H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. There is no information in the record indicating that this action would be inconsistent with the stated goals of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

K. Congressional Review Act

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 3, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: January 25, 2023.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, 40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Section 81.323 is amended in the table for ''Michigan—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Detroit, MI'' to read as follows:

§ 81.323 Michigan.

* * * * *

MICHIGAN-2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* * *	*	*	*	*
Detroit, MI:		Nonattainment	March 1, 2023	Moderate.
Livingston County				
Macomb County				
Monroe County				
Oakland County				
St. Clair County				
Washtenaw County				
Wayne County				
* * *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[FR Doc. 2023–01936 Filed 1–31–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0449; FRL–10566–01–OCSPP]

Fluopyram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises the tolerance for residues of fluopyram in or on coffee, green bean and establishes tolerances for residues of fluopyram in or on multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective on February 1, 2023. Objections and requests for hearings must be received

on or before April 3, 2023, 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–2021–0449, is available at *https://www.regulations.gov* or in-person 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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2021–0449 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 April 3, 2023. 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–2021–0449, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 22, 2021 (86 FR 52624) (FRL–8792–03–OCSPP), 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 1E8932) by the Interregional Research Project Number 4 (IR–4), Project Headquarters, North Carolina University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requests to amend 40 CFR 180.661(a)(1) by establishing tolerances for residues of the fungicide fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on the following raw agricultural commodities: *Brassica,* leafy greens, subgroup 4–16B at 50 parts per million (ppm); celtuce at 20 ppm; coffee, green bean at 0.03 ppm; fennel, Florence, fresh leaves and stalk at 20 ppm; kohlrabi at 4 ppm; leafy greens subgroup 4–16A at 40 ppm; leaf petiole vegetable subgroup 22B at 20 ppm; papaya at 1.5 ppm; peppermint, dried leaves at 0.8 ppm; peppermint, fresh leaves at 0.6 ppm; spearmint, dried leaves at 0.8 ppm; spearmint, fresh leaves at 0.6 ppm; spice group 26 at 70 ppm; vegetable, *Brassica,* head and stem, group 5–16 at 4 ppm; individual commodities of proposed crop subgroup 6–XXA; edible podded bean legume vegetable subgroup at 4 ppm; individual commodities of proposed crop subgroup 6–XXB edible podded pea legume vegetable subgroup at 4 ppm; individual commodities of proposed crop subgroup 6–XXC: succulent shelled bean subgroup at 0.2 ppm; individual commodities of proposed crop subgroup 6–XXD: succulent shelled pea subgroup at 0.2 ppm; and the individual commodities of proposed crop subgroup 6–XXE: dried shelled bean, except soybean, subgroup at 0.7 ppm. Due to the length of the list of commodities, please refer to the document EPA issued in the **Federal Register** on September 22, 2021, for a complete list of the tolerances requested. The petition also requested the removal of the tolerances for residues of fluopyram in or on bean, dry at 0.70 ppm; *Brassica,* head and stem, subgroup 5A at 4.0 ppm; *Brassica,* leafy greens, subgroup 5B at 50 ppm; dill, seed at 70 ppm; leafy greens subgroup 4A at 40 ppm; leafy petioles subgroup 4B at 20 ppm; pea and bean, succulent shelled, subgroup 6B at 0.20 ppm; and vegetable, legume, edible podded, subgroup 6A at 4.0 ppm. That document referenced a summary of the petition prepared by IR–4, the petitioner, which is available in the docket, *https://www.regulations.gov.* Three comments were received on the Notice of Filing; however, the comments were not relevant to the petition for fluopyram tolerances that are the subject of this action.

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 therein 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 fluopyram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopyram 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 toxicological database for fluopyram has been re-evaluated as part of registration review and relevant studies were updated in accordance with current practices. The fluopyram database is considered complete.

