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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0520; FRL-9390-5]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenbuconazole in or on pepper. 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-2012-0520, 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), EPA West 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: Erin Malone, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0253; email address: *malone.erin@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-2012-0520 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-2012-0520, 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.htm*.

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 September 28, 2012 (77 FR 59578) (FRL-9364-6), 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 2F8034) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268. The petition requested that 40 CFR 180.480 be amended by modifying the tolerance for residues of the fungicide fenbuconazole, alpha-[2-(4-chlorophenyl)-ethyl]-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile, and its metabolites RH-9129, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, and RH-9130, trans-5-(4- chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, in or on pepper from 0.4 parts per million (ppm) to 1.0 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*. A comment was received on the notice of filing. EPA's response to this comment is discussed 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 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. The main target organ of fenbuconazole is the liver. Increased liver weight, hepatocellular hypertrophy, and clinical chemistry changes were observed in the rat, dog, and mouse following subchronic and chronic exposure. In the rat (but not the dog or mouse), effects on the thyroid were also observed. A mechanistic study demonstrated

that these findings are secondary to changes in liver metabolic enzyme activities, which result in alterations to levels of circulating thyroid hormone due to increased clearance via increased liver metabolism and, eventually, thyroid hyperplasia. The rat is significantly more sensitive to these effects than other species. Clear NOAELs and LOAELs were established for these findings, and the endpoints selected for human health risk assessment are protective of the thyroid effects. The endpoints are also protective of potential thyroid perturbation to offspring, as the developmental NOAELs were significantly higher than the NOAELs for thyroid and liver effects in adults (e.g., chronic dietary endpoint based on rat chronic/carcinogenicity NOAEL of 3 mg/kg/day vs. rat developmental NOAEL of 30 mg/kg/day), and no increased quantitative susceptibility was observed for thyroid and liver effects among the offspring relative to the parental animals. Kidney and adrenal weights were increased in dogs after chronic exposure. Although acute and subchronic neurotoxicity have not been submitted, EPA concluded that these studies are not required, taking into consideration the lack of observed neurotoxic effects in the available studies for fenbuconazole as well as many other triazole fungicides. There was no evidence of increased quantitative or qualitative susceptibility to *in utero* or post-natal exposure to fenbuconazole. Since the previous assessment, new rabbit developmental toxicity and rat metabolism studies were submitted; the findings of these studies are consistent with the data EPA assessed previously and do not affect the overall characterization of hazard or selection of doses and endpoints for risk assessment. Fenbuconazole is classified as a "Group C," or possible human carcinogen, based on an increased incidence of liver tumors in male and

female mice. A cancer potency factor has been used to quantify potential cancer risk associated with fenbuconazole uses.

Specific information on the studies received 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 document "Fenbuconazole: Human Health Risk Assessment for an Increased Tolerance for Residues in Peppers and a Label Amendment for the Enable 2F Product" at page 14 in docket ID number EPA-HQ-OPP-2012-0520.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*. A summary of the toxicological endpoints for fenbuconazole used for human risk assessment is shown in Table 1 of this unit.

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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 = 0.3mg/kg/day	Developmental rat study LOAEL = 75 mg/kg/day based on increased resorptions, postimplantation loss and decreased live fetuses per dam.
Acute dietary (General population including infants and children)	None	None	Not selected No appropriate single dose and endpoint could be identified for these population groups.
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 = 30.6/43.1 (M/F) mg/kg/day based on decreased body weight gain, increased thyroid weight, and hispathological lesions in the liver and thyroid gland.
Cancer (Oral, dermal, inhalation)	Under the 1986 cancer classification scheme, fenbuconazole was classified as a Group C – Possible Human Carcinogen, with a low dose extrapolation model applied to the animal data for the quantification of human risk (Q_1*). This classification was based on a statistically significant increase in combined hepatocellular adenomas and/or carcinomas by pair-wise comparison with concurrent controls, and significantly increasing trend in both the incidences of adenomas, and combined 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.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligrams/kilogram/day. NOAEL = no-observed-adverse-

effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_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. For the acute, chronic, and cancer dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey/What We Eat In America (NHANES/WWEIA) collected from 2003-2008. In addition, 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.

