insecticide cyromazine, including its metabolites and degradates, in or on the commodities in the table 3 to this paragraph (d)(2) when present therein as a result of the application of poultry manure-based fertilizer containing cyromazine to soil in which the crops identified in this section are grown. Compliance with the tolerance levels specified in this paragraph (d)(2) is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on the commodity.

TABLE 3 TO PARAGRAPH (d)(2)

Commodity	Parts per million
Grain, cereal, forage, fodder and straw, group 16	0.6
Grain, cereal, group 15	0.6
Herbs and spices, group 19	0.6
Oilseed, group 20	0.6
Onion, bulb, subgroup 3–07A	0.6
Strawberry	0.6
Vegetable, foliage of legume, group 7	0.6
Vegetable, fruiting, group 8–10	0.6
Vegetable, leaves of root and tuber, group 2	0.6
Vegetable, legume, group 6	0.6
Vegetable, root and tuber, group 1	0.6

■ 3. In § 180.415, amend table 1 to paragraph (a) by:
■ a. Removing the entry ''Ginseng [1]'' and adding in its place the entry ''Ginseng [2]''; and
■ b. Redesignating the second footnote 1 as footnote 2.

The addition reads as follows:

§ 180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * * * *	
Ginseng [2]	0.1
* * * * * * *	

[2] This tolerance expires on January 19, 2024.

* * * * *

[FR Doc. 2023–17800 Filed 8–18–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0235; FRL–10953–01–OCSPP]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on stevia, dried leaves and stevia, fresh leaves and revises the tolerance for residues of pyraclostrobin in or on coffee, green bean. The Interregional Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 21, 2023. Objections and requests for hearings must be received on or before October 20, 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–2022–0235, 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, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, 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(g), 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–2022–0235 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 20, 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–2022–0235, 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 Tolerances

In the **Federal Register** of April 28, 2022 (87 FR 25178) (FRL–9410–12–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 (PP1E8981) by IR–4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.582 be amended to establish tolerances for residues of the fungicide pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin in or on the following raw agricultural commodities: stevia, dried leaves at 150 parts per million (ppm) and stevia, fresh leaves at 40 ppm. The petition also requested the revision of the tolerance for residues of pyraclostrobin in or on coffee, green bean at 0.3 ppm to support the domestic use on coffee rather than being a tolerance on coffee imported into the U.S. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified 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 pyraclostrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclostrobin follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for pyraclostrobin in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyraclostrobin and established tolerances for residues of that chemical. In this rulemaking, EPA is incorporating previously published sections from the September 20, 2021, rulemaking (86 FR 52083) (FRL–8857–01–OCSPP) as described further below, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of pyraclostrobin, see Unit III.A. of the September 20, 2021, rulemaking.

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the human risk assessment, see Unit III.B. of the September 20, 2021, rulemaking and pages 11–13 of the document titled ''Pyraclostrobin. Human Health Risk Assessment of Proposed Tolerances and Uses on Coffee, Green Bean; Stevia, Dried Leaves; and Stevia, Fresh Leaves'' (hereinafter ''Pyraclostrobin Human Health Risk Assessment'') in docket ID number EPA–HQ–OPP–2022–0235.

Exposure assessment. Much of the exposure assessment remains the same, although updates have occurred to account for exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the September 20, 2021, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposures from the new uses of pyraclostrobin on coffee and stevia. In conducting the acute dietary

exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food and Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses the 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is partially refined, assuming tolerance level residues or highest field trial residues and 100 percent crop treated (PCT) for all crop and livestock commodities.

The chronic dietary exposure assessment also uses the DEEM–FCID Version 4.02 software with the 2005–2010 NHANES/WWEIA data. The chronic dietary exposure assessment is refined and uses the same assumptions as the Unit III.C.1.ii in the September 20, 2021, rulemaking; specifically, anticipated residues based on average field trial residue levels for plant raw agricultural commodities or tolerance-level residues, PCT information where available, and experimentally determined processing factors where available. Anticipated residues for livestock commodities were also calculated and incorporated into the assessment.

Anticipated residue and PCT information. For a discussion of the FFDCA requirements regarding use of anticipated residue and PCT information and the PCT assumptions used in the chronic dietary exposure assessment, see Unit III.C.1.iv. of the September 20, 2021, rulemaking.

