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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0161; FRL-9997-41]

Buprofezin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of buprofezin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0161, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0161 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0161, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 24, 2018 (83 FR 34968) (FRL-9980-31), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8654) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of buprofezin, 2-(1,1-dimethylethyl)iminotetrahydro-3(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one in or on the following raw agricultural commodities: Fig at 0.70 parts per million (ppm), Leafy greens subgroup 4-16A, except head lettuce and radicchio at 35 ppm; *Brassica*, leafy greens, subgroup 4-16B at 60 ppm; Vegetable, *brassica*, head and stem, group 5-16 at 12.0 ppm; Leaf petiole vegetable subgroup 22B at 35 ppm; Celtuce at 35 ppm; Fennel, Florence at 35 ppm; Kohlrabi at 12.0 ppm; Tropical and subtropical, small fruit, edible peel, subgroup 23A at 5.0 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 0.30 ppm; Cottonseed subgroup 20C at 0.35 ppm; Fruit, citrus, group 10-10 at 2.5 ppm; Fruit, stone, group 12-12, except apricot and peach at 2.0 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.5 ppm and Nut, tree, group 14-12 at 0.05 ppm. The petition also requested to remove the established tolerances for residues of buprofezin in or on the following raw agricultural commodities: Acerola at 0.30 ppm; Brassica, head and stem, subgroup 5A at 12.0 ppm; *Brassica*, leafy greens, subgroup 5B at 60 ppm; Cotton, undelinted seed at 0.35 ppm; Fruit, citrus, group 10 at 2.5 ppm; Fruit, stone, group 12, except apricot and peach at 1.9 ppm; Grape at 2.5 ppm; Longan at 0.30 ppm; Lychee at 0.30 ppm; Nut, tree group 14 at 0.05 ppm; Olive at 3.5 ppm; Olive, oil at 4.8 ppm; Pistachio at 0.05 ppm; Spanish lime at 0.30 ppm; Turnip, greens at 60 ppm; Vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio at 35 ppm; and Wax jambu at 0.30 ppm. That document referenced a summary of the petition prepared by Nichino America,

Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. No comments were received on the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established and has corrected some of the commodity definitions to be consistent with Agency nomenclature. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for buprofezin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with buprofezin 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 primary organs of buprofezin toxicity are the liver and the thyroid. In subchronic toxicity studies in rats, increased microscopic lesions in liver and thyroid, increased liver weights, and increased thyroid weight in males were seen. In chronic studies in the rat, an increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males were reported. In chronic studies in the dog, increased relative liver weights were reported in females. Effects observed in a 24-day dermal toxicity study in rats included inflammatory infiltrate of the liver and an increase in acanthosis and hyperkeratosis of the skin in females. Following inhalation exposure of rats, the adrenal gland was the target of buprofezin toxicity (i.e., increased weight and microscopic findings of minimal hypertrophy of the cortex).

The developmental toxicity study in the rat showed reduced ossification and reduced pup weight at maternally toxic doses (death, decreased pregnancy rates, increased resorption rates). No developmental toxicity was observed in the rabbit at or below maternally toxic dose levels. The reproductive toxicity study showed decreased pup body weights at dose levels where liver effects (increased relative and/or absolute liver weights) and decreased body weight gains were observed in the parental generations. In contrast, evidence of post-natal offspring sensitivity was observed in the comparative thyroid toxicity assay (CTA) study. Rat pups experienced decreased body weight during early lactation and increased thyroid stimulating hormone (TSH) levels at a dose that did not elicit toxicity in the dams. Higher doses were required to elicit maternal toxicity which included increased serum TSH concentration, decreased serum T4 levels and histopathological findings in the thyroid (increased follicular cell

height and follicular cell hypertrophy). Pre-natal sensitivity was not evident in the CTA study as fetal toxicity (increased thyroid weight in males and increased TSH levels in males and females) was observed only at maternally toxic doses.

