Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number and title for the program affected by this document is 64.114, Veterans Housing—Guaranteed and Insured Loans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on September 16, 2016, for publication.

List of Subjects in 38 CFR Parts 36 and 42

Condominiums, Housing, Individuals with disabilities, Loan programs-housing and community development, Loan programs-veterans, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements, Veterans.

PART 36—LOAN GUARANTY

PART 42—STANDARDS IMPLEMENTING THE PROGRAM FRAUD CIVIL REMEDIES ACT

■ Accordingly, the interim rule amending 38 CFR parts 36 and 42 which was published at 81 FR 40523 on June 22, 2016, is adopted as a final rule without change.

Dated: September 16, 2016.

Michael Shores

Acting Director, Regulation Policy & Management Office of the Secretary Department of Veterans Affairs

[FR Doc. 2016–22732 Filed 9–22–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0226; FRL–9951–68]

Flupyradifurone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flupyradifurone in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2016. Objections and requests for hearings must be received on or before November 22, 2016, 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–2013–0226, 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 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–2013–0226 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 22, 2016. 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–2013–0226, 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 March 16, 2016 (81 FR 14030) (FRL–9942–86), 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 5F8404) by Bayer CropScience LP, 2 T.W. Alexander

Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide, flupyradifurone, in or on abiu at 0.6 parts per million (ppm); akee apple at 0.6 ppm; avocado at 0.6 ppm; bacury at 0.6 ppm; banana at 0.6 ppm; binjai at 0.6 ppm; caneberry, subgroup 13–07A at 5 ppm; canistel at 0.6 ppm; cilantro, fresh leaves at 30 ppm; cupuacú at 0.6 ppm; etambe at 0.6 ppm; jatobá at 0.6 ppm; kava, fresh leaves at 40 ppm; kava, roots at 0.9 ppm; kei apple at 0.6 ppm; langstat at 0.6 ppm; lanjut at 0.6 ppm; lucuma at 0.6 ppm; mabolo at 0.6 ppm; mango at 0.6 ppm; mangosteen at 0.6 ppm; paho at 0.6 ppm; papaya at 0.6 ppm; pawpaw, common at 0.6 ppm; pelipisan at 0.6 ppm; pequi at 0.6 ppm; pequia at 0.6 ppm; persimmon, american at 0.6 ppm; plantain at 0.6 ppm; pomegranate at 0.6 ppm; poshte at 0.6 ppm; quandong at 0.6 ppm; quinoa at 3 ppm; sapote at 0.6 ppm; sataw at 0.6 ppm; screw-pine at 0.6 ppm; star apple at 0.6 ppm; stone fruit, stone group 12–12 at 1.5 ppm; tamarind-of-the-Indies at 0.6 ppm; and wild loquat at 0.6 ppm. That document referenced a summary of the petition prepared by Bayer CropScience LP, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified some of the commodity definitions that were proposed. The reason for these changes are explained in Unit IV.D.

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 flupyradifurone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flupyradifurone 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 most sensitive effects seen in the flupyradifurone database were skeletal muscle atrophy/degeneration in dogs. With repeated dosing, reductions in body weight and food consumption were commonly seen in various studies and in all species of test animals (rats, mice, dogs, and rabbits). The liver and thyroid were shown to be the common findings of flupyradifurone toxicity. The database appears to suggest that dogs are more sensitive to the effects of flupyradifurone; however, with body weight adjustments (based on a ¾ scaling factor), the dog and rat are almost equally as sensitive in response to flupyradifurone toxicity. The skeletal muscle atrophy/degeneration seen in the 90-day and 1-year dog studies formed the basis for chronic dietary exposure toxicity endpoints.

The developmental toxicity study in rats demonstrated no evidence of susceptibility in developing animals. In the rabbit developmental toxicity study, there was an increase in the incidence of fetal death at 80 milligram/kilogram/day (mg/kg/day) (the highest dose tested), a dose that did not produce adverse effects in the maternal animals.

