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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2014-0878; FRL-9966-67]

**Fluazifop-P-Butyl; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluazifop-p-butyl in or multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 27, 2017. Objections and requests for hearings must be received on or before November 27, 2017, 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-2014-0878, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-id?&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-2014-0878 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 November 27, 2017. 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-2014-0878, by one of the following methods:

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

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

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**II. Summary of Petitioned-for Tolerance**

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL-9924-00), 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 4E8328) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide fluazifop-p-butyl in or on the raw agricultural commodities lettuce, head and leaf at 5.0 parts per million (ppm); strawberry at 3.0 ppm; onion, green at 1.5 ppm; caneberry subgroup 13-07A at 0.05 ppm; bushberry subgroup 13-07B at 0.3 ppm; tuberous and corm vegetables (except for potato) subgroup 1D at 1.5 ppm; small fruit vine climbing, except for fuzzy kiwifruit subgroup 13-07F at 0.03 ppm; and onion, bulb subgroup 3-07A at 0.5 ppm as well as tolerances with regional registration for grass hay at 15 ppm; and grass forage at 4.0 ppm. Upon the approval of the aforementioned tolerances, IR-4 requested removal of the existing tolerances for grape at 0.01 ppm; onion, bulb at 0.5 ppm; and sweet potato, roots at 0.05 ppm; and also requested amend the existing tolerance for rhubarb from 0.5 ppm to 0.4 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities. 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 fluzifop-P-butyl including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with fluzifop-P-butyl 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 toxicity profile shows that the principal toxic effects of fluzifop-P-butyl are changes in the liver and kidney following exposure *via* the oral route. Liver toxicity is observed in rats, hamster, and dogs, while kidney toxicity is observed in rats.

Other adversely effected organs included the testes and eyes in rats and hamsters. Adrenal fatty vacuolation and increased incidence of thymic involution were noted in the chronic

dog study. Gall bladder stones and ovarian cell hyperplasia were noted in the carcinogenicity study in hamsters. From the toxicity studies, the lowest LOAELs were observed in long-term studies, suggesting progression of toxicity with duration of treatment.

Quantitative sensitivity of the fetus was observed in the rat developmental studies in which no maternal toxicity was observed. Developmental toxicity in the rat was generally related to incomplete ossification. At higher doses, decreased fetal body weight and an increased incidence of diaphragmatic hernia were observed. In the rabbit, maternal and developmental toxicity were observed at the same dose. Maternal toxicity included abortions, weight loss, and death, and fetal toxicity included abortions, skeletal effects, and fetuses that were small and/or had cloudy eyes. In the rat reproduction and fertility study, maternal (increased liver weight, bile duct hyperplasia, geriatric nephropathy) and offspring (decreased pup viability, decreased pup body weight, and hydronephrosis) toxicity were observed at the same dose level, and decreased female fertility was observed at the highest dose.

No immunotoxicity was observed at the highest dose tested in the immunotoxicity study in rats. Although other studies indicated effects on the immune system organs (*e.g.*, thymus effects in the dog), all points of departure (PODs) are protective of any possible immunotoxic response. Delayed neurotoxicity was not observed in hens, and there was no evidence of toxicity in the subchronic neurotoxicity study. In the acute neurotoxicity study at the lowest dose tested (500 milligrams/kilogram (mg/kg)), where a bolus dose is administered by gavage, clinical signs indicative of toxicity (reduced activity, decreased rearing, hunched posture, and/or piloerection) were observed, as well as decreased motor activity (total distance and number of rearings) in both sexes. There was no evidence of carcinogenicity or mutagenicity in the toxicity profile.

Specific information on the studies received and the nature of the adverse effects caused by fluzifop-P-butyl 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 title “*Fluzifop-P-butyl. Human-Health Risk Assessment for New Uses on Lettuce (Leaf and Head), Rhubarb, Green Onion, Strawberry, Caneberry Subgroup 13-07A, Bushberry Subgroup 13-07B, Fescue Grasses (Grown for Seed); and for Amendments to Existing Tolerances [Subgroups 1D, 3-07A, and 13-07F]*” on page 42 in docket ID number EPA-HQ-OPP-2014-0878.