EPA has classified buprofezin into the category of "Suggestive Evidence of Carcinogenicity, but not sufficient to assess human carcinogenic potential" based on liver tumors in female mice only. Buprofezin was negative in *in vitro* and *in vivo* genotoxicity assays. The Agency noted findings from the published literature indicate that buprofezin causes cell transformation and induces micronuclei *in vitro,* but determined that, in the absence of a positive response in an *in vivo* micronucleus assay, buprofezin may have aneugenic potential which is not expressed *in vivo*. The Agency has determined that the cRfD is protective for carcinogenic effects.

Aniline is a substance that may be formed in food from buprofezin and its aniline-containing metabolites as a result of cooking but is toxicologically different from buprofezin and its other metabolites. EPA has classified aniline as a B2-probable human carcinogen with an oral cancer slope factor of $5.7x10^{-3}$ $(mg/kg/day)^{-1}$ which is considered very conservative for cancer assessment of aniline. The Agency did not identify any other oral endpoint.

Specific information on the studies received and the nature of the adverse effects caused by buprofezin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "***Buprofezin.*** *Human Health Risk Assessment for Proposed New Uses on Figs and Greenhouse-Grown Peppers and the Establishment of Permanent Tolerances in/on Fig and Tolerance Conversions to Leafy Greens, Subgroup 4-16A, Except Head Lettuce and Radicchio; Brassica, Leafy Greens, Subgroup 4-16B; Vegetable, Brassica, Head and Stem, Group 5-16; Leaf Petiole Vegetable Subgroup 22B; Celtuce; Florence Fennel;*

Kohlrabi; and Tolerance Expansions to All Members of Fruit, Citrus Group 10-10; Fruit, Stone, Group 12-12; Nut, Tree, Group 14-12; Tropical and Subtropical, Small Fruit, Edible Peel, Subgroup 23A; Tropical and Subtropical, Small Fruit, Inedible Peel, Subgroup 24A; Cottonseed Subgroup 20C; and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13-07F" on pages 59-63 in docket ID number EPA-HQ-OPP-2018-0161.

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 buprofezin and aniline used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Buprofezin and Aniline for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	An acute RfD for the general population including infants and children was not selected because the effects observed in the animal studies that could be attributed to a single day exposure were not applicable to the general population.		
Acute dietary (Females 13 to 49 years of age)	NOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day aPAD = 2.0 mg/kg/day	Developmental Toxicity Study - Rat Developmental LOAEL = 800 mg/kg/day based on reduced ossification & decreased fetal body weight.
Chronic dietary (All populations)	LOAEL = 10 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 10x (UF_L)	Chronic RfD = 0.033 mg/kg/day cPAD = 0.033 mg/kg/day	Comparative Thyroid Toxicity Analysis (CTA) Study-rats Offspring LOAEL = 10.0 mg/kg/day based on significantly decreased pup body weight (↓8-13% in males during LD 4-10 and ↓8-9% in females during LD 4-7) compared to controls and increased TSH levels on LD 4 and LD 21 (↑23-34% in males).
Cancer - Buprofezin (Oral, dermal, inhalation)	"Suggestive Evidence of Carcinogenicity, but not sufficient to assess human carcinogenic potential". The cRfD is considered protective of the cancer effects.		
Cancer - Aniline (Oral, dermal, inhalation)	B2-probable human carcinogen with an oral cancer slope factor of $5.7x10^{-3}$ $(mg/kg/day)^{-1}$		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. 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). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to buprofezin, EPA considered exposure under the petitioned-for tolerances as well as all existing buprofezin tolerances in 40 CFR 180.511. EPA assessed dietary exposures from buprofezin 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 buprofezin.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003-2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) for all commodities. Total residues of concern in crop commodities (i.e., buprofezin and the BF4 Conjugate (2-(2-hydroxy-1,1-dimethylethylimino)-3-isopropyl-5- phenyl-1,3,5-thiadiazinan-4-one) which is not detectable by data collection methods but which may be estimated from metabolism data) were based on tolerance level residues of buprofezin and available metabolism/magnitude of the data to estimate other residues of concern. Given the potential for BF9 (3-isopropyl-5-phenyl-1,3,5-thiadiazinan-2,4-dione) and BF12 (1-isopropyl-3-phenylurea) to concentrate to a greater degree than buprofezin in processed commodities, Dietary Exposure Evaluation Model (DEEM) default