Therefore, a quantitative increase in susceptibility was demonstrated in the rabbit developmental toxicity study. In the 2-generation reproduction study in rats, decreased parental body weights (≥10%) were seen at the lowest-observed-adverse-effect-level (LOAEL) of 137 mg/kg/day (parental no-observed-adverse-effect-level (NOAEL) = 37.8 mg/kg/day). In contrast, body weight decreases that were considered adverse were seen in F2 pups at 37.8 mg/kg/day (the parental NOAEL and the offspring LOAEL; offspring NOAEL = 7.7 mg/kg/day). These findings suggest quantitative susceptibility for developing young animals.

The acute neurotoxicity study (dosing by gavage) showed that at the time of peak-effect, flupyradifurone caused increases in the incidence of piloerection and dilated pupils at 50 mg/kg. At the next higher dose level (200 mg/kg) and above, it produced a large host of clinical signs, which were related to neurotoxicity. The clinical signs included dilated pupils, lower muscle tone, low arousal, tremors, myoclonic jerks, chewing, repetitive licking of lips, gait incoordination, flattened or hunched posture, and impaired righting reflex. In the 90-day neurotoxicity study, no neurotoxicity or other adverse effects were seen at dose levels as high as 174 mg/kg/day. The developmental neurotoxicity study at 102 mg/kg/day yielded an increased incidence of increased amplitude in startle response.

Flupyradifurone is classified as ''not likely to be carcinogenic to humans.'' Carcinogenicity studies in rats and mice did not yield a compound-related increase in tumor incidence, and the genotoxicity battery did not show flupyradifurone to produce any genotoxicity. Flupyradifurone did not demonstrate any immunotoxic effects.

Specific information on the studies received and the nature of the adverse effects caused by flupyradifurone as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''*Flupyradifurone (122304) Human Health Risk Assessment in Support of Proposed Uses on Kava, Cilantro, Stone Fruit, Group 12–12, Caneberry, Subgroup 13–07A, Quinoa, and Tropical Fruits; Amended Use Requests for Soil Applications to Leafy Vegetables, Group 4 and Brassica (Cole) Leafy Vegetables, Group 5; Use on Greenhouse Grown Tomato, Pepper, Cucumber, and Lettuce; Label Amendment to Add Commodities of Tree Nuts, Group 14–12 to label; and Label Amendment to Add Use Directions for Clover Grown for Forage, Fodder, Seed, Straw, and Hay*'' on page 49 in docket ID number EPA–HQ–OPP–2013–0226.

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 flupyradifurone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUPYRADIFURONE 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 (All populations) ..	NOAEL = 35 mg/kg/day. UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	Acute RfD = 0.35 mg/kg/day. aPAD = 0.35 mg/kg/day.	Acute neurotoxicity study—rat LOAEL = 50 mg/kg/day based on increased incidences of piloerection in both sexes and pupil dilation in females on Day 1. At the next higher dose level (200 mg/kg) or above, lower muscle tone, rapid respiration, low arousal, tremors, myoclonic jerks, chewing, repetitive licking of lips, gait incoordination, flattened or hunched posture, dilated pupils, impaired (uncoordinated or slow) righting reflex, impaired flexor and tail pinch responses and reduced rectal temperature. Automated measures of motor activity were also reduced in both sexes, compared to controls.
Chronic dietary (All populations)	NOAEL= 7.8 mg/kg/day. UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	Chronic RfD = 0.078 mg/kg/day. cPAD = 0.078 mg/kg/day.	Oral toxicity study—dog (1-year) LOAEL = 28 mg/kg/day based on minimal to slight, focal to multifocal areas of skeletal muscle degeneration in gastrocnemius and/or biceps femoris muscle.
Dermal short-term (1 to 30 days).	Dermal (or oral) study NOAEL = 12 mg/kg/day (dermal absorption rate = 7.42%. UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	LOC for MOE = 100	Oral toxicity study—dog (90-day) LOAEL = 33 mg/kg/day based skeletal muscle atrophy/degeneration. 2-Generation reproduction study—rat (co-critical study) NOAEL = 7.7 mg/kg/day. Offspring LOAEL = 38.7 mg/kg/day based on pup body weight decrease.
Inhalation short-term (1 to 30 days).	Oral study NOAEL = 12 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	LOC for MOE = 100	Oral toxicity study—dog (90-day) LOAEL = 33 mg/kg/day based on skeletal muscle atrophy/degeneration. 2-Generation reproduction study—rat (co-critical study) NOAEL = 7.7 mg/kg/day. Offspring LOAEL = 38.7 mg/kg/day based on pup body weight decrease.
Cancer (Oral, dermal, inhalation).	Classification: Not likely to be carcinogenic to humans—based on data showing no treatment-related increase in tumors incidence in rat and mouse carcinogenicity studies. No mutagenic concern was reported in the genotoxicity studies.		