Liver effects, thyroid effects, and decreased body weight were the most common and frequent findings in the subchronic and chronic oral toxicity studies in rats, mice, and dogs, and appeared to be the most sensitive effects in the fluopyram toxicological database. Increased liver tumors were observed in female rats in the carcinogenicity study at the highest dose tested (89 mg/kg/day). Thyroid effects (increased thyroid weight along with follicular cell hypertrophy and hyperplasia) were observed at dose levels similar to those that produced liver effects in rats and mice. In male mice, there was an increased incidence of thyroid adenomas at the highest dose tested (105 mg/kg/day). Fluopyram induces liver enzymes following constitutive androstane receptor and pregnane X receptor (CAR/PXR) activation, which causes increased metabolism of thyroid hormones. These changes lead to liver and thyroid hypertrophy and proliferation, eventually leading to liver tumors (female rat) and thyroid tumors (male mice). EPA classified fluopyram as ''Not Likely to be Carcinogenic to Humans'' at doses that do not induce cellular proliferation in the liver or thyroid glands. This classification was based on evidence that non-genotoxic modes of action for liver tumors in rats and thyroid tumors in mice have been established and that the carcinogenic effects have been demonstrated as a result of a mode of action dependent on activation of the CAR/PXR receptors. EPA determined that quantification of risk is not required. There is sufficient data to ascertain the mode of action of fluopyram. The chronic Reference Dose (RfD) is derived using the no-observed adverse-effect level (NOAEL) of 6 mg/kg/day as the POD which is below the dose of 11 mg/kg/day that caused cell proliferation in the liver (a key event in tumor formation) and the subsequent liver tumors at a higher dose (89 mg/kg/day). Additionally, there is no concern for mutagenicity.

Fluopyram did not elicit developmental or offspring effects, nor did it adversely affect reproductive parameters. No evidence of increased qualitative or quantitative susceptibility was observed in developmental or reproduction toxicity studies. There is no evidence of neurotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by fluopyram 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 in the document titled ''Fluopyram. Human Health Risk Assessment for Proposed Uses on Coffee, Green Bean, Papaya, Peppermint, Spearmint and Crop Group Expansions/Conversions.'' (hereinafter ''Fluopyram Human Health Risk Assessment'') on pages 43–52 in docket ID number EPA–HQ–OPP–2021–0449.

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 NOAEL and 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints and PODs for fluopyram used for human risk assessment can be found in the Fluopyram Human Health Risk Assessment on pages 25–26.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopyram, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopyram tolerances in 40 CFR 180.661. EPA assessed dietary exposures from fluopyram in food as follows:

i. *Acute and 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 fluopyram.

In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM–FCID) Version 4.02, which uses the 2005–2010 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). As to residue levels in food, a partially refined acute dietary exposure assessment was conducted, incorporating field trial residues for coffee and the commodities of crop group 15 and crop subgroup 20A, and tolerance-level residues for all other crop commodities. One hundred percent crop treated (PCT) was assumed.

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

assessment, EPA used the food consumption data from the USDA's 2005–2010 NHANES/WWEIA and DEEM–FCID; version 4.02. As to residue levels in food, the chronic dietary exposure assumed tolerance-level residues for mint and papaya and used mean field trial data and empirical processing factors for all other commodities. Average PCT estimates were used for some crops.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopyram 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 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 the following conditions are met:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

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

The Agency estimated the PCT for existing uses as follows: almonds, 20%; apples, 25%; apricots, 5%; artichoke, 15%; broccoli, 2.5%; cabbage, 2.5%; carrots, 1%; cauliflower, 1%; cherries, 25%; cotton, 1%; dry beans and peas, 1%; grapefruit, 10%; grapes, raisins, 1%; table grapes, 5%; wine grapes; 20%; lemons, 1%; lettuce, 1%; onions, 1%; oranges, 15%; peaches, 1%; peanuts, 2.5%; pears, 5%; peppers, 5%; pistachios, 15%; potatoes, 20%; strawberries, 10%; tomatoes, 1%; walnuts, 10%; and watermelons, 15%. EPA assumed 100 PCT for all other commodities included in the chronic assessment.

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

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 fluopyram 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 fluopyram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopyram. Further information regarding EPA drinking water models used in pesticide exposure assessments can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-risk-assessment.*

Based on the Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model—Ground Water (PRZM–GW) model, the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are estimated to be 50.6 parts per billion (ppb) for surface water and 97.6 ppb for ground water. For chronic exposures for non-cancer assessments, the EDWCs of fluopyram are estimated to be 17.3 ppb for surface water and 90.5 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 97.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of 90.5 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).