processing factors were retained for all commodities, except for tomato paste and puree, which were reduced based on empirical data. Based on the submitted lemon metabolism data, which indicated that residues of concern are primarily found in/on the peel, the maximum theoreti cal concentration factor for peel was used to estimate residues of concern in citrus peel. Total residues of concern in meat (i.e., buprofezin and BF2 (2-tert-butylimino-5-(4-hydroxyphenyl)-3-isopropyl-1,3,5-thiadiazinan-4-one)) and milk (i.e., buprofezin and BF23 (N-(4-hydroxyphenyl) acetamide)) were based on the feeding study data which were used to establish meat and milk tolerances. Based on the submitted data, which indicated a 5x concentration of residues into milk cream and fat and a Log K_{ow} of 4.31, a default 25x concentration factor was applied for milk fat.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA (2003–2008). A partially refined chronic dietary analysis was conducted using the same residue estimates used for the acute dietary analysis and average PCT estimates when available.

iii. *Cancer*. Buprofezin: Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to buprofezin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

Aniline: 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 sufficien t 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 aniline should be classified as "Probable human carcinogen" and a linear approach has been used to quantify cancer risk. A refined cancer dietary analysis was conducted for this assessment using percent crop treated estimates when available along with USDA Pesticide Data Program (PDP) monitoring data for buprofezin. In addition, residues of aniline from the B4 conjugate was estimated using a cooking residue study.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

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

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

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

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

The Agency estimated the PCT for registered uses as follows:

The acute dietary exposure analyses assumed 100 PCT. Average PCT was used for the following crops for refinement of the chronic analyses: almond 1%, apple 2.5%, apricot 10%, broccoli 5%, Brussels sprout 2.5%, cabbage 5%, cantaloupe 5%, cauliflower 10%, cherry 2.5%, cotton 1%, grapefruit 5%, grape 5%, lemon 2.5%, lettuce
10%, nectarine 5%, olive 2.5%, orange 2.5%, peach 5%, pear 10%, pepper 2.5%, pistachio 10%, plum/prune 5%, pomegranate 15%, pumpkin 1%, spinach 1%, squash 1%, strawberry 15%, tomato 1%, walnut 1%, and watermelon 2.5%. These average PCT data were also used to refine the cancer dietary exposure analysis for buprofezin-derived aniline.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up

to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for buprofezin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of buprofezin. 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 version 5 and Variable Volume Water Model (PRZM5/VVWM) and Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) of buprofezin for acute exposures are estimated to be 78.8 parts per billion (ppb) for surface water and for chronic exposures are estimated to be 19 ppb for surface water. There was no breakthrough of buprofezin into ground water during a 100-year simulation using the PRZM-GW model. Buprofezin, therefore, is not expected to be detected in shallow ground water. For aniline, the Agency has determined that there is no expectation of buprofezin-derived aniline in drinking water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 78.8 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 19 ppb was used to assess the contribution to drinking water.

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

Buprofezin 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."

In 2016, EPA's Office of Pesticide Programs released a guidance document entitled "*Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*" (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework*). This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA). EPA has utilized this framework for buprofezin and determined that the available toxicological data suggests buprofezin does not share a similar toxicological profile, and thus no common mechanism of toxicity, with other pesticides. No further cumulative evaluation is necessary for buprofezin.