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_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flupyradifurone, EPA considered exposure under the petitioned-for tolerances as well as all existing flupyradifurone tolerances in 40 CFR 180.679. EPA assessed dietary exposures from flupyradifurone 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 flupyradifurone. In estimating acute dietary exposure, EPA used food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed 100% crop treated (PCT), tolerance level residues and Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment

EPA used the food consumption data from the USDA's NHANES/WWEIA; 2003–2008. As to residue levels in food, EPA assumed 100 PCT, tolerance level residues and DEEM (ver. 7.81) default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flupyradifurone 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.* EPA did not use anticipated residue or PCT information in the dietary assessment for flupyradifurone. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flupyradifurone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flupyradifurone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of flupyradifurone for acute exposures are estimated to be 112 parts per billion (ppb) for surface water and 352 ppb for ground water, and for chronic exposures are estimated to be 112 ppb for surface water and 307 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 352 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 307 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).

Currently there are no registered uses for flupyradifurone that could result in residential exposures. However, there is a proposal to register uses that could result in residential exposures for application to ornamental plants (gardens, trees, shrubs, flowers). Therefore, the EPA considered the proposed residential uses and assessed residential exposure using the following assumptions: For residential handlers, short-term dermal and inhalation exposures were assessed for adults mixing, loading and applying liquids and ready to use formulations to gardens and trees using a variety of application equipment. For post-application exposure, short-term dermal exposures to adults and children (6 to <11 years old) to gardens, trees, and retail plants and indoor plants was evaluated. Only short-term residential exposures are expected. 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 flupyradifurone to share a common mechanism of toxicity with any other substances, and flupyradifurone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flupyradifurone 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 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.* There is no evidence that flupyradifurone produces increased susceptibility in in the rat developmental study. There is quantitative increase in susceptibility in the rabbit developmental and rat reproduction studies. In the rabbit developmental study, no maternal effect was seen at the highest tested dose (80 mg/kg/day), while there was an increase in fetal death and decrease fetal body weight at the same dose level. In the rat reproduction study, maternal effect, decrease in body weight, was seen at 137 mg/kg/day, whereas decreases in pup body weight was seen at the next lower dose, 38.7 mg/kg/day or above. However, the PODs selected for risk assessment are protective of the quantitative susceptibility seen in the rabbit fetuses and rat pups.

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 flupyradifurone is complete.

ii. Although there is evidence that flupyradifurone has neurotoxic effects, EPA has a complete set of neurotoxicity studies (acute, subchronic, and developmental). The effects of those studies are well-characterized and indicate neurotoxic effects that occur at levels above the chronic POD that was selected for risk assessment. The NOAEL for the acute neurotoxicity study is being used for the acute POD. Therefore, there is no need to retain the 10X FQPA SF to account for any uncertainty concerning these effects.

iii. There is no evidence that flupyradifurone results in increased susceptibility in *in utero* rats. There is quantitative increase in susceptibility in the rabbit developmental and rat reproduction studies. However, the PODs selected for risk assessment are protective of the quantitative susceptibility seen in the rabbit fetuses and rat pups.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to

flupyradifurone in drinking water. EPA used similarly conservative assumptions to assess the proposed residential post-application exposure of children. These assessments will not underestimate the exposure and risks posed by flupyradifurone.

