E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

EPA-HQ-OPP-2024-0460; FRL-13046-01-OCSPP

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of azoxystrobin in or on black pepper. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the American Spice Trade Association (ASTA) submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodity.

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 this document.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0460, is available at *http://www.regulations.gov*. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *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; telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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. . ."

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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the docket ID number EPA-HQ-OPP-2024-0460 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*]**.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf*. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf.*

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Tolerance

In the *Federal Register* of July 3, 2025 (90 FR 29515) (FRL-12474-05 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 4E9103) by the American Spice Trade Association (1101 17th Street, NW, Suite 700 Washington, DC 20036). The petition requested that 40 CFR 180.507 be amended by establishing a tolerance for residues of the fungicide azoxystrobin in or on pepper, black at 1 part per million (ppm). That document referenced a summary of the petition prepared by the petitioner and included in the docket at *http://www.regulations.gov*.

There were no comments received in response to the notice of filing.

III. Final Tolerance Action

A. *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 azoxystrobin, including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with azoxystrobin 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 of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, 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 several tolerance rulemakings for azoxystrobin in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to azoxystrobin 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.

Specific information on the risk assessment conducted in support of this action can be found in the document titled "*Azoxystrobin. Human Health Risk Assessment for the Establishment of Tolerance without U.S. registration for Residues in/on Pepper, Black"* and the documents cited therein, which are available in the docket for this action at *https://www.regulations.gov.*

B. *Toxicological Profile*

For a discussion of the toxicological profile of azoxystrobin, see Unit III.A. of the final rule published in the *Federal Register* of November 15, 2018 (83 FR 57333) (FRL-9985-45).

C. *Toxicological Points of Departure/Levels of Concern*

For a summary of the toxicological points of departure/levels of concern used for the risk assessment, see Unit III.B. of the final rule published in the *Federal Register* of November 15, 2018 (83 FR 57333) (FRL-9985-45).

D. Exposure Assessment

For a description of EPA's approach to and assumptions used for the hazard assessment and residential exposure assessment for azoxystrobin, see Unit III.C. of the final rule published in the *Federal Register* of November 15, 2018 (83 FR 57333) (FRL-9985-45) and for the dietary and aggregate assessments see the final rule published in the *Federal Register* of March 20, 2023 (88 FR 16570) (FRL-10603-01), along with the updates described below.

1. *Dietary exposure from food and feed uses.* EPA's dietary exposure assessments have been updated to include the additional exposure associated with the petitioned-for tolerance. For the acute dietary exposure assessment, EPA used tolerance-level residues for all commodities, except citrus fruits (which used the highest residues from residue trials), 100 percent crop treated (PCT) for all commodities, and default processing factors with the Dietary Exposure Evaluation Model (DEEM 4.02) for all commodities except where tolerances were established for processed commodities, and utilizing USDA NHANES/WWEIA food consumption data (2005-2010). For the chronic dietary exposure assessment, EPA used tolerance-level residues for all commodities, 100 PCT for all commodities, and default processing factors with DEEM for all commodities except where tolerances were established for processed commodities.

2. *Anticipated residue and percent crop treated (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 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.

EPA did not use PCT information in the dietary exposure assessment for azoxystrobin. 100 PCT was assumed for all food commodities.

3. *Drinking water exposure.* Drinking water exposures are not impacted by this action, which is for a tolerance without a corresponding U.S. registration (i.e., an import tolerance). The estimated drinking water concentrations (EDWCs) of azoxystrobin are 69.4 parts per billion (ppb) for acute exposure and 20.7 ppb for chronic exposure, which were calculated with the Surface Water Concentration Calculator.

4. *Non-occupational exposure.* Non-occupational/residential exposures are not impacted by the import tolerance in this action. Azoxystrobin is currently registered for use on turf, ornamentals, and antimicrobial uses as a materials preservative in paints and plastics that could result in residential exposures. The residential risk estimate that was used in the aggregate assessment is hand-to-mouth incidental oral exposures to preserved vinyl flooring for children aged 1 to less than 2 years old.

5. *Cumulative exposures.* FFDCA section 408(b)(2)(D)(v) 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 azoxystrobin and any other substances, and azoxystrobin does not appear to produce a toxic metabolite produced by other substances.

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

E. *Safety Factor for Infants and Children*

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. 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.

EPA continues to conclude that there is reliable data to support the reduction of the FQPA safety factor to 1X for all exposure scenarios except acute exposure. For assessing acute dietary risk, EPA continues to retain an FQPA safety factor of 3X. See Unit III.D. of the final rule published in the *Federal Register* of November 15, 2018 (83 FR 57333) (FRL-9985-45) for a discussion of the Agency's rationale for that determination.

F. *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 points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

1. Acute risk. Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 29% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. Chronic risk. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 66% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. Short- and intermediate-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).

The Agency analyzed short-term aggregate risk by aggregating chronic dietary (food and drinking water) exposure with incidental oral hand-to- mouth post-application exposure to children 1 to less than 2 years old from preserved vinyl flooring uses of azoxystrobin. The combined short-term food, water, and residential exposures result in an aggregate MOE of 200 for children 1 to less than 2 years old, the population group receiving the greatest exposure. Because EPA's level of concern for azoxystrobin is an MOE of less than 100, this MOE is not of concern.

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). Because no intermediate-term adverse effect was identified, azoxystrobin is not expected to pose an intermediate-term risk. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate.

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

5. Determination of safety. Based on the 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 azoxystrobin residues.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the final rule published in the *Federal Register* of November 15, 2018 (83 FR 57333) (FRL-9985-45). 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). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for azoxystrobin in or on black pepper.

C. *Effective and Expiration Date(s)*

In general, a tolerance action is effective on the date of publication of the final rule in the *Federal Register*. For actions in the final rule that lower or revoke existing tolerances, EPA will set an expiration date for the existing tolerance of six months after the date of publication of the final rule in the *Federal Register*, in order to allow a reasonable interval for producers in

exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

V. Conclusion

Therefore, a tolerance is established for residues of azoxystrobin in or on pepper, black at 1 ppm.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

Since tolerance actions 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 RFA, 5 U.S.C. 601 *et seq*., do not apply to this action.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or on the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ...” (FFDCA 408(b)(2)(C)). The Agency’s consideration is summarized in Unit III.E.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, 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).

List of Subjects in 40 CFR Part 180

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

Dated: November 26, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, 40 CFR chapter I is amended 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 § 180.507, in paragraph (a)(1) amend Table 1 to Paragraph (a)(1) by:

a. Adding in alphabetical order the entry "Pepper, black"; and

b. Adding footnote 3 at the end of the table.

The additions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Pepper, black[3]	1
* * * * * * *	

* * * * *

[3] There are no U.S. registrations for use of azoxystrobin on pepper, black as of [**INSERT DATE OF PUBLICATION IN *FEDERAL REGISTER***].

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[FR Doc. 2025-22174 Filed: 12/5/2025 8:45 am; Publication Date: 12/8/2025]