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*. Developmental toxicity studies in rats and rabbits and reproduction studies in rats provided no indication of increased susceptibility of rats or rabbits following *in utero* exposure or of rats following pre/postnatal exposure to buprofezin. However, a comparative thyroid study demonstrated offspring susceptibility, but not fetal susceptibility to buprofezin oral (gavage) administration. Points of departure (PODs) for risk assessment that are derived from this comparative thyroid study are based on the most sensitive endpoint of concern.

3. *Conclusion*. For exposure scenarios using a NOAEL as POD (i.e., acute dietary exposure for females 13 to 49 years of age), EPA has determined that the FQPA SF which was previously retained due to data deficiency may be reduced to 1x. However, for assessments that use the comparative thyroid study to derive a POD (i.e., chronic dietary, incidental oral, short-term and intermediate-term dermal, and cancer), a FQPA SF of 10x is retained to account for the lack of a NOAEL. That decision is based on the following findings:

i. The toxicity database for buprofezin is complete, with the exception of a NOAEL in the comparative thyroid study.

ii. There was no evidence of neurotoxicity in the toxicity database.

iii. There was no evidence in developmental and reproductive toxicity studies of quantitative or qualitative sensitivity in the young; however, the comparative thyroid study demonstrated enhanced sensitivity in pups but not fetuses relative to maternal animals. A NOAEL could not be established for rat pups in the comparative thyroid study and, as a result,

the 10x FQPA SF was retained to account for the uncertainty in the offspring sensitivity introduced by the lack of a NOAEL.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment uses conservative assumptions which result in protective estimates of dietary exposure. The dietary drinking water assessment uses values generated by models and associated modeling parameters which are designed to provide protective, high-end estimates of water concentrations. These assessments will not underestimate the exposure and risks posed by buprofezin.

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 buprofezin will occupy 4.8% of the aPAD at the 95th percentile of exposure for females 13 to 49 years old, the only population group of concern.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to buprofezin from food and water will utilize 51% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate

exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, buprofezin is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short-or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for buprofezin.

4. *Aggregate cancer risk for U.S. population.* Buprofezin: As explained in Unit III.A., the Agency has determined that the quantification of risk using a non-linear (*i.e.,* RfD) approach will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to buprofezin. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., buprofezin is not expected to pose a cancer risk to humans.

Aniline: A highly refined cancer dietary exposure and risk assessment for buprofezin-derived aniline residues was conducted for cooked foods only using an oral cancer slope factor of 5.7×10^{-3} $(mg/kg/day)^{-1}$ for aniline. Average residues of buprofezin and its aniline-containing metabolites in/on foods prior to cooking were estimated using (1) monitoring data for uncooked raw agricultural commodities (RACs) provided by USDA PDP, where available, (2) an additional factor based on metabolism data (1.8x) to estimate aniline-containing metabolites, where needed, and (3) average buprofezin PCT data where available. A conversion factor of 18.9%, the highest found in the hydrolysis study, was applied to estimate residues of buprofezin-derived

aniline which may form in food as a result of cooking. Only cooked food forms were included in the dietary analysis. The highly refined estimated exposure of the highest exposed adult population (adults 20 to 49 years old) to buprofezin-derived aniline is 0.000053 mg/kg/day which results in an upper bound cancer risk estimate of 3×10^{-7} and is below the Agency's level of concern.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to buprofezin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available in Pesticide Analytical Manual Volume I (PAM I) and PAM II for enforcement of buprofezin tolerances, including gas chromatography (GC) methods with nitrogen phosphorus detection (GC/NPD), and a GC/mass spectrometry (MS) method for confirmation of buprofezin residues in plant commodities. The validated limit of quantitation (LOQ) is 0.05 ppm.

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.

No Codex MRLs have been established for residues of buprofezin in/on fig.

Codex has established several MRLs for residues of buprofezin in/on other raw agricultural commodities (RACs) included in this petition, including cherries, plums, grapes, almonds, and table olives, which are harmonized with the U.S. tolerances being established in this action. Additionally, Codex has an established MRL on dried grapes (including currants, raisins, and sultanas), which is harmonized with the U.S. tolerance being established for grape, raisin. Codex has also established a more restrictive MRL in/on citrus fruits which is too low to harmonize with U.S. tolerances due to significant differences in good agricultural practices (GAP).