Drinking water exposure. The new uses do not result in an increase in the estimated residue levels in drinking water, so EPA used the same estimated drinking water concentrations in the acute and chronic dietary exposure assessments as identified in Unit III.C.2. of the September 20, 2021, rulemaking.

Non-occupational exposure. There are no new proposed residential (non-occupational) uses expected for pyraclostrobin at this time; however, pyraclostrobin is currently registered for uses on turf, ornamental, and residential fruit and nut trees that may result in residential handler and post-application exposures from commercial and residential use. For a summary of those exposures, see Unit III.C.3 of the September 20, 2021, rulemaking as it has not changed since then.

Cumulative exposure. 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 pyraclostrobin and any other substances. For purposes of this tolerance action, therefore, EPA has not assumed that pyraclostrobin has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the September 20, 2021, rulemaking for a discussion of the Agency's rationale for that determination as nothing has changed since the 2021 rulemaking.

Aggregate risk and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 86% of the aPAD for females 13 to 49 years old, the only population subgroup for which an acute toxic effect was identified. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 54% of the cPAD for children 1 to 2 years, the most highly exposed population subgroup.

EPA determined that it is inappropriate to combine the oral route of exposure with dermal and inhalation exposures because of dissimilar toxic response observed from exposures to pyraclostrobin via the oral, dermal and inhalation routes. Therefore, the short-term aggregate exposure assessment includes dietary (food and drinking water) and incidental oral hand to mouth exposure from high contact lawn activity on treated lawns for children 1 to less than 2 years old. The short-term aggregate MOE is 260 and is not of concern because it is above the Agency's level of concern of 100.

Pyraclostrobin is classified as ''Not Likely to Be Carcinogenic to Humans'' due to an absence of carcinogenicity in the available studies; therefore, EPA does not expect pyraclostrobin exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to pyraclostrobin residues. More detailed information on this action can be found in the Pyraclostrobin Human Health Risk Assessment in docket ID EPA–HQ–OPP–2022–0235.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method for various crops, see Unit IV.A of the September 20, 2021, rulemaking.

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 U.S. tolerance for pyraclostrobin in or on coffee, green bean is harmonized with the Codex MRL at 0.3 ppm. There are no Codex MRLs for stevia.

C. Response to Comments

One comment was received in response to the notice of filing, which opposed EPA establishing the requested tolerances and objected to the use of pesticides on crops. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that pyraclostrobin tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

V. Conclusion

Therefore, tolerances are established for residues of pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-

yl]oxy]methyl] phenylcarbamate) in or on stevia, dried leaves at 150 ppm and stevia, fresh leaves at 40 ppm. The established tolerance for residues of pyraclostrobin in or on coffee, green bean at 0.3 ppm is revised to remove footnote 1.

Additionally, EPA is correcting the active ingredient name in the introductory paragraph from ''pyradostrobin'' to ''pyraclostrobin''. EPA is also removing the Section 18 emergency exemption tolerance for residues of pyraclostrobin in or on endive, Belgium at 11.0 ppm as a housecleaning measure since that tolerance expired on December 31, 2013. These changes have no substantive effect and can be accomplished without further notice and comment.

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: August 8, 2023.

Charles Smith,

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 § 180.582:

■ a. In paragraph (a)(1):

■ i. In the introductory text,'';

■ ii. Amend the table by adding the heading ''Table 1 to Paragraph (a)(1)'';

■ b. In Table 1 to Paragraph (a)(1):

■ i. Revise the entry for ''Coffee, green bean'';

■ ii. Add, in alphabetical order, the entries ''Stevia, dried leaves'' and ''Stevia, fresh leaves'';

■ iii. Remove footnote 1 from the end of the table.

■ c. Remove and reserve paragraph (b).

The additions and revision read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) * * *

(1) Tolerances are established for residues of the fungicide pyraclostrobin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Coffee, green bean	0.3
* * * * *	
Stevia, dried leaves	150
Stevia, fresh leaves	40
* * * * *	

* * * * *

(b) [Reserved]

* * * * *

[FR Doc. 2023–17431 Filed 8–18–23; 8:45 am]

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