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 flupyradifurone will occupy 37% 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 flupyradifurone from food and water will utilize 86% 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 flupyradifurone 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). For flupyradifurone there are uses pending which the Agency has included in this action 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 flupyradifurone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and proposed residential exposures result in aggregate MOEs of 170 for adults and 190 for children (6 to <11 years old). Because EPA's level of concern for flupyradifurone 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, flupyradifurone 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 flupyradifurone.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flupyradifurone 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 flupyradifurone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method (Method RV–001–P10–03) which uses high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS/MS) to quantitate residues of flupyradifurone and difluoroacetic acid (DFA) in various crops is available for enforcement.

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

B. International Residue Limits

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

The Codex has not established any MRLs for flupyradifurone.

C. Response to Comments

EPA received two comments to the Notice of Filing. The first stated, in part, that EPA should deny this petition because it is a harmful and toxic chemical. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

The second comment was from Interregional Research Project Number 4 (IR–4) and was in support of the petition.

D. Revisions to Petitioned-For Tolerances

Bayer CropScience LP petitioned for tolerances on abiu, akee apple, avocado, bacury, banana, binjai, canistel, cupuacú, etambe, jatobá, kei apple, langstat, lanjut, lucuma, mabolo, mango, mangosteen, paho, papaya, common pawpaw, pelipisan, pequi, pequia, American persimmon, plantain, pomegranate, poshte, quandong, sapote, sataw, screw-pine, star apple, tamarind-of-the-Indies, and wild loquat. These commodities are all listed in the newly established crop subgroup 24B for tropical and subtropical, medium to large fruit, with a smooth, inedible peel. Subgroup 24B further breaks out the different types of avocado (to include Guatemalan, Mexican, and West Indian avocado), mango (to include horse and Saipan mango), and sapote (to include

black, green, and white sapote). Although the petitioner did not specify any particular kind of avocado, mango, and sapote, the Agency considers the request for avocado, mango, and sapote to be general in nature and include all varieties of those commodities. As a result, the requested commodities align with the commodities contained in the new subgroup 24B.

In the **Federal Register** of May 3, 2016 (81 FR 26471) (FRL–9944–87) establishing that crop group, EPA indicated that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on crop subgroup 24B, the tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup, rather than all the commodities individually. EPA's dietary and aggregate risk assessments are based on data from the required representative commodities and account for flupyradifurone exposure from all of the subgroup 24B commodities.

V. Conclusion

Therefore, tolerances are established for residues of flupyradifurone, including its metabolites and degradates, in or on caneberry subgroup 13–07A at 5.0 ppm; cilantro, fresh leaves at 30 ppm; fruit, stone, group 12–12 at 1.5 ppm; kava, fresh leaves at 40 ppm; kava, roots at 0.90 ppm; quinoa, grain at 3.0 ppm; and the tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B at 0.60 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) 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: September 14, 2016.

Daniel J. 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 § 180.679, add alphabetically the commodities ''Caneberry subgroup 13–07A''; ''Cilantro, fresh leaves''; ''Fruit, stone, group 12–12''; ''Kava, fresh leaves''; ''Kava, roots''; ''Quinoa, grain''; and ''Tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B'' to the table in paragraph (a) to read as follows:

§ 180.679 Flupyradifurone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Caneberry subgroup 13–07A	5.0
* * * * *	
Cilantro, fresh leaves	30
* * * * *	
Fruit, stone, group 12–12	1.5
* * * * *	
Kava, fresh leaves	40
Kava, roots	0.90
* * * * *	
Quinoa, grain	3.0
* * * * *	
Tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B	0.60
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