

477–4727; website: <https://spokanecleanair.org>.

(i) SRCAA Regulation I, Article VI, Section 6.17: Standards for Municipal Solid Waste Combustors, effective July 7, 2022.

(ii) [Reserved]

§ 62.11881 Identification of sources—Spokane Regional Clean Air Agency.

The plan in § 62.11880 applies to all existing large municipal waste combustors in the Spokane County, Washington, excluding Indian country, constructed on or before September 20, 1994.

§ 62.11882 Effective date—Spokane Regional Clean Air Agency.

The effective date of the plan identified in § 62.11880 and submitted on July 18, 2022, by the Spokane Regional Clean Air Agency for existing large municipal waste combustors is January 27, 2025.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0596; FRL–12457–01–OCSPP]

Ethiprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance (without U.S. registrations) for residues of ethiprole in or on sugarcane. Bayer CropScience LP requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 27, 2024. Objections and requests for hearings must be received on or before February 25, 2025 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–2023–0596, is available at <http://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 **Federal Register** Office’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–2023–0596 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 February 25, 2025. 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–2023–0596, by one of the following methods:

- *Federal eRulemaking Portal:* <http://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 <http://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, are available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 1, 2024 (89 FR 54398) (FRL–11682–05–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 3F9067) by Bayer CropScience LP, 800 N Lindbergh Blvd., St. Louis, MO 63167. The petition requested to amend 40 CFR part 180 by establishing a tolerance for residues of ethiprole in or on the raw agricultural commodity sugarcane at 0.1 parts per million (ppm).

That document referenced a summary of the petition, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has revised the tolerance from 0.1 ppm to 0.07 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ethiprole including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with ethiprole follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking 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 tolerance rulemakings for ethiprole, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to ethiprole 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 ethiprole, can be found in the document titled “*Ethiprole. Human Health Risk Assessment for Tolerance without U.S. Registration in/on Imported Sugarcane*” which is available in the docket for this action at <https://www.regulations.gov>.

Toxicological profile. For a discussion of the Toxicological Profile of ethiprole, see Unit III.A. of the rulemaking published in the **Federal Register** of June 28, 2019 (84 FR 30933) (FRL–9985–41).

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 ethiprole, see Unit III.B. of the June 28, 2019, rulemaking.

Exposure assessment. Much of the exposure assessment remains unchanged from the rulemaking published in the June 28, 2019, rulemaking, although the new exposure assessment incorporates the additional dietary exposure from the petitioned-for tolerance. Other changes are described below.

Acute and chronic dietary exposure assessments were conducted using DEEM–FCID Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/ WWEIA). Unrefined acute and chronic dietary exposure and risk assessments were conducted using tolerance-level residues, empirical and default processing factors, and assuming 100% crop treated.

Drinking water and non-occupational exposures. There are no registered or proposed U.S. uses of ethiprole. As a result, estimated drinking water concentrations (EDWCs) were not included in the dietary exposure and risk assessments because residues of ethiprole and its degradates are not anticipated to be present in U.S. drinking water.

A residential handler and residential post-application assessment is not necessary since the action is to establish an import tolerance without a U.S. registration on sugarcane.

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 ethiprole and any other substances and ethiprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed

that ethiprole has a common mechanism of toxicity with other substances.

In 2016, EPA’s Office of Pesticide Programs released a guidance document titled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>). This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRAs).

Ethiprole is a phenyl-pyrazole insecticide. As part of the ongoing process to review registered pesticides, the Agency intends to apply this framework to determine if the available toxicological data for ethiprole suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

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 June 28, 2019, rulemaking.

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 only) risks are below the Agency’s level of concern of 100% of the aPAD; they are 2.4% of the aPAD for all infants (less than 1 year old), which is the population subgroup with the highest exposure estimate. Chronic dietary (food only) risks are below the Agency’s level of concern of 100% of the cPAD; they are 6% of the cPAD for all infants less than one year

old, which is the population subgroup with the highest exposure estimate.

The short- and intermediate-term aggregate risks combine chronic dietary (food and drinking water) and short- and intermediate-term residential exposures. Since there are no U.S. registrations, aggregate risk is the same as the chronic dietary risk, which is below the Agency’s level of concern.

Because ethiprole is classified as “Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenicity Potential,” EPA has concluded that a cancer aggregate assessment was not required.

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 ethiprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the June 28, 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, Canada, and Mexico have not established MRLs for residues of ethiprole on sugarcane commodities; therefore, there are no harmonization issues at this time.

C. Revisions to Petitioned-For Tolerances

Review of the field trial data determined one of the nine independent sugarcane field trials was to be a replicate; therefore, the residues were averaged, and the pair of sites was taken to be one independent trial. The Organization for Economic Cooperation and Development (OECD) MRL calculator recommended a tolerance of 0.07 ppm for residues of ethiprole in sugarcane.

V. Conclusion

Therefore, a tolerance is established for residues of ethiprole in or on sugarcane at 0.07 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, titled “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, titled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, titled “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, titled “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, titled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, titled “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: December 16, 2024.

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 § 180.652, amend the table in paragraph (a) by adding a table heading and adding in alphabetical order the commodity “Sugarcane” to read as follows:

§ 180.652 Ethiprole; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	*
Sugarcane ¹	0.07
* * * * *	*

¹ There are no U.S. registrations for this commodity as of December 27, 2024.