C. Revisions to Petitioned-For Tolerances

The tolerances being established by the Agency differ from the requested tolerances as follows:

All trailing zeroes have been removed from petitioned-for tolerances in accordance with Agency policy.

The following requested commodity definitions have been revised to be consistent with Agency nomenclature: Florence fennel is changed to fennel, Florence, fresh leaves and stalk; and vegetable, *brassica*, head and stem, group 5-16 is changed to vegetable, *Brassica*, head and stem, group 5-16.

The petitioned-for tolerance in/on the fruit, stone, group 12-12, except apricot and peach at 2.0 ppm which is based on cherry and plum data has been revised to fruit, stone, group 12-12, except nectarine and peach at 2 ppm. The petitioned-for stone fruit crop group conversion from group 12 to 12-12 has resulted in a change of the representative commodity

for apricot from peach to plum; hence, the petitioned-for tolerance was revised to remove the exclusion for apricot and the established tolerance in/on apricot (9.0 ppm) is removed as inappropriate, thus lowering the tolerance level for apricot from 9.0 ppm to the appropriate tolerance level of 2 ppm. Nectarine was added to the tolerance exclusion since the higher established tolerance in/on peach (9.0 ppm) also covers residues in/on nectarine (40 CFR 180.1(g)). This does not represent a tolerance level change for nectarine.

The petitioned-for tolerance in/on the citrus crop group 10-10 has been revised from 2.5 ppm to 4 ppm. The tolerance level has been increased to harmonize with the Canadian MRL for citrus fruit commodities. The Canadian MRL was determined using U.S. orange data and the Organization for Economic Cooperation and Development (OECD) calculation procedures, while the established U.S. tolerance was determined with older tolerance calculation procedures, including the North American Free Trade Agreement (NAFTA) spreadsheet.

The petitioned-for tolerance in/on the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F has been revised from 2.5 ppm to 1 ppm to harmonize with the currently established Codex and Canada MRLs in/on grapes.

A tolerance of 2 ppm in/on grape, raisin has been be added due to the crop group expansion and lowering of the currently established tolerance in/on grape (2.5 ppm) to the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F (1 ppm).

The petitioned-for tolerance in/on leafy greens subgroup 4-16A, except head lettuce and radicchio at 35 ppm is changed to leafy greens subgroup 4-16A at 35 ppm. The tolerances in/on head lettuce and radicchio are covered by the crop subgroup 4-16A tolerance and are being increased to 35 ppm to harmonize with the Canadian MRLs for head lettuce and radicchio. Currently established separate tolerances in/on head lettuce and radicchio at 6.0 ppm are being removed as unnecessary.

D. International Trade Considerations

In this final rule, EPA is reducing the existing tolerances for the commodities of apricot from 9 ppm to 2 ppm and of grape from 2.5 ppm to 1 ppm. The Agency is reducing the tolerances since data indicate the higher tolerance is no longer needed to cover residues from approved domestic uses and in order to harmonize the tolerance in/on grapes with Codex and Canadian MRLs.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision in order to satisfy its obligation. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address this requirement. After the six-month period expires, residues of buprofezin on apricot and grape cannot exceed the new tolerance levels established in this rulemaking.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of buprofezin in or on *Brassica*, leafy greens, subgroup 4-16B at 60 ppm; celtuce at 35 ppm; cottonseed subgroup 20C at 0.35 ppm; fennel, Florence, fresh leaves and stalk at 35 ppm; fig at 0.7 ppm; fruit, citrus, group 10-10 at 4 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1 ppm; fruit, stone,

group 12-12, except nectarine and peach at 2 ppm; grape, raisin at 2 ppm; kohlrabi at 12 ppm; leaf petiole vegetable subgroup 22B at 35 ppm; leafy greens subgroup 4-16A at 35 ppm; nut, tree, group 14-12 at 0.05 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 5 ppm; tropical and subtropical, small fruit, inedible peel, subgroup 24A at 0.3 ppm; and vegetable, *Brassica*, head and stem, group 5-16 at 12 ppm.