There are no residential exposures associated with the proposed uses of fluopyram on coffee, mint, and papaya in this action; however, residential post-application exposures are anticipated from other registered uses of fluopyram on golf course turf, residential lawns, fruit trees, nut trees, ornamentals, and gardens. From the reevaluation of the toxicity database, the endpoints selected for residential exposures include incidental oral and short- and intermediate-term inhalation endpoints, but a dermal endpoint is no longer selected. A dermal endpoint was not selected as there were no adverse effects observed in the route-specific dermal

toxicity study, which included evaluation of fluopyram target organs, up to the limit dose of 1,000 mg/kg/day. Additionally, there was no evidence of increased quantitative susceptibility in the fluopyram database.

EPA assessed residential exposure using the following assumptions. Residential handler exposures and risk are not assessed in this document because the existing registered uses for residential sites are from end-use products that require handlers to wear specific clothing and personal protective equipment (PPE). Thus, EPA has assumed that those products are not for homeowner use and a quantitative residential handler assessment is not warranted at this time. There are residential post-application exposures from existing turf uses that have been previously assessed. The residential exposure for use in the children 1 to less than 2 years old aggregate assessment reflects incidental oral hand-to-mouth post-application exposure to treated lawns. The MOE is 5,400, which is greater than the level of concern of 100 and therefore is not of concern. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluopyram and any other substances, and fluopyram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that fluopyram has 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 website at *https://www.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 (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 of increased susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, or in the 2-generation rat reproduction study. There is no evidence of neurotoxicity, and there are no residual uncertainties in the exposure database. While thyroid effects are observed throughout the database, EPA determined that the comparative thyroid assay (CTA) be waived based on a weight-of-evidence approach.

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 from 10X to 1X. That decision is based on the following findings:

i. The toxicology database for fluopyram is complete and adequate for risk assessment. EPA waived the subchronic inhalation toxicity study requirement and the previously required CTA for fluopyram for the following reasons: (1) the margins of exposure are low using the current endpoints; (2) thyroid effects are well-characterized and protected for using the current endpoints; and (3) acute inhalation toxicity is low and the compound is unlikely to volatilize. The toxicology database includes acceptable developmental toxicity studies in the rat and rabbit and an acceptable reproductive toxicity study in the rat, as well as acute and subchronic neurotoxicity studies.

ii. Potential signs of neurotoxicity were observed in the rat acute neurotoxicity study (decreased motor activity) and in the rat chronic/carcinogenicity study (reduced use of hind-limbs and limited motor activity). However, these effects are not specific to neurotoxicity, occur in the presence of other effects, and can also be attributed to systemic toxicity. There is a low degree of concern for potential neurotoxic effects since (1) clear NOAELs were identified for these effects, (2) no other neurotoxic effects were identified in the database, (3) potentially neurotoxic effects are not the most sensitive effect in the toxicity database, and (4) the endpoints chosen for risk assessment are protective of these potentially neurotoxic effects.

iii. The available developmental toxicity studies in rats and rabbits and the multi-generation reproduction in rats demonstrate no evidence of increased susceptibility in the developing or young animals which were exposed during pre- or post-natal periods. No developmental or offspring effects were noted in these studies.

iv. There are no residual uncertainties in the exposure database. The acute dietary exposure assessment was performed using conservative exposure inputs, including field trial residue levels or tolerance level residues for all crops; and average field-trial residue levels were assumed for all crops in the chronic dietary exposure assessment. The acute dietary assessment assumed 100 PCT, whereas the chronic dietary assessment utilized average PCT numbers for some crops. Both acute and chronic dietary assessments incorporated empirical or default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopyram 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 fluopyram.

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 population adjusted dose (aPAD) and chronic population adjusted dose (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 fluopyram will occupy 25% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. The aggregate acute risk estimate includes only exposure to residues of fluopyram in food and drinking water, which is below the Agency's level of concern of 100% of the aPAD and is not of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopyram from food and water will utilize 16% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Chronic residential exposure to residues of fluopyram is not expected. Therefore, the chronic aggregate exposure is equivalent to the chronic dietary exposure, which is below the Agency's level of concern of 100% of the cPAD and is not of concern.

