum available in the docket EPA–HQ–OPP–2017–0032.

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.''

Tebuconazole is a member of the conazole class of fungicides containing the 1,2,4-triazole moiety. 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. In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no conclusive data to indicate that conazoles share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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. Although the conazoles 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 conazoles. The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. 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.

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.* The toxicity database for tebuconazole includes prenatal developmental toxicity studies in three species (mouse, rat, and rabbit), a reproductive toxicity study in rats, and a developmental neurotoxicity study in rats. The data from prenatal developmental toxicity studies in mice and a developmental neurotoxicity study in rats indicated an increased quantitative and qualitative susceptibility following *in utero* exposure to tebuconazole. The NOAELs/LOAELs for developmental toxicity in these studies were found at dose levels less than those that induce maternal toxicity or in the presence of slight maternal toxicity. There was no indication of increased quantitative susceptibility in the rat and rabbit developmental toxicity studies, the NOAELs for developmental toxicity were comparable to or higher than the NOAELs for maternal toxicity. In all three species, however, there was indication of increased qualitative susceptibility. For most studies, minimal maternal toxicity was seen at the LOAEL (consisting of increases in

hematological findings in mice, increased liver weights in rabbits and rats, and decreased body weight gain/food consumption in rats) and did not increase substantially in severity at higher doses. However, there was more concern for the developmental effects at each LOAEL, which included increases in runts, increased fetal loss, and malformations in mice; increased skeletal variations in rats; and increased fetal loss and frank malformations in rabbits. Additionally, more severe developmental effects (including frank malformations) were seen at higher doses in mice, rats and rabbits. In the developmental neurotoxicity study, maternal toxicity was seen only at the high dose (decreased body weights, body weight gains, and food consumption, prolonged gestation and dystocia as well as decreased offspring survival).

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 3X. That decision is based on the following findings:

i. The toxicity database for tebuconazole is complete.

ii. Tebuconazole demonstrated neurotoxicity in the acute neurotoxicity study in rats; the lowest observable adverse effect level (LOAEL) of 100 mg/kg/day was based on increased motor activity in male and female rats and decreased footsplay in female rats. Although the subchronic neurotoxicity study was unacceptable since there was inadequate dosing, a new subchronic neurotoxicity study is not needed to evaluate levels at which subchronic neurotoxicity might occur; neurotoxicity was seen in other studies in the database at considerably lower doses than those tested in the subchronic neurotoxicity study. Malformations indicative of nervous system development disruption were seen in developmental toxicity studies in mice, rats, and rabbits. Neurotoxicity was also seen in the rat developmental neurotoxicity study as decreases in body weights, decreases in absolute brain weights, changes in brain morphometric parameters, and decreases in motor activity in offspring at the LOAEL of 8.8 mg/kg/day; a no observable adverse effect level (NOAEL) could not be established. The LOAEL (8.8 mg/kg/day) was employed as the point of departure (POD) for assessing risk for all exposure scenarios, and an FQPA SF of 3X has been retained as an uncertainty factor for use of a LOAEL to extrapolate a NOAEL (UFL). To determine whether the UFL is protective of any potential neurotoxicity, a Benchmark Dose (BMD) analysis of the datasets relevant to the adverse offspring effects (decreased body weight and brain weight) seen at the LOAEL in the developmental neurotoxicity (DNT) study was conducted. All of the BMDLs (benchmark dose lower limit) modeled successfully on statistically significant effects were 1–2X lower than the LOAEL. Therefore, an extrapolated NOAEL is not likely to be 10X lower than the LOAEL and that use of an UFL of 3X would not underestimate risk. Using an FQPA SF of 3X in risk assessment results in a NOAEL of 2.9 mg/kg/day (8.8 mg/kg/day ÷ 3X = 2.9 mg/kg/day), which is further supported by other studies in the tebuconazole toxicity database, with the lowest NOAELs being 3 and 2.9 mg/kg/day, from a developmental toxicity study in mice and a chronic toxicity study in dogs, respectively (respective LOAELs 10 and 4.5 mg/kg/day).

iii. There were increases in qualitative susceptibility in the prenatal developmental studies in rats, mice, and rabbits and in quantitative susceptibility in mice and developmental neurotoxicity in rats. However, the toxicity endpoint observed in developmental neurotoxicity study in rats was employed to establish the point of departure (POD) for risk assessment for all exposure scenarios. This toxicity endpoint was the most sensitive one, and the resulting POD was protective of all adverse effects found in the tebuconazole toxicity database. Therefore, the degree of concern for residual uncertainties for prenatal and/or postnatal toxicity was low.

iv. There are no residual uncertainties identified in the exposure databases. EPA utilized a tiered approach in estimating exposure to tebuconazole. While some refinements were incorporated into dietary and residential exposure calculations, EPA is confident that the aggregate risk from exposure to tebuconazole in food, water and residential pathways will not be underestimated. The acute and chronic dietary exposure assessments incorporated somewhat refined estimates of residues in food commodities from reliable field trial data reflecting maximum use conditions, recent monitoring data from USDA's Pesticide Data Program (PDP), and relevant market survey data on the percentage of crops treated. Estimated concentrations of tebuconazole in drinking water were incorporated into the chronic dietary analysis as the upper bound point estimate and into the probabilistic acute dietary analysis as a distribution. For the residential exposure pathways (ornamentals, golf course turf, and treated wood products), potential exposure resulting from tebuconazole outdoor uses in the residential setting was assessed using screening-level inputs that assumes an adult or child will come in contact with turf and other surfaces immediately after application.