Additionally, the existing tolerances on the following commodities are removed as unnecessary due to the establishment of the above tolerances: acerola; *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; cotton, undelinted seed; fruit, citrus, group 10; fruit, stone, group 12, except apricot and peach; lettuce, head; longan; lychee; nut, tree group 14; olive; olive, oil; pistachio; radicchio; Spanish lime; turnip, greens; vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio; and wax jambu. Finally, expiration dates are added to the existing tolerances for apricot and grape.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501

et seq.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 16, 2019.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.511, amend the table in paragraph (a) as follows:

a. Remove the entry for "Acerola";

b. Revise the entry for "Apricot";

c. Remove the entries for "Brassica, head and stem, subgroup 5A" and "Brassica, leafy greens, subgroup 5B";

d. Add alphabetically the entries for "*Brassica,* leafy greens, subgroup 4-16B" and "Celtuce";

e. Remove the entry for "Cotton, undelinted seed";

f. Add alphabetically the entries for "Cottonseed subgroup 20C"; "Fennel, Florence, fresh leaves and stalk"; "Fig"; and "Fruit, citrus, group 10-10";

g. Remove the entry for "Fruit, citrus, group 10";

h. Add alphabetically the entries for "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F" and "Fruit, stone, group 12-12, except nectarine and peach";

i. Remove the entry for "Fruit, stone, group 12, except apricot and peach";

j. Revise the entry for "Grape";

k. Add alphabetically the entries for "Grape, raisin"; "Kohlrabi"; "Leaf petiole vegetable subgroup 22B"; and "Leafy greens subgroup 4-16A";

l. Remove the entries for "Lettuce, head"; "Longan"; "Lychee"; and "Nut, tree group 14";

m. Add alphabetically the entry for "Nut, tree, group 14-12";

n. Remove the entries for “Olive”; “Olive, oil”; “Pistachio”; “Radicchio”; and “Spanish lime”;

o. Add alphabetically the entries for “Tropical and subtropical, small fruit, edible peel, subgroup 23A” and “Tropical and subtropical, small fruit, inedible peel, subgroup 24A”;

p. Remove the entry for “Turnip, greens”;

q. Add alphabetically the entry for “Vegetable, *Brassica*, head and stem, group 5-16”;

r. Remove the entries for “Vegetable, leafy, except Brassica, group 4, except head lettuce and radicchio” and “Wax jambu”; and

s. Add footnote 3.

The revisions and additions read as follows:

§ 180.511 Buprofezin; tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * * * *	
Apricot[3]	9.0
* * * * * * *	
Brassica, leafy greens, subgroup 4-16B	60
* * * * * * *	
Celtuce	35
* * * * * * *	
Cottonseed subgroup 20C	0.35
* * * * * * *	
Fennel, Florence, fresh leaves and stalk	35
Fig	0.7
Fruit, citrus, group 10-10	4
* * * * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	1
Fruit, stone, group 12-12, except nectarine and peach	2
* * * * * * *	

Grape[3]	2.5
Grape, raisin	2
* * * * * * *	
Kohlrabi	12
Leaf petiole vegetable subgroup 22B	35
Leafy greens subgroup 4-16A	35
* * * * * * *	
Nut, tree, group 14-12	0.05
* * * * * * *	
Tropical and subtropical, small fruit, edible peel, subgroup 23A	5
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	0.3
Vegetable, *Brassica*, head and stem, group 5-16	12
* * * * * * *	

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[3] This tolerance expires on March 2, 2020.

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[FR Doc. 2019-18365 Filed: 8/28/2019 8:45 am; Publication Date: 8/29/2019]