EPA-APPROVED NEW JERSEY NONREGULATORY AND QUASI-REGULATORY PROVISIONS

SIP element	Applicable geographic or nonattainment area	New Jersey submittal date	EPA approval date	Explanation
*	*	*	*	*
2011 VOC, NO_X and CO ozone summer season and annual emission inventory.	Northern New Jersey portion of the New York-Northern New Jersey-Long Island NY-NJ-CT 8-hour ozone nonattainment area.	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad and on-road.
2011 base year emissions inventory.	State-wide	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2017 VOC, NO_X and CO ozone summer season daily and annual emission inventory.	Northern New Jersey portion of the New York-Northern New Jersey-Long Island NY-NJ-CT 8-hour ozone nonattainment area.	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2017 VOC, NO_X and CO ozone summer season daily and annual emission inventory.	Southern New Jersey portion of the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE 8-hour ozone nonattainment area.	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2017 base year emissions inventory.	State-wide	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2017 $PM_{2.5}$/Regional Haze associated precursor annual emission inventory.	State-wide	November 23, 2021	August 16, 2023, [insert **Federal Register** citation].	• Full approval. • The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0234 and EPA–HQ–OPP–2022–0258; FRL–10679–01–OCSPP]

Fluxapyroxad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective August 16, 2023. Objections and requests for hearings must be received on or before October 16, 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 dockets for this action, identified by docket identification (ID) numbers EPA–HQ–OPP–2022–0234 and EPA–HQ–OPP–2022–0258, are available at *https://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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/.*

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 numbers EPA–HQ–OPP–2022–0234 and EPA–HQ–OPP–2022–0258 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 16, 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 numbers EPA–HQ–OPP–2022–0234 and EPA–HQ–OPP–2022–0258, 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 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 (PP 1E8980) 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 180.666 be amended to establish tolerances for residues of the fungicide fluxapyroxad, 3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide in or on stevia, dried leaves at 60 parts per million (ppm) and stevia, fresh leaves at 20 ppm and to revise the established tolerance in or on coffee, green bean at 0.2 ppm to remove the footnote indicating a tolerance without U.S. registrations. That document referenced a summary of the petition prepared by IR–4, which is available in the docket, *https://www.regulations.gov.* One comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit. IV.C.

In the **Federal Register** of July 20, 2022 (87 FR 43231) (FRL–9410–03–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 1F8974) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.666 be amended to establish a tolerance for residues of the fungicide fluxapyroxad, 3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide in or on avocado at 0.6 ppm. One comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit. IV.C.

Based upon review of the data supporting the petition, EPA is establishing two tolerances at a different level than the petitioners requested. The reasons 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 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 fluxapyroxad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluxapyroxad 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 rulemakings 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 a number of tolerance rulemakings for fluxapyroxad, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluxapyroxad and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of fluxapyroxad, see Unit III.A. of the May 5, 2016, rulemaking (81 FR 27019) (FRL–9945–48).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the May 5, 2016, rulemaking.

Exposure assessment. Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; the remaining discussion of EPA's assumptions for exposure remain unchanged since the 2016 rulemaking. For a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the May 5, 2016, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of fluxapyroxad on avocado, coffee, and stevia. A partially refined acute dietary exposure analysis was performed for the general population and all population subgroups. Tolerance level residues were adjusted to account for the metabolite of concern (M700F008) and 100 percent crop treated (PCT) assumptions were used for all plant commodities. For livestock commodities, anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. A partially refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Average field trial residues for parent plus maximum metabolite residue were used for all plant commodities. For livestock commodities, anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. An assumption of 100 PCT was also used for the chronic dietary analysis.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 May 5, 2016, rulemaking.

The new uses do not impact residential exposures and thus the residential exposures have not changed since the last assessment described in the May 5, 2016, rulemaking.

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 fluxapyroxad and any other substances. For the purposes of this action, therefore, EPA has not assumed that fluxapyroxad has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there is 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 May 5, 2016, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks 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 chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure (PODs) 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 15% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD. They are 94% of the cPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate.

The short-term aggregate exposure assessment for children 1 to less than 2 years old includes dietary (food and drinking water) and incidental oral exposure from hand-to-mouth activities from post-application exposure to turf applications. For adults, the short-term aggregate exposure assessment includes dietary (food and drinking water) and inhalation exposure during application to turf using a backpack sprayer. The short-term MOEs are greater than the Agency's level of concern of 100 and therefore are not of concern. They are 1,100 for adults and 400 for children.

There are no residential use scenarios that would result in potential intermediate-term exposure to fluxapyroxad; therefore, an intermediate-term aggregate risk assessment is not required.

There are no residential use scenarios that would result in potential long-term (chronic) exposure; therefore, the chronic aggregate risk is equivalent to the chronic dietary (food and water) risk, and there are no risks of concern.

Fluxapyroxad has been classified as ''not likely to be carcinogenic to humans below a defined dose range.'' The Agency has determined that the quantification of risk using a non-linear approach (*i.e.,* reference dose or RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluxapyroxad and, as indicated above, there are no chronic risks of concern for fluxapyroxad.

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 fluxapyroxad residues. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the document titled ''Fluxapyroxad. Human Health Risk Assessment for the Section 3 Registrations Proposing Use on Avocado, Coffee (green bean); Stevia (dried leaves), and Stevia (fresh leaves)'' in docket ID numbers EPA–HQ–OPP–2022–0234 and EPA–HQ–OPP–2022–0258.

IV. Other Conclusions

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A of the July 13, 2021, rulemaking (86 FR 36666) (FRL–8663–01).

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).

Codex does not have MRLs for residues of fluxapyroxad in or on avocado or stevia. It is not possible to harmonize the U.S. tolerance of 0.2 ppm for residues in or on coffee, green bean with the Codex MRL of 0.15 ppm because establishing the tolerance at the lower level may result in exceedances for U.S. growers despite compliance with U.S. label instructions.

C. Response to Comments

Two comments were received in response to the Notices of Filing. One comment stated in part that the Agency

should not approve the petitions because of the ''further pollution of the air water soil of this earth'' and the other expressed similar sentiments. 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 tolerances are 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 the fluxapyroxad tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

A tolerance of 1.5 ppm is being established for avocado rather than 0.6 ppm as requested. This reflects the use of proportionality to adjust the field trial residue data to the labeled rate because the field trials were conducted at 0.5x the labeled single/seasonal rate. A tolerance of 70 ppm is being established for stevia, dried leaves rather than the petitioned for tolerance of 60 ppm because EPA used the highest residue from the residue decline trial for calculations rather than the residue at the labeled pre-harvest interval.

V. Conclusion

Therefore, tolerances are established for residues of fluxapyroxad in or on avocado at 1.5 ppm; stevia, dried leaves at 70 ppm; and stevia, fresh leaves at 20 ppm. In addition, the established tolerance for residues of fluxapyroxad in or on coffee, green bean at 0.2 ppm is revised to remove the footnote indicating a tolerance without U.S. registrations.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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 § 180.666, in paragraph (a) amend table 1 by:

■ a. Adding in alphabetical order the entry ''Avocado'';

■ b. Revising the entry ''Coffee, green bean'';

■ c. Adding in alphabetical order the entries ''Stevia, dried leaves'' and ''Stevia, fresh leaves''.

The additions and revision read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Avocado	1.5
* * * * *	
Coffee, green bean	0.2
* * * * *	
Stevia, dried leaves	70
Stevia, fresh leaves	20
* * * * *	

* * * * *

[FR Doc. 2023–17430 Filed 8–15–23; 8:45 am]

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