#### B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (PODs) 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 fluzifop-P-butyl used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZIFOP-P-BUTYL 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 (General population including infants and children and females 13–49 years of age).	LOAEL = 500 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF (UF <sub>L</sub> ) = 10x	Acute RfD = 0.50 mg/kg/day. aPAD = 0.50 mg/kg/day	Acute neurotoxicity—rat. LOAEL = 500 mg/kg, based on clinical signs indicative of toxicity (reduced activity, decreased rearing, hunched posture and/or piloerection), and decreased motor activity (total distance and number of rearings) in both sexes.
Chronic dietary (All populations)	NOAEL = 0.51 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.0051 mg/kg/day. cPAD = 0.0051 mg/kg/day	Combined chronic toxicity/carcinogenicity—rat. LOAEL = 4.15 mg/kg/day, based on increased mortality associated with increased severity of nephropathy during the first year in males.
Incidental oral short-term (1 to 30 days).	NOAEL = 5.8 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction—rat. Offspring LOAEL = 17.5 mg/kg/day, based on decreased pup viability (both generations), decreased pup weights (↓15%) in the F2-generation, and hydronephrosis in the F1 pups.
Dermal short-term (1 to 30 days) (General population except children).	Oral study NOAEL = 2.0 mg/kg/day (dermal absorption rate = 9%). UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity—rat. Developmental LOAEL = 5.0 mg/kg/day based on delayed ossification in skull bones, sternbrae bipartite, sternbrae partially ossified and calcenum unossified in fetuses and litters.
Dermal short-term (1 to 30 days) (Children only).	Dermal study NOAEL = 100 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	21-Day dermal toxicity in rabbits. Offspring LOAEL = 500 mg/kg/day based on death in 1/10 males.
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100%). UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF (UF <sub>DB</sub> ) = 10x	LOC for MOE = 1,000.	Developmental toxicity—rat. Developmental LOAEL = 5.0 mg/kg/day based on delayed ossification in skull bones, sternbrae bipartite, sternbrae partially ossified and calcenum unossified in fetuses and litters.
Cancer (Oral, dermal, inhalation).	Not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>DB</sub> = to account for the absence of data or other data deficiency. UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluzifop-P-butyl, EPA considered exposure under the petitioned-for tolerances as well as all existing fluzifop-P-butyl tolerances in 40 CFR 180.411. EPA assessed dietary exposures from fluzifop-P-butyl 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 fluzifop-P-butyl. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance

level residues with a ratio adjustment for additional metabolites of concern.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA’s NHANES/WWEIA. As to residue levels in food, the Agency used mean residue levels from crop field trials with a ratio adjustment for additional metabolites of concern, average percent crop treated estimates, and experimentally determined processing factors.

iii. *Cancer*. EPA has concluded that fluzifop-P-butyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 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 average PCT for existing uses as follows:

Asparagus, 2.5%; carrots, 15%; cotton, 1%; dry beans/peas, 1%; garlic, 10%; grapefruit, 15%; grapes, 2.5%; nectarines, 1%; onions, 10%; oranges, 2.5%; peaches, 2.5%; peanuts, 1%; plums, 2.5%; potatoes, 1%; prunes, 2.5%; soybeans, 2.5%; and sugar beets, 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) and proprietary market surveys for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary

risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 2.5%. The maximum PCT figure is the highest observed maximum value reported within the most recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for situations in which the maximum PCT is less than 2.5%. In cases where the estimated value is less than 2.5% but greater than 1%, the average and maximum PCT used are 2.5%. If the estimated value is less than 1%, 1% is used as the average PCT and 2.5% is used as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluzifop-P-butyl 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 fluzifop-P-butyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluzifop-P-butyl. 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 Surface Water Concentration Calculator (SWCC) model and the Pesticide Root Zone Model Ground Water (PRZM-GW) model, the estimated drinking water concentrations (EDWCs) of fluzifop-P-butyl for acute exposures are estimated to be 56.6 parts per billion (ppb) for surface water and 6.8 ppb for ground water and for chronic exposures are estimated to be 4.41 ppb for surface water and 3.39 ppb for ground 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 56.6 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 4.41 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).

Fluzifop-P-butyl is currently registered for the following uses that could result in residential exposures: Lawns/turf and ornamentals. EPA assessed residential exposure using the following assumptions: For handlers, exposure is expected as a result of application to turf and ornamentals. Post-application exposure is also expected as a result of being in an environment that has been previously treated with fluzifop-P-butyl.

For adult handlers, risk estimates are presented as an aggregated risk index (ARI) since the PODs for dermal and inhalation routes of exposure are based on the same study/effects, but have different LOCs (dermal LOC = 100 and inhalation LOC = 1000). The target ARI is 1; ARIs of less than 1 are risk estimates of concern. None of the residential handler scenarios resulted in a risk estimate of concern (*i.e.*, all ARIs  $\geq 1$ ).

For post-application, only dermal and incidental oral (for kids only) exposures were assessed. Since the PODs for these routes are based on the same effects and have the same LOC, risk estimates can be combined. All residential post-application MOEs are greater than the LOC of 100, and are therefore not of concern.

