



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2024-0169; FRL-12202-02-OCSP]

### Sulfentrazone; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is finalizing tolerance actions it previously proposed on its own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of sulfentrazone in or on corn, pop, grain and corn, pop, stover.

**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.D. of this document).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0169, is available online at <https://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; main telephone number: (202) 566-1030; email address: [RDFRNotices@epa.gov](mailto: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:

- 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 proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What action is the Agency taking?*

EPA is finalizing tolerance actions that the Agency previously proposed on its own initiative under section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), for residues of the herbicide sulfentrazone in or on corn, pop, grain at 0.15 parts per million (ppm) and corn, pop, stover at 0.3 ppm. EPA had previously registered the use of sulfentrazone on field corn and established tolerances on corn, field, grain at 0.15 ppm, and corn, field, stover at 0.30 ppm. As part of that process, the use on popcorn was added to the sulfentrazone label (same use pattern as field corn), but, in error, separate tolerances on corn, pop, grain and corn, pop, stover were not established. EPA proposed establishing the tolerances required to support the use on popcorn in order to rectify this oversight as described in the proposed rule and is now finalizing that proposal in this rulemaking.

Four comments were received in response to the proposed rule. EPA's response to these comments is discussed in Unit III.C.

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

FFDCA section 408(e), 21 U.S.C. 346a(e), authorizes EPA to establish, modify, or

revoke tolerances or exemptions from the requirement of a tolerance on its own initiative.

FFDCA section 408(e)(2) requires EPA to issue a notice of proposed rulemaking for a 60-day public comment period, unless the Administrator for good cause finds that it would be in the public interest to have a shorter period and states the reasons in the rulemaking.

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. . . .”

*D. 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 include the chemical specific docket ID number as provided in the heading of this rulemaking as part of 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*]**.

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 Service and Filing”, 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 EPA’s regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, 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](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 for inclusion in the public docket through <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. Aggregate Risk Assessment and Determination of Safety**

Consistent with FFDCA section 408(b)(2)(D), 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, consistent with FFDCA section 408(b)(2), for tolerances for residues of sulfentrazone on corn, pop, grain and corn, pop, stover. EPA's assessment of exposures and risks associated with establishing these tolerances 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 sulfentrazone in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to sulfentrazone and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by sulfentrazone, can be found in the document titled “Sulfentrazone – Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Establishment of Tolerances for Residues in/on Pop Corn Commodities” which is available in the docket for this action at [https:// www.regulations.gov](https://www.regulations.gov).

*Toxicological profile.* For a discussion of the Toxicological Profile of sulfentrazone, see Unit III.A. of the rulemaking published in the *Federal Register* of April 13, 2018 (83 FR 15977) (FRL-9975-77).

*Toxicological points of departure/Levels of concern.* For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment of sulfentrazone, see Unit III.B. of the rulemaking that published in the *Federal Register* of September 12, 2014 (79 FR 54620) (FRL-9915-47).

*Exposure assessment.* Much of the exposure assessment remains unchanged from that discussed in Unit III.C. of the rulemaking that published in the *Federal Register* of April 13, 2018, although the new exposure assessment incorporates the additional dietary exposure from the finalized tolerances.

In conducting both the acute and chronic dietary exposure assessments, EPA used the

Dietary Exposure Evaluation Model, Food Consumption Intake Database (DEEM–FCID, ver.4.02), which incorporates consumption data from United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, NHANES/WWEIA; 2005-2010). As to residue levels in food, EPA assumed tolerance-level residues, 100 percent crop treated (PCT), and EPA default processing factors.

EPA has concluded that sulfentrazone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

*Anticipated residue and percent crop treated information.* EPA did not use anticipated residue or PCT information in the dietary assessment for sulfentrazone. Tolerance-level residues and 100 PCT were assumed for all food commodities.

*Drinking water and non-occupational exposures.* For a summary of the drinking water numbers used, see Unit III.C.2. of the rulemaking that published in the *Federal Register* of April 13, 2018. An acute estimated drinking water concentration (EDWC) of 134 parts per billion (ppb) and a chronic EDWC of 98 ppb were used in the acute and chronic dietary exposure assessments, respectively.

