E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0853; FRL-10967-01-OCSPP]

Sulfoxaflor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfoxaflor in or on coffee, green bean. Corteva Agriscience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], 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-2021-0853, is 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/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-2021-0853 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2021-0853, 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/where-send-comments-epa-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 March 24, 2023 (88 FR 17778) (FRL-10579-02-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 1E8945) by Corteva Agriscience, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide sulfoxaflor in or on the raw agricultural commodity coffee, green bean at 0.3 parts per million (ppm) and in or on coffee, instant at 0.5 ppm. That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov*. There were no comments submitted in response to the notice of

filing. This notice supersedes the previous notice of August 30, 2022 (87 FR 52868) (FRL-9410-04-OCSPP). One comment was received but was unrelated to pesticides.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is not establishing the tolerance for coffee, instant as proposed because it is covered by the tolerance being established on coffee, green bean. For details, see 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 sulfoxaflor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfoxaflor 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 tolerance rulemakings for sulfoxaflor in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to sulfoxaflor and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of sulfoxaflor, see Unit III.A. of the sulfoxaflor tolerance rulemaking published in the *Federal Register* of May 17, 2013 (78 FR 29041) (FRL-9371-4).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for sulfoxaflor used for human health risk assessment, see Unit III.B. of the sulfoxaflor tolerance rulemaking published in the *Federal Register* of July 24, 2019 (84 FR 35546) (FRL-9995-63).

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the requested tolerance for residues of sulfoxaflor in or on coffee, green bean and were conducted with 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). Both the acute and the chronic dietary assessments relied primarily on residue data from supervised crop field trials. For the acute assessment, the Agency used maximum field trial residue values. For the chronic assessment, EPA used mean field trial residue values. Several residue estimates were based on tolerance levels. The acute and chronic assessments used empirical processing factors, where available, and EPA's default processing factors in all other cases. Empirical processing factors were translated to similar commodities per standard Agency practice.

Tolerance-level residue estimates were used for livestock commodities and the Agency assumed 100 percent crop treated (PCT) for the acute and chronic assessments.

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

Drinking water and non-occupational exposures. Because the requested tolerance for residues of sulfoxaflor in or on coffee, green bean does not include registrations for use on coffee in the U.S., the estimated drinking water concentrations have not changed. For a detailed summary of the drinking water analysis for sulfoxaflor used for the human health risk assessment, see Unit III.C.2. of the July 24, 2019, rulemaking.

No residential uses and no commercial/professional uses at residential sites are registered or proposed for sulfoxaflor; therefore, no residential risk assessments are needed. Sulfoxaflor is not proposed or registered for any specific use patterns that would result in residential exposure.

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 sulfoxaflor and any other substances and sulfoxaflor does not appear to produce a toxic metabolite produced by other substances. For the

purposes of this action, therefore, EPA has not assumed that sulfoxaflor 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 July 24, 2019, 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 (food and drinking water) exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short- and intermediate-term 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 27% of the aPAD for females 13 to 49 years old and 25% of the aPAD for children 1 to 2 years old, the groups with the highest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 38% of the cPAD for children 1 to 2 years old, the group with the highest exposure.

Sulfoxaflor is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Therefore, the aggregate risk estimates are equivalent to the dietary risk estimates and are not of concern.

Sulfoxaflor is classified as "Suggestive Evidence of Carcinogenic Potential." Quantification of risk using a non-linear approach (*i.e.*, reference dose (RfD)) adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to sulfoxaflor. As the chronic dietary endpoint and dose are protective of potential cancer effects, sulfoxaflor is not expected 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 sulfoxaflor residues. More detailed information on this action can be found in the document titled "Sulfoxaflor. Human Health Risk Assessment for the Proposed Tolerance Without a U.S. Registration on Coffee" in docket ID EPA-HQ-OPP-2021-0853.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 24, 2019, 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).

Codex is in the process of establishing an MRL for sulfoxaflor in/on coffee at a level of 0.3 mg/kg. The proposed U.S. tolerance for sulfoxaflor in/on coffee green bean will be harmonized with Codex's MRL.

C. Revisions to Petitioned-For Tolerance

EPA is not establishing the tolerance for coffee, instant as requested because instant coffee is covered by the tolerance being established on coffee, green bean. EPA considers instant coffee to be a blended commodity; therefore, the average raw agricultural commodity (RAC) value is used to calculate residues in processed commodities. When the mean concentration for the RAC (0.047 ppm) is multiplied by the average processing factor for instant coffee (2.4x), the anticipated residue is 0.11 ppm, which is covered by the tolerance for coffee, green bean.

As a housekeeping measure, EPA is removing tolerances that have expired. Specifically,

EPA is removing the general tolerances for residues of sulfoxaflor in or on arugula at 6 ppm; cress, garden at 6 ppm; and cress, upland at 6 ppm from paragraph (a) of 40 CFR 180.668 because they expired on January 24, 2020. Additionally, EPA is removing the time-limited tolerances for residues of sulfoxaflor in or on sorghum, forage at 0.4 ppm; sorghum, grain at 0.3 ppm; and sorghum, stover at 0.9 ppm from paragraph (b) of 40 CFR 180.668 because they expired on December 31, 2020.

V. Conclusion

Therefore, a tolerance is established for residues of sulfoxaflor in or on coffee, green bean at 0.3 ppm. In addition, EPA is removing the expired general tolerances for residues of sulfoxaflor in or on arugula at 6 ppm; cress, garden at 6 ppm; and cress, upland at 6 ppm and the expired time-limited tolerances for residues of sulfoxaflor in or on sorghum, forage at 0.4 ppm; sorghum, grain at 0.3 ppm; and sorghum, stover at 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under

FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 9, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 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 § 180.668:

a. Amend the table in paragraph (a) by:

i. Adding a heading for the table.

ii. Removing the entry for "Arugula[1]".

iii. Adding alphabetically the commodity "Coffee, green bean".

iv. Removing the entries for "Cress, garden[1]" and "Cress, upland[1]".

v. Revising footnote 1.

b. Remove and reserve paragraph (b).

The additions read as follows:

§ 180.668 Sulfoxaflor; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Coffee, green bean[1]	0.3
* * * * * * *	

[1] There are no U.S. registrations as of [*insert date of publication in the* **Federal Register**].

(b) [Reserved]

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[FR Doc. 2023-12720 Filed: 6/16/2023 8:45 am; Publication Date: 6/20/2023]