EPA-APPROVED MISSOURI NONREGULATORY SIP PROVISIONS—Continued

| Name of nonregulatory SIP provision | Applicable geographic or nonattainment area | State submittal date | EPA approval date | Explanation |
|---|---|---|---|---|
| (60) Section 128 Declaration: Missouri Air Conservation Commission Representation and Conflicts of Interest Provisions; Missouri Revised Statutes (RSMo) RSMo 105.450, RSMo 105.452, RSMo 105.454, RSMo 105.462, RSMo 105.463, RSMo 105.466, RSMo 105.472, and RSMo 643.040.2. | Statewide | 8/08/12 | 6/21/13; 78 FR 37457 | [EPA–R07–OAR–2013–0208; FRL–9825–7]. |
| (61) Section 110(a)(2) Infrastructure Requirements for the 2008 Pb NAAQS. | Statewide | 12/20/11 | 8/19/14, 79 FR 48994 | [EPA–R07–OAR–2014–0290; FRL–9915–28-Region 7] This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M). |
| (62) Implementation Plan for the 2008 Lead NAAQS. | City of Herculaneum, MO. | 4/18/13 | 10/20/14, 79 FR 62574 | [EPA–R07–OAR–2014–0448; FRL–9918–18-Region-7] |

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2014–0441; FRL–9930–99]**

### Fluazifop-P-Butyl; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation amends a tolerance for residues of fluazifop-P-butyl in or on sweet potato, roots. Syngenta Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 6, 2015. Objections and requests for hearings must be received on or before October 5, 2015, 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–2014–0441, 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:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this action apply to me?*

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

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

*B. How can I get electronic access to other related information?*

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

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0441 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 October 5, 2015. 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–2014–0441, 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 September 5, 2014 (79 FR 53009) (FRL–9914–98), 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 4F8262) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.411 be amended by amending the established tolerance for residues of the herbicide fluazifop-P-butyl in or on sweet potato, roots from 0.05 parts per million (ppm) to 1.5 ppm. That document referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, *http://www.regulations.gov.* No FFDCA-related comments were received on the notice of filing.

## III. Aggregate Risk Assessment and Determination of Safety

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

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

Fluazifop-P-butyl is the R enantiomer of fluazifop-butyl [(*R,S*)-2-(4-((5-(trifluoromethyl)-2-pyridinyl)oxy)phenoxy)propanoic acid, butyl ester]. The toxicology database for fluazifop-P-butyl consists of studies conducted using fluazifop-butyl (racemic mixture) and its enriched R-isomer, fluazifop-P-butyl. Comparison studies have shown similar toxicities from both compounds. Metabolism studies have been conducted in the rat with fluazifop-butyl, and absorption, excretion, and confirmatory metabolism studies in the dog with fluazifop-butyl, and hamster with fluazifop-P-butyl. Comparative metabolism studies in the rat show that both fluazifop-P-butyl and fluazifop-butyl mixed isomers are rapidly hydrolyzed to fluazifop acid and the [S] enantiomer is rapidly converted to the [R] enantiomer in the blood, yielding similar toxicities. *In vivo,* the S-isomer quickly converts to the R-isomer.

Oral dog and female rat studies show similar results, while male rats show greater toxicity. Fluazifop-butyl is rapidly absorbed through the gut after oral dosing and the ester linkage is hydrolyzed to produce the fluazifop acid in the blood. No parent fluazifop-ester was detected in plasma at any time. Male rats show similar fluazifop acid excretion to the female, but excretion is slower, because fluazifop is excreted in the bile and results in a higher percentage in the feces.

The liver and kidney are its target organs expressed for the most part as liver toxicity in the presence of peroxisome proliferation and exacerbation of age-related kidney toxicity. These data are reasonably consistent among the rat with fluazifop-butyl and fluazifop-P-butyl, dog with fluazifop-butyl, and hamster with fluazifop-P-butyl. Fluazifop-P-butyl shows similar toxicity by both the inhalation and oral routes.

Although the liver and kidney were the organs most consistently affected, other findings were used as endpoints for selection of the points of departure. A rat developmental study exhibiting diaphragmatic hernia effects was used as the basis to select the acute dietary endpoint for females 13–49 years of age. The short-term incidental oral and children's dermal endpoints were selected based upon a maternal body weight gain decrement exhibited in the developmental toxicity studies performed on rats. The chronic dietary (all populations), intermediate-term dermal and inhalation, as well as the intermediate-term incidental oral endpoints, were selected from the 2-generation reproduction study in rats. This study was significant in exhibiting decreased testes and epididymal weights in males, along with decreased uterine and pituitary weights in females. In regard to the short-term dermal for adults and inhalation endpoints used in this assessment, the developmental toxicity studies performed on rats were used as the basis for endpoint selection. These studies were notable in exhibiting decreased fetal weights, as well as hydroureter and delayed ossification effects. An additional endpoint was chosen that was specific for short-term dermal exposure to children, as a developmental effect is generally protective of pregnant women and fetuses. In this case, the maternal toxicity (body weight gain decrement) was chosen to be protective of children.