Sulfentrazone is currently registered for the following uses that could result in residential exposures: Residential home lawns/turf and recreational turf, such as golf courses. For a summary of the assumptions used for residential exposures, see Unit III.C.3. of the rulemaking that published in the *Federal Register* of April 13, 2018.

The adult residential exposure scenario used in the aggregate assessment reflects short-term dermal exposure from applications to turf via backpack sprayer. The residential exposure scenario used in the combined short- and intermediate-term aggregate assessment for children ages 1 to 2 years old, the population subgroup with the highest exposure estimate, reflects dermal and hand-to-mouth exposures from post-application exposure to turf applications, which is protective of the other children subpopulations.

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

*Safety factor for infants and children.* EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D. of the rulemaking that published in the *Federal Register* of April 13, 2018.

*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 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 (food and drinking water) risks are below the Agency’s level of concern of 100% of the aPAD; the risk estimate is 1.1% of the aPAD for all infants less than 1-year-old and 6.4% of the aPAD for females 13 to 49 years old, the population group with the highest risk estimate. Chronic dietary (food and drinking water) risks are below the Agency’s level of concern of 100% of the cPAD; they utilize 7.6% of the cPAD for all infants less than 1-year-old, the population group receiving the greatest exposure.

The combined short-term food, water, and residential exposures result in an aggregate MOE of 490 for adults. The combined short- and intermediate-term food, water, and residential

exposures result in an aggregate MOE of 260 for children 1 to 2 years old, the population subgroup for children with the greatest exposure, and is protective of the older children subpopulations. MOEs below 100 are of concern; these MOEs are above 100 and therefore are not of concern.

Because sulfentrazone is classified as “not likely to be carcinogenic to humans,” EPA has concluded that aggregate exposure to sulfentrazone is not likely to pose a 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 sulfentrazone residues.

### **III. Other Considerations**

#### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology, gas chromatography (GC), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto: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 FFDC section 408(b)(4).

No Codex MRLs have been established for sulfentrazone on popcorn.

#### *C. Response to Comments*

Four comments were received in response to the Notices of Filing. One comment stated in part that “The public should not be the test subject for companies trying new products.” The existing legal framework provided by section 408 of the FFDC 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 sulfentrazone tolerance is safe. The commenter has provided no information indicating that a safety determination cannot be supported.

The other three comments received were in support of the tolerance being established but requested EPA conduct enforcement checks of grain and stover for residues of sulfentrazone, monitoring of water bodies for sulfentrazone levels, and after the tolerance has been established, “Develop a system for when farms do not meet requirements”. Although the EPA sets safe residue tolerances for pesticides, EPA is not responsible for the enforcement of the tolerances once they have been established. Under FFDCA, the U.S. Food and Drug Administration (FDA) is the federal agency that enforces the tolerance regulations and ensures that pesticide residues in food and feed commodities are within legal limits. *See, e.g.*, 21 U.S.C. 371, 372, 374.

#### **IV. Conclusion**

Tolerances are established for residues of sulfentrazone on corn, pop, grain at 0.15 ppm and corn, pop, stover at 0.3 ppm.

#### **V. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/lawsregulations/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.

##### *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)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 et seq. In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities and that the Agency is certifying that this action will not have a significant economic impact on a substantial number of small entities because the action has no net burden on small entities subject to this rulemaking. As discussed in the proposed rule, this determination takes into account several EPA analyses of potential small entity impacts for tolerance actions. EPA did not receive any comments about the Agency's determination for this rulemaking.

*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 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 it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (see Unit V.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's 2021 Policy on Children's Health applies to this action as discussed in Unit II.

*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 does not meet the criteria set forth in 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:** May 6, 2025.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

For the reasons set forth in the preamble, EPA is amending 40 CFR part 180 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 § 180.498, amend table 2 to paragraph (a)(2) by adding, in alphabetical order, entries for “Corn, pop, grain” and “Corn, pop, stover” to read as follows:

**§ 180.498 Sulfentrazone; tolerances for residues.**

(a) \* \* \*

(2) \* \* \*

**Table 2 to Paragraph (a)(2)**

<b>Commodity</b>	<b>Parts per million</b>
* * * * *	*
Corn, pop, grain	0.15
Corn, pop, stover	0.3
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