The Agency used the worst-case exposure scenarios for all population subgroups for recommendation for inclusion in the aggregate assessment. The residential exposure scenario used in the adult aggregate assessment is dermal and inhalation handler exposure

from applications to gardens/trees using a backpack sprayer. The residential exposure scenario used in the youth (11 to <16 years) aggregate assessment is dermal post-application exposure from golfing on treated turf. The residential exposure scenario used in the child (6 to <11 years) aggregate assessment is dermal post-application exposure from activities in treated gardens. The residential exposure scenario used in the child (1 to <2 years) aggregate assessment reflects combined dermal plus hand-to-mouth post-application exposure from high contact activities on treated turf. The PODs for the adult dermal and inhalation routes of exposure are based on the same study and based on the same effects; however, the LOCs are different (dermal LOC = 100 and inhalation LOC = 1000). Therefore, a total aggregated risk index (ARI) was used to combine risk estimates. The aggregate risk index (ARI) is calculated as follows:

$$\text{Aggregate Risk Index (ARI)} = 1 \div [(\text{Dermal LOC} \div \text{Dermal MOE}) + (\text{Inhalation LOC} \div \text{Inhalation MOE})]$$

The target ARI is 1; ARIs of less than 1 are risk estimates of concern. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found fluzifop-P-butyl to share a common mechanism of toxicity with any other substances, and fluzifop-P-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluzifop-P-butyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### 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 Food Quality Protection Act Safety Factor (FQPA 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.* Quantitative sensitivity of the fetus was observed in the rat developmental studies in which no maternal toxicity was observed. Developmental toxicity in the rat was generally related to incomplete ossification. At higher doses, decreased fetal body weight and an increased incidence of diaphragmatic hernia were observed. In the rabbit, maternal and developmental toxicity were observed at the same dose. Maternal toxicity included abortions, weight loss, and death, and fetal toxicity included abortions, skeletal effects, and fetuses that were small and/or had cloudy eyes. In the rat reproduction and fertility study, maternal (increased liver weight, bile duct hyperplasia, geriatric nephropathy) and offspring (decreased pup viability, decreased pup body weight, and hydronephrosis) toxicity were observed at the same dose level, and decreased female fertility was observed at the highest dose.

3. *Conclusion.* For acute dietary and inhalation short-term exposure scenarios, the Agency is retaining the FQPA safety factor of 10x for the use of a LOAEL to extrapolate a NOAEL (acute dietary) and to account for the lack of a subchronic inhalation toxicity study (inhalation short-term). 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 for the chronic dietary, incidental oral, and dermal short-term exposure scenarios. That decision is based on the following findings:

- i. The toxicity database for fluzifop-P-butyl for assessing these scenarios is complete.
- ii. Possible signs of neurotoxicity were observed at 500 mg/kg in the acute neurotoxicity study. The clinical signs

observed included reduced activity, decreased rearing, hunched posture and/or piloerection, and decreased motor activity (total distance and number of rearings) in both sexes. However, considering that this was a bolus (gavage) dose at half the limit dose, the nature of the observations and the lack of neuropathology suggests that the findings were a result of generalized toxicity rather than neurotoxicity.

Slight increases in absolute (2.5%) and relative (1.6%) brain weights were seen in both sexes at 3,000 ppm (~194 mg/kg/day) at termination in the carcinogenicity study in hamsters. Slight increases in brain weights were seen in female rats (2.9%) at 100 mg/kg/day and in male hamsters (4%) at 120 mg/kg/day after subchronic exposures with fluzifop-P-butyl. The toxicological significance of the marginal increases in brain weights at high doses is unknown in the absence of corroborative histopathological lesions.

The Agency concluded that there was not a concern for neurotoxicity resulting from exposure to fluzifop-P-butyl at relevant exposure levels. The only indication of potential neurotoxicity was due to a large (500 mg/kg) bolus dose (gavage) in the acute neurotoxicity study. No developmental or central nervous system malformations were seen in any of the developmental toxicity studies with rats or rabbits. No increased offspring sensitivity over parent was seen in the rabbit pre-natal developmental studies or in the rat post-natal reproduction study, and no evidence of neurotoxicity or neuropathology was observed in adult animals. Although malformed fetuses were seen at high dose levels in the absence of maternal toxicity in the rat developmental toxicity studies, the definitive developmental endpoint in five developmental studies was selected based on delayed ossification and fetal weight decrement at much lower doses (100-fold lower). Therefore, the conditions were not met for requiring a developmental neurotoxicity study.

iii. There was no indication of fetal or offspring susceptibility in rabbit developmental or rat reproduction studies. Quantitative sensitivity of the fetus was noted in the rat developmental studies as described above. However, the selected PODs are protective for all exposure scenarios where the developing fetus is of concern. Therefore, the degree of concern is low.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments include assumptions that result in high-end estimates of dietary food exposure.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluzifop-P-butyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluzifop-P-butyl.