Such effects were identified for fenbuconazole only for females age 13-49. As to residue levels in food, EPA used tolerance-level residues and assumed 100% crop treated for all commodities in the acute dietary exposure assessment.

ii. *Chronic exposure*. As to residue levels in food, EPA used a combination of tolerance-level residues and, for many foods, average residue levels from crop field trials. One-hundred percent crop treated was assumed for all commodities in the chronic dietary exposure assessment.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is

appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that fenbuconazole should be classified as "Possibly Carcinogenic to Humans" and a linear approach has been used to quantify cancer risk.

In its assessment of dietary cancer risk, EPA used the same residue levels as described for the chronic assessment. EPA also assumed 100% crop treated, except for the percent crop treated estimates described in Unit III.C.1.iv., below.

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.

The Agency estimated the PCT for existing uses as follows for the cancer assessment: 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%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The

maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

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 are 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.

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 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 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, and 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. For acute dietary risk assessment, the water concentration value of 24.1 ppb was used to assess the contribution from drinking water. For chronic dietary risk assessment, the water concentration of value 16.5 ppb was used to assess the contribution from drinking water. For cancer dietary risk assessment, the water concentration of value 11.7 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). 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."

Fenbuconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in 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 conazoles are hepatotoxic and hepatocarcinogenic in mice, some induce thyroid tumors in rats, and some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that 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/pesticides/cumulative*.

Fenbuconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole as well as the common triazole conjugates (triazolylalanine, triazolylacetic acid, and triazolylpyrivic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including

fenbuconazole, EPA conducted human health risk assessments for exposure to 1,2,4-triazole and the common triazole conjugates resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). The 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.

Aggregate risk from exposure to the common triazole metabolites were recently estimated by the Agency (1 May 2013) and found to be not of concern. An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP), reflecting the revised tolerance for residues of fenbuconazole in/on pepper was completed on May 21, 2013. Given that the updated dietary risk estimate increased by less than 1% relative to the previous assessment, new aggregate risk estimates were not made, and aggregate risk estimates for the common triazole metabolites remain below the Agency's level of concern. These documents may be found on *http://www.regulations.gov* by searching for the following titles and docket numbers: "*Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations For Use of Prothioconazole on Bushberry Crop Subgroup 13-07B, Low Growing Berry, Except Strawberry, Crop Subgroup 13-07H, and Cucurbit Vegetables*

Crop Group 9; Use of Flutriafol on Coffee; and Ipconazole on Crop Group 6" (located in docket ID number EPA-HQ-OPP-2012-0876) and "*Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Revised Tolerance for Residues of Fenbuconazole in Peppers*" (docket ID number EPA-HQ-OPP-2012-0520).

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*. In the rat and rabbit developmental toxicity studies and the 2-generation study in rats, all effects in the pups occurred in the presence of maternal toxicity, including changes in body weight and body weight gains in rats and decreased food consumption and clinical signs in rabbits. Developmental effects included increased post-implantation loss and decreased live 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. In the rat developmental toxicity study, although a decrease in the number of live fetuses per litter was observed at the LOAEL, this effect was due largely to reduced implantation sites, which may reflect maternal toxicity. Additionally, the increases in postimplantation loss and early resorptions were marginal at the LOAEL. Therefore, the findings in this study were not considered indicative of increased offspring susceptibility. In the rabbit developmental study, developmental effects were observed at a higher dose than maternal effects. In the rat reproduction study, effects on pup viability were observed at a dose that resulted in maternal mortality during delivery. There was no evidence of neurotoxicity in any of the studies available in the toxicology database. Therefore, a developmental neurotoxicity study is not required.

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 is complete, except for an immunotoxicity study; however, due to the lack of any evidence of immunotoxicity based upon the available studies, EPA does not believe that an immunotoxicity study will result in a lower point-of-departure than those being relied upon for the present risk assessments. Therefore, an uncertainty factor is not required to account for the lack of this study.

ii. There is no evidence of neurotoxicity in the available database, and a developmental neurotoxicity study is not required.