Indications of possible neurotoxicity were observed in the acute neurotoxicity study, including clinical signs indicative of toxicity (reduced activity, decreased rearing, hunched posture and/or piloerection), decreased body temperature, and decreased motor activity (total distance and number of rearings). No signs of neurotoxicity were observed in the subchronic neurotoxicity test at doses up to 70 mg/kg/day in males and 328 mg/kg/day in females. There was no observed immunotoxicity resulting from fluazifop-P-butyl exposure in the submitted study. There was no carcinogenicity observed in acceptable studies in the rat with fluazifop-butyl or in the hamster for fluazifop-P-butyl. The hamster was selected for cancer study, because liver peroxisome proliferation more closely resembled what was found for human liver cells. There was no mutagenicity observed for fluazifop-butyl or fluazifop-P-butyl.

In a dermal absorption and pharmacokinetic study in humans, most of the applied dose appeared to be in the stratum corneum and easily removed (the unrecovered test material was speculated to be in the outer layers of the skin). Peak plasma levels were shown to occur 24 to 31 hours after application in these men. The one half-life for excretion was about 18 hours. Specific information on the studies received and the nature of the adverse effects caused by fluazifop-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 document ''*Fluazifop-P-Butyl. Human-Health Risk Assessment for Sweet Potato Label Amendment and Resulting Tolerance Increase.''* at pages 28–36 in docket ID number EPA–HQ–OPP–2014–0441.

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

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

A summary of the toxicological endpoints for fluazifop-P-butyl used for human risk assessment is shown in Table 1 of this unit.

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute dietary (Females 13–49 years of age). | NOAEL = 50 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Acute RfD = 0.50 mg/kg/day. | MRIDs: 00088857, 92067047, 00088858, 92067048, Rat developmental.<br>Developmental LOAEL = 200 mg/kg/day based on diaphragmatic hernia. |
| Acute dietary (General population including infants and children). | ..... | ..... | An appropriate endpoint for the general population attributable to a single dose was not identified in the available studies. |
| Chronic dietary (All populations) | NOAEL = 0.74 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = cPAD = 0.0074 mg/kg/day. | MRIDs: 00088859, 92067050, Rat reproduction study; reproductive<br>LOAEL = 5.8 mg/kg/day based on decreased testes and epididymal weights. |
| Incidental oral short-term (1 to 30 days). | NOAEL = 100 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Residential LOC for MOE = 100. | MRIDs: 46082913, 46158401, Rat developmental study; maternal<br>LOAEL = 300 mg/kg/day based on maternal body weight gain decrement during GD 7–16. |
| Dermal short-term (1 to 30 days: Children). | NOAEL = 100 mg/kg/day.<br>DAF= 9% (low exposure) or 2% (high exposure).<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Residential LOC for MOE = 100. | MRIDs: 46082913, 46158401, Rat developmental study; maternal.<br>LOAEL = 300 mg/kg/day based on maternal body weight gain decrement during GD 7–16. |
| Dermal short-term (1 to 30 days: Adults). | NOAEL = 2.0 mg/kg/day.<br>DAF = 9% (low exposure) or 2% (high exposure).<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Residential LOC for MOE = 100. | MRIDs: 46082903, 46082013, Rat developmental study; Developmental<br>LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydroureter, and delayed ossification. |
| Inhalation short-term (1 to 30 days). | Inhalation (or oral) study NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100%).<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Residential LOC for MOE = 100. | MRIDs: 46082903, 46082013, Rat developmental study; Developmental<br>LOAEL = 5.0 mg/kg/day based on fetal weight decrement, hydroureter, and delayed ossification. |