#### *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 fluzifop-P-butyl will occupy 42% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluzifop-P-butyl from food and water will utilize 49% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluzifop-P-butyl is not expected.

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).

Fluzifop-P-butyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluzifop-P-butyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate ARIs of 2.1 for adults, 51 for youths 11–16 years old, 13 for children 6–11 years

old, and 1.7 for children 1–2 years old. Because EPA's level of concern for fluzifop-P-butyl is an ARI of 1 or below, these ARIs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Intermediate-term adverse effects were identified; however, fluzifop-P-butyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluzifop-P-butyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluzifop-P-butyl is not expected to pose a cancer risk to humans.

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 fluzifop-P-butyl residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultra-Violet Spectrometry (HPLC/UV)) is available to enforce the tolerance expression.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting

organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for fluzifop-P-butyl.

##### *C. Revisions to Petitioned-For Tolerances*

The petitioner requested a tolerance of 5.0 ppm for "Lettuce, head and leaf". This is not a standard commodity definition. Rather, the Agency is establishing separate tolerances for "Lettuce, head" and "Lettuce, leaf" at 3.0 and 5.0 ppm, respectively, as determined by the Organization for Economic Cooperation and Development (OECD) MRL calculation procedures. The caneberry subgroup 13–07A tolerance is being established at 0.08 ppm instead of 0.05 ppm as requested since two of the raspberry trials were determined not to be independent. The requested tolerances for grass forage and hay is being established as fescue forage and hay because the use requested for the corresponding pesticide registration is limited to fescue grass varieties. In addition, where appropriate, EPA has modified the numerical expression of tolerance values in order to conform to current Agency policy on significant figures.

#### **V. Conclusion**

Therefore, tolerances are established for residues of fluzifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the bushberry subgroup 13–07B at 0.30 ppm; caneberry subgroup 13–07A at 0.08 ppm; fescue, forage at 4.0 ppm (tolerance with regional registrations); fescue, hay at 15 ppm (tolerance with regional registrations); fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.03 ppm; lettuce, head at 3.0 ppm; lettuce, leaf at 5.0 ppm; onion, bulb, subgroup 3–07A at 0.50 ppm; onion, green at 1.5 ppm; strawberry at 3.0 ppm; and vegetable, tuberous and corm, except potato, subgroup 1D at 1.5 ppm.

Additionally, the existing tolerances for grape; onion, bulb; and sweet potato, roots are removed as unnecessary, since they are covered by the newly established crop group tolerances, and the tolerance with regional registrations for rhubarb at 0.5 ppm, currently under section 180.411(c), will now be listed in

section 180.411(a) since it will now have a national registration.

**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). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action

does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: August 30, 2017.

**Michael L. Goodis**,  
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. In § 180.411:

■ a. Add alphabetically the commodities “Bushberry subgroup 13–07B”; “Caneberry subgroup 13–07A”; and “Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F” to the table in paragraph (a);

■ b. Remove the commodity “Grape” in the table in paragraph (a);

■ c. Add alphabetically the commodities “Lettuce, head” and “Lettuce, leaf” to the table in paragraph (a);

■ d. Remove the commodity “Onion, bulb” in the table in paragraph (a);

■ e. Add alphabetically the commodities “Onion, bulb, subgroup 3–07A”; “Onion, green”; “Rhubarb”; and “Strawberry”;

■ f. Remove the commodity “Sweet potato, roots” in the table in paragraph (a);

■ g. Add alphabetically the commodity “Vegetable, tuberous and corm, except

potato, subgroup 1D” to the table in paragraph (a);

■ h. Add alphabetically the commodities “Fescue, forage”; and “Fescue, hay” to the table in paragraph (c); and

■ i. Remove the commodity “Rhubarb” from the table in paragraph (c).

The additions read as follows:

**§ 180.411 Fluzifop-P-butyl; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Bushberry subgroup 13–07B .....	0.30
Caneberry subgroup 13–07A .....	0.08
* * * * *	*
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F .....	0.03
* * * * *	*
Lettuce, head .....	3.0
Lettuce, leaf .....	5.0
* * * * *	*
Onion, bulb, subgroup 3–07A ....	0.50
Onion, green .....	1.5
* * * * *	*
Rhubarb .....	0.50
* * * * *	*
Strawberry .....	3.0
Vegetable, tuberous and corm, except potato, subgroup 1D ...	1.5

\* \* \* \* \*

(c) \* \* \*

Commodity	Parts per million
* * * * *	*
Fescue, forage .....	4.0
Fescue, hay .....	15
* * * * *	*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2016–0049; FRL–9966–68]

**Oxathiapiprolin; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.