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 tebuconazole will occupy 77% 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 tebuconazole from food and water will utilize 22% of the cPAD for all infants (< 1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of tebuconazole is not expected.

3. *Short-term risk and Intermediate-term risk.* Short-term and intermediate-term risk aggregate exposure takes into account short-term residential exposure and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Tebuconazole is currently registered for uses that could result in short-term residential exposure that could 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. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that residential exposures result in aggregate MOEs of 580 for adults, 600 for youths 11 to <16 years old, and children 6 to <11 years

500 for the activity of golfing and 330 for children (1–2 years old) engaging in activities on pressure treated wood surfaces. Because EPA's level of concern (LOC) for tebuconazole is a MOE of 300 or below, these MOEs are not of concern. Therefore, aggregate risk estimates for all examined population subgroups were not of concern to the Agency.

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. *Aggregate Assessment for Free Triazole & its Conjugates.* The conazole class of compounds, which includes tebuconazole, 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-containing pesticides, including tebucaonazole, 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-containing 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. The Agency's latest updated aggregate risk assessment for the triazole-containing metabolites was finalized on July 18, 2017 and includes the proposed new uses of tebuconazole. That assessment concluded that aggregate exposure to the triazole metabolites does not exceed the Agency's level of concern.

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 tebuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography/Nitrogen Phosphorus Detector (GC/NPD) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for tebuconazole in or on ginseng and ginseng, dried at 0.15 ppm and 0.40 ppm, respectively. These MRLs are the same as the tolerances established for tebuconazole in the United States.

C. Revisions to Petitioned-For Tolerances

For dried ginseng, the Agency is revising the commodity definition for the requested tolerance to reflect the correct commodity vocabulary currently used by the Agency. Specifically, *ginseng dried/red* was changed to *ginseng, dried.* Additionally, the Agency is revising the significant figures for the tolerance level based on current policy.

V. Conclusion

Therefore, tolerances are established for residues of tebuconazole, α-[2-(4-Chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on ginseng, dried at 0.40 ppm and ginseng, fresh at 0.15 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); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or 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: April 30, 2018.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Program.

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, add alphabetically the entries ''Ginseng, dried'' and ''Ginseng, fresh'' to the table in paragraph (a)(1) to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Ginseng, dried [1]	0.40
Ginseng, fresh [1]	0.15
* * *	* *

[1] There are no U.S. registrations.

* * * * *

[FR Doc. 2018–10345 Filed 5–15–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160426363–7275–02]

RIN 0648–XF920

Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; 2017–2018 Commercial Closure for King Mackerel in the Gulf of Mexico Northern Zone

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for commercial king mackerel in the northern zone of the Gulf of Mexico (Gulf) exclusive economic zone (EEZ) through this temporary rule. NMFS has determined that the commercial quota for king mackerel in the northern zone of the Gulf EEZ will be reached by May 15, 2018. Therefore, NMFS closes the northern zone of the Gulf EEZ to commercial king mackerel fishing on May 15, 2018. This closure is necessary to protect the Gulf king mackerel resource.

DATES: The closure is effective at 12:01 a.m., local time, May 15, 2018, until 12:01 a.m., local time, on October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *kelli.odonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish includes king mackerel, Spanish mackerel, and cobia, and is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights for Gulf king mackerel below apply as either round or gutted weight.

On April 11, 2017, NMFS published a final rule to implement Amendment 26 to the FMP in the **Federal Register** (82 FR 17387). That final rule adjusted the management boundaries, zones, and annual catch limits for Gulf migratory group king mackerel (Gulf king mackerel). The commercial quota for the Gulf king mackerel in the Gulf northern zone is 511,200 lb (231,876 kg) for the current fishing year, October 1, 2017, through September 30, 2018 (50 CFR 622.384(b)(1)(ii)).

The Gulf king mackerel northern zone is located in the EEZ between a line at 87°31.6′ W long., which is a line extending due south of the state boundary of Alabama and Florida, and a line at 26°19.48′ N lat., which is a line extending west from the boundary of Lee and Collier Counties in southwest Florida.

Regulations at 50 CFR 622.388(a)(1)(i) require NMFS to close the commercial sector for Gulf king mackerel in the northern zone when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined the commercial quota of 511,200 lb (231,876 kg) for Gulf king mackerel in the northern zone will be reached by May 15, 2018. Accordingly, the northern zone is closed to commercial fishing for Gulf king mackerel effective from 12:01 a.m., local time, on May 15, 2018, through September 30, 2018, the end of the current fishing year.

During the closure, a person on board a vessel that has been issued a valid Federal commercial or charter vessel/headboat permit for coastal migratory pelagic fish may continue to retain the king mackerel in the northern zone under the recreational bag and possession limits specified in 50 CFR 622.382(a)(1)(ii) and (a)(2), as long as the recreational sector for Gulf king mackerel in the northern zone is open (50 CFR 622.384(e)(1)).

Also during the closure, king mackerel from the closed zone, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to king mackerel from the closed zone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(2)).

Classification

The Regional Administrator for the NMFS Southeast Region has determined this temporary rule is necessary for the conservation and management of Gulf king mackerel and is consistent with the Magnuson-Stevens Act and other applicable laws.