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Cancer (Oral, dermal, inhalation). | Not likely to be carcinogenic to humans. | | |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. 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. $UF_S$ = use of a short-term study for long-term risk assessment. $UF_{DB}$ = to account for the absence of key data (*i.e.,* lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable. DAF = dermal absorption factor.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluazifop-P-butyl, EPA considered exposure under the petitioned-for tolerance as well as all existing fluazifop-P-butyl tolerances in 40 CFR 180.411. EPA assessed dietary exposures from fluazifop-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 fluazifop-P-butyl. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA) database. The acute dietary analysis was conducted using 100% crop treated assumptions and tolerance-level residues, adjusted as appropriate using factors from the metabolism studies, to account for residues of concern not measured by the analytical method.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA database. As to residue levels in food, the chronic dietary analysis was conducted assuming 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.* Based on the data summarized in Unit III.A., EPA has concluded that fluazifop-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 percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: For the acute dietary analysis, 100 PCT was assumed for all crops. The following average percent crop treated estimates were used in the chronic dietary risk assessments for the following crops that are currently registered for fluazifop-P-butyl: Apricots, 2.5%; asparagus, 2.5%; carrots, 15%; cherries, 1%; 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%; pecans, 1%; peppers, 2.5%; plums, 2.5%; potatoes, 1%; prunes, 2.5%; soybeans, 2.5%; and sugar beets, 1%; 100 PCT was assumed for sweet potatoes and all other registered crops not listed above.

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

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations 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 fluazifop-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 fluazifop-P-butyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluazifop-P-butyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Estimated drinking water concentrations (EDWCs) in ground water were modeled using Tier I SCIGROW (version 2.3) and surface water EDWCs were modeled using Tier II PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System). Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the surface water concentration value of 33.4 ppb was used to assess the contribution from drinking water. For the chronic dietary risk assessment, the surface water concentration value of 6.6 ppb was used to assess the contribution from drinking water.

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

Fluazifop-P-butyl is currently registered for the following uses that could result in residential exposures: Non-agricultural outdoor buildings, building foundations, curbs, driveways, fencerows, non-agricultural areas (wildlife refuge), non-crop areas, ornamentals (lawns, flowering shrubs, flowering plants, gardens, ground covers, plants, trees, turf, and woody shrubs), patios, pathways, rights-of-way, sidewalks, and storage yards. EPA assessed residential exposure using the following assumptions. For handlers, there is a potential for short-term inhalation and dermal exposure. Residential handler exposure scenarios include handwand, hose and sprayer, backpack, sprinkler can, and RTU hose end sprayer.

There is also the potential for short-term post-application exposure for dermal exposure to all groups: Adult and child (1 to <2 years) turf-high contact; adult and youth (11–16 years) mowing; adult, child (6 to <11 years) and youth (11–16 years) golfing; adult and child (6 to <11 years) garden. Two separate dermal absorption values were used: 9% is used for assessing dermal exposures while golfing or mowing a lawn, since these are representative of low exposure activities (*i.e.,* the Agency assumes that 9% of dermal exposures will be absorbed), whereas 2% is used for assessing dermal exposures from high-contact lawn activities, since these are representative of high-exposure activities (*i.e.,* the Agency assumes that 2% of dermal exposures will be absorbed). In addition, there is potential for short-term post-application incidental oral exposure for children (1 to <2 years). Chemical-specific dislodgeable foliar residue (DFR) data are available and were used for the residential post application exposure assessment for gardens. Since Turf Transferable Residue (TTR) data are not available for fluazifop-P-butyl, default TTR values were used for the residential post application exposure assessment for turf. Given the conservatisms associated with default TTR values and the potential compounding nature of conservatisms in the turf assessment, EPA is able to rely upon the calculated exposure estimates with confidence that exposure is not being underestimated. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 fluazifop-P-butyl to share a common mechanism of toxicity with any other substances, and fluazifop-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 fluazifop-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://www.epa.gov/pesticides/cumulative.*

*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 (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.* No increased offspring sensitivity over parent was seen in the rabbit pre-natal developmental studies or the rat post-natal reproduction study, and no evidence of neurotoxicity was observed. Several rat developmental toxicity studies conducted on both fluazifop-butyl and fluazifop-P-butyl indicate fetal effects (ranging from delayed ossification, fetal weight decrements, increased incidence of small fetuses, cervical arches and centrum in fetuses and litters at levels from 5 to 20 mg/kg/day to diaphragmatic hernia at 200 mg/kg/day) in the absence of maternal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for assessing potential prenatal and postnatal toxicity of fluazifop-P-butyl to infants and children is complete.

ii. As there is limited indication of developmental neurotoxicity resulting from exposure to fluazifop-P-butyl with the current data sets, there is no need for a developmental neurotoxicity study. There were no developmental or central nervous system malformations seen in any of the developmental toxicity studies with rats or rabbits and

no evidence of neurotoxicity or neuropathology in adult animals in the available studies. The toxicological significance of the marginal increases in brain weights at high doses is unknown in the absence of corroborative histopathological lesions. EPA therefore concludes that there is not a concern for developmental neurotoxicity resulting from exposure to fluazifop-butyl or fluazifop-P-butyl.