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). Fluopyram is currently registered for uses that could result in short-term residential post-application exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluopyram. 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 2,100 for children (1 to less than 2 years old). Because EPA's level of concern for fluopyram is an MOE of 100 or below, the short-term aggregate risk is 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).

The short-and intermediate-term PODs are the same and the intermediate-term exposures are smaller than the short-term exposures, thus, the short-term aggregate exposure assessment is protective of any intermediate-term exposures.

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

6. *Determination of safety.* Based on these risk assessments and information described above, 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 fluopyram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology DFG Method S19 using GC/MSD (gas chromatography with mass-selective detection) is available to enforce the tolerance expression.

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

B. International Residue Limits

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

There are no established Codex MRLs for *Brassica,* leafy greens, subgroup 4–16B; celtuce; coffee, green bean; fennel, Florence, fresh leaves and stalk; kohlrabi; leaf petiole vegetable subgroup 22B; mint; papaya; or edible podded peas. The U.S. tolerance for spice group 26 is harmonized with the Codex MRL of 70 ppm in/on dill seed, which is the representative crop for spice group 26. The U.S. tolerances for the succulent shelled bean subgroup 6–22C and succulent shelled pea subgroup 6–22D are harmonized with the Codex MRL of 0.2 ppm for the commodities in those subgroups.

For the remaining commodities (leafy greens subgroup 4–16A; vegetable, *Brassica,* head and stem, group 5–16; edible podded bean subgroup 6–22A; and dried shelled bean, except soybean, subgroup 6–22E), the established Codex MRLs are lower than the U.S. tolerances. Harmonization is not possible because decreasing the U.S. tolerances would put U.S. growers at risk of having violative residues despite legal use of fluopyram according to the label.

C. Revisions to Petitioned-For Tolerances

Because the final Phase VI crop group rule has been published, EPA is establishing tolerances for new subgroups in legume vegetable crop group 6–22 rather than for each individual commodity in those subgroups as requested by the petitioner. The Phase VI crop group rule allows the commodities to be covered as part of the new group or subgroups instead of needing to be listed separately. The Phase VI crop group was published on September 21, 2022, and was effective on November 21, 2022 (87 FR 57627) (FRL–5031–13–OCSPP).

V. Conclusion

Therefore, tolerances are established for residues of fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on *Brassica,* leafy greens, subgroup 4–16B at 50 ppm; celtuce at 20 ppm; fennel, Florence, fresh leaves and stalk at 20 ppm; kohlrabi at 4 ppm; leaf petiole vegetable subgroup 22B at 20 ppm; leafy greens subgroup 4–16A at 40 ppm; papaya at 1.5 ppm; peppermint, dried leaves at 0.8 ppm; peppermint, fresh leaves at 0.6 ppm; spearmint, dried leaves at 0.8 ppm; spearmint, fresh leaves at 0.6 ppm; spice group 26 at 70 ppm; vegetable, *Brassica,* head and stem, group 5–16 at 4 ppm; vegetable, legume, bean, edible podded, subgroup 6–22A at 4 ppm; vegetable, legume, pea, edible podded, subgroup 6–22B at 4 ppm; vegetable, legume, bean, succulent shelled, subgroup 6–22C at 0.2 ppm; vegetable, legume, pea, succulent shelled, subgroup 6–22D at 0.2 ppm; and vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E at 0.7 ppm. The tolerance for coffee, green beans at 0.03 ppm is revised to remove the footnote. The following tolerances are removed: bean, dry at 0.70 ppm; *Brassica,* head and stem, subgroup 5A at 4.0 ppm; *Brassica,* leafy greens, subgroup 5B at 50 ppm; dill, seed at 70 ppm; leafy greens subgroup 4A at 40 ppm; leafy petioles subgroup 4B at 20 ppm; pea and bean, succulent shelled, subgroup 6B; and vegetable, legume, edible podded, subgroup 6A.