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

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure assessment is a screening-level assessment, utilizing tolerance-level residues and assuming 100% crop treated. The chronic dietary exposure assessment is slightly refined, utilizing some tolerance-level residues and some average residue levels from crop field trials and assuming 100% crop treated. The cancer dietary exposure assessment is also slightly refined, utilizing the same residue estimates as for the chronic assessment and some percent crop treated estimates. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to fenbuconazole in drinking water. There are no registered residential uses for fenbuconazole. 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. The only population subgroup that is relevant for an acute assessment is females of child-bearing age (i.e., females 13-49 years old). The acute risk estimate that results from this analysis is 2.9% of the acute population adjusted dose (aPAD) at the 95th percentile of exposure.

This risk estimate is considerably lower than EPA's level of concern (100% of the aPAD).

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 will utilize 6.7% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. 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). For fenbuconazole, there are no residential uses and therefore a short-term aggregate risk assessment was not needed.

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 residential uses for fenbuconazole at this time, therefore an intermediate-term risk assessment was not needed.

5. *Aggregate cancer risk for U.S. population*. Fenbuconazole is classified as a Group C (possible human) carcinogen under the Agency's 1986 Cancer Guidelines, based on increased incidences of liver tumors in male and female mice and thyroid tumors in male rats. Using the conservative exposure assumptions described in this unit for cancer risk from chronic exposure and an upper bound estimate of unit risk (Q_1*) of 3.59×10^{-3} $(mg/kg/day)^{-1}$, EPA has derived a cancer risk estimate of 2.2×10^{-6} from dietary exposure to fenbuconazole.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1 x 10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3 x 10^{-7} and 3 x 10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described in this unit, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3 x 10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the fenbuconazole exposure risk assessment is somewhat refined, it retains significant conservatism in that the analysis relies on field trial data and assumes 100% crop treated for many commodities. Accordingly, EPA has concluded the aggregate cancer risk for all existing fenbuconazole uses and the uses associated with the tolerances established in this action fall within the range of 1 x 10^{-6} and are thus negligible.

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

Adequate enforcement methodology (GC/NPD method, TR 34-940-47 and TR34-90-47R) 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 an MRL for fenbuconazole in or on pepper at 0.6 ppm. This MRL is different than the tolerance established for fenbuconazole in the United States. The Codex MRL for pepper was most likely established before the Enable® 2F formulation was proposed for use on peppers and includes only residues of the parent compound. This new formulation has higher residues values ranging up to 0.7 ppm, and the U.S. tolerance includes the two lactone metabolites. Harmonization with the 0.6 ppm tolerance is not feasible given the proposed new use pattern/formulation and the observed residue levels.

C. Response to Comments

EPA received a comment to the notice of filing which said that residue levels of fenbuconazole should not be raised. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural corps. However, the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

V. Conclusion

Therefore, tolerances are modified to establish residues of fenbuconazole in or on pepper at 1.0 ppm. Consistent with the petition and EPA's policy for clarifying its tolerance expressions, EPA is revising the tolerance expression for fenbuconazole to clarify that the tolerance includes metabolites and degradates of fenbuconazole and that compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of fenbuconazole, alpha-[2-(4-chlorophenyl)-ethyl]-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile, and its metabolites RH-9129, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, and RH-9130, trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)–2-3 H-furanone, calculated as the stoichiometric equivalent of fenbuconazole,

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: June 21, 2013.

Lois Rossi,

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 revise paragraph (a) introductory text and revise the entry "Pepper" in the table in paragraph (a) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) Tolerances are established for residues of the fungicide fenbuconazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of fenbuconazole, alpha-[2-(4-chlorophenyl)-ethyl]-alpha-phenyl-3-(1H-1,2,4-triazole)-1–propanenitrile, and its metabolites RH-9129, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4- triazole-1-ylmethyl)-2-3 H-furanone, and RH-9130, trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-ylmethyl)-2-3 H-furanone, calculated as the stoichiometric equivalent of fenbuconazole, in or on the following agricultural commodities.

Commodity	Parts per million
* *	* * * * *
Pepper	1.0
* *	* * * * *

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[FR Doc. 2013-15867 Filed 07/02/2013 at 8:45 am; Publication Date: 07/03/2013]