iii. While there was quantitative evidence of increased susceptibility in the fetuses of rats exposed *in utero* to fluazifop-butyl and fluazifop-P-butyl, EPA concludes that there is no residual uncertainty for prenatal or postnatal toxicity that would warrant an additional 10X safety factor. The available studies clearly identify well-defined NOAELs and LOAELs that are consistent across the five developmental rat toxicity studies. In addition, the Agency has selected, based on these studies, a developmental endpoint of concern (diaphragmatic hernia) for assessing acute dietary risk. As this endpoint is relevant to single exposures, the acute risk assessment based on this endpoint will be protective of any fetal effects resulting from a single exposure. Further, the Agency has selected, based these studies, a developmental endpoint of concern (delayed ossifications) for repeat exposure scenarios, which will be protective of any developmental effects in those scenarios.

iv. There are no residual uncertainties identified in the exposure databases. There is an adequate toxicity database for fluazifop-P-butyl and exposure data are complete. The dietary and residential assessments are based on reliable data and will not underestimate exposure/risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluazifop-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. Although EPA has required additional data on transferable residues from treated turf for fluazifop-P-butyl, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (*e.g.,* assuming residues do not degrade over the thirty day assessment period and assuming high-end activities on turf for every day of the assessment period). The additional data on transferable turf residues have been required in case refinement of exposure assessments is needed in the future and to further EPA's general understanding of the availability of turf transferable pesticide residues. These assessments will not underestimate the exposure and risks posed by fluazifop-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 fluazifop will occupy 14% of the aPAD for females 13–49 years old, the only relevant population subgroup for the acute dietary endpoint.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazifop-P-butyl from food and water will utilize 64% 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 fluazifop-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). Fluazifop-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 Fluazifop-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 MOEs of 210 for adults and 3100 for children. Because EPA's level of concern for fluazifop-P-butyl is a MOE of 100 or below, these MOEs 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).

An intermediate-term adverse effect was identified; however, fluazifop-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 fluazifop-P-butyl.

5. *Aggregate cancer risk for U.S. population.* Fluazifop-P-butyl has been classified as ''Not likely to be carcinogenic to humans''; therefore, EPA concludes that fluazifop-P-butyl will not pose a cancer risk.

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 fluazifop-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. The method is available in Pesticide Analytical Methods (PAM), Volume II: Method I for animal tissues and milk and Method II for crops. The stated detection limits are 0.02–0.05 ppm for crops, 0.01 ppm for milk, and 0.02 ppm for animal tissues. Improved enforcement methods based on liquid chromatography and tandem mass spectroscopy, LC/MS/MS, are available as Method GRM044.01A and Method GRM044.02A. Both of these methods have been validated at 0.01 ppm on a wide variety of crop matrices.

*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 a MRL for fluazifop-P-butyl.

## V. Conclusion

Therefore, the tolerance is amended for residues of fluazifop-P-butyl in or on sweet potato, roots from 0.05 ppm to 1.5 ppm.

## VI. Statutory and Executive Order Reviews

This action amends a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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: July 23, 2015.

**Susan Lewis,**

*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, revise the commodity ''Sweet potato, roots'' in the table in paragraph (a) to read as follows:

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

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Sweet potato, roots | 1.5 |

* * * * *

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## CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

## 40 CFR Part 1600

## Organization and Functions of the Chemical Safety and Hazard Investigation Board

**AGENCY:** Chemical Safety and Hazard Investigation Board.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the quorum and voting regulations of the Chemical Safety and Hazard Investigation Board (CSB). The amendments add a requirement for the Chairperson to place notation votes that have been calendared for discussion at a Board Meeting to the agenda of a public meeting within 90 days of the calendared notation vote. The rule also adds a requirement for the Chairperson to conduct a minimum of four public meetings per year in Washington, DC.

**DATES:** Effective August 6, 2015.

**SUPPLEMENTARY INFORMATION:** This final rule will promote increased transparency and accountability for Board activities. It aligns with the Open Government principles of transparency, participation, and collaboration, as outlined in the Memorandum on Transparency and Open Government (74 FFR 4685, Jan. 26, 2009).

The Board conducts most votes through a process of notation voting. In notation voting, Board Members may vote to approve, disapprove, or calendar a notation item for discussion at a public meeting. In recent years, notation items have been calendared but then not placed on the agenda for discussion at a public meeting of the Board. The addition of language to 40 CFR 1600.5(b) will ensure that calendaring is used in the way it was intended. It will require the consideration of calendared notation votes at a public meeting within 90 days of the calendaring action. Prior to the adoption of this amendment to the rule, calendaring