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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: January 26, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.661, table 1 to paragraph (a)(1) is amended by:
■ a. Removing the entries for ''Bean, dry'' and ''*Brassica,* head and stem, subgroup 5A'';
■ b. Adding in alphabetical order the entry ''*Brassica,* leafy greens, subgroup 4–16B'';
■ c. Removing the entry for ''*Brassica,* leafy greens, subgroup 5B'';
■ d. Adding in alphabetical order the entry ''Celtuce'';
■ e. Revising the entry for ''Coffee, green beans'' by removing the footnote;
■ f. Removing the entry for ''Dill, seed'';
■ g. Adding in alphabetical order the entries ''Fennel, Florence, fresh leaves and stalk'', ''Kohlrabi'', ''Leaf petiole vegetable subgroup 22B'' and ''Leafy greens subgroup 4–16A'';
■ h. Removing the entries for ''Leafy greens subgroup 4A'' and ''Leafy petioles subgroup 4B'';
■ i. Adding in alphabetical order the entry ''Papaya'';
■ j. Removing the entry ''Pea and bean, succulent shelled, subgroup 6B'';
■ k. Adding in alphabetical order the entries ''Peppermint, dried leaves'', ''Peppermint, fresh leaves'', ''Spearmint, dried leaves'', ''Spearmint, fresh leaves'', ''Spice group 26'', ''Vegetable, *Brassica,* head and stem, group 5–16'', ''Vegetable, legume, bean, edible podded, subgroup 6–22A'', and ''Vegetable, legume, bean, succulent shelled, subgroup 6–22C'';
■ l. Removing the entry ''Vegetable, legume, edible podded, subgroup 6A'';
■ m. Adding in alphabetical order the entries ''Vegetable, legume, pea, edible podded, subgroup 6–22B'', ''Vegetable, legume, pea, succulent shelled, subgroup 6–22D''and ''Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E''; and
■ n. Removing footnote 2.

The additions and revisions read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *
(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * * * *	
Brassica, leafy greens, subgroup 4–16B	50
* * * * * * *	
Celtuce	20

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
* * * * * * *	
Coffee, green beans	0.03
* * * * * * *	
Fennel, Florence, fresh leaves and stalk	20
* * * * * * *	
Kohlrabi	4
Leaf petiole vegetable subgroup 22B	20
Leafy greens subgroup 4–16A	40
* * * * * * *	
Papaya	1.5
* * * * * * *	
Peppermint, dried leaves	0.8
Peppermint, fresh leaves	0.6
* * * * * * *	
Spearmint, dried leaves	0.8
Spearmint, fresh leaves	0.6
Spice group 26	70
* * * * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	4
* * * * * * *	
Vegetable, legume, bean, edible podded, subgroup 6–22A	4
Vegetable, legume, bean, succulent shelled, subgroup 6–22C	0.2
Vegetable, legume, pea, edible podded, subgroup 6–22B	4
Vegetable, legume, pea, succulent shelled, subgroup 6–22D	0.2
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E	0.7
* * * * * * *	

[1] There are no U.S. registrations.

* * * * *

[FR Doc. 2023–02109 Filed 1–31–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4185–F2]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule announces certain policies to improve program integrity and payment accuracy in the Medicare Advantage (MA) program. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level MA Risk Adjustment Data Validation (RADV) program. Specifically, this final rule codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018 and will not extrapolate RADV audit findings for PYs 2011 through 2017. We are also finalizing a policy whereby CMS will not apply an adjustment factor (known as a Fee-For-Service (FFS) Adjuster) in RADV audits. We are also codifying in regulation the requirement that MA organizations (MAOs) remit improper payments identified during RADV audits in a manner specified by CMS.

DATES: This final rule is effective on April 3, 2023.

FOR FURTHER INFORMATION CONTACT: Joseph Strazzire, 410–786–2775 or David Gardner, 410–786–7791.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Contract-level Risk Adjustment Data Validation (RADV) audits are our main corrective action for overpayments made to Medicare Advantage organizations (MAOs) when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level RADV program. Specifically, this final rule codifies in regulation our approach to the use of extrapolation, our decision to not apply an FFS Adjuster in RADV audits, and the payment years in which these policies will apply.

We are finalizing that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings. We are not adopting any specific sampling or extrapolated audit methodology, but will rely on any statistically valid method for sampling and extrapolation that is determined to be well-suited to a particular audit. Rather than applying extrapolation beginning for payment year (PY) 2011 audits as we proposed,