E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0538; FRL-9194-01-OSCPP]

Mefentrifluconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefentrifluconazole in or on banana and coffee, green bean. BASF Corporation requested these tolerances 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-2020-0538, 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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns relating to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide customer service via email, phone, and webform. For the latest status information on

EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; 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-2020-0538 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-2020-0538, 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/contacts.html*. 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 December 21, 2020 (85 FR 82998) (FRL-10016-93), 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 0E8849) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 22709-3528. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of mefentrifluconazole in or on banana at 1.5

parts per million (ppm) and coffee at 0.4 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket for this action, docket ID number EPA-HQ-OPP-2020-0538 at, *https://www.regulations.gov*. One comment from an anonymous citizen was received in response to the notice of filing (NOF). The Agency response is listed in Unit IV.C.

With respect to the subject action, the proposed tolerance levels were not altered, but the commodity definition for coffee was revised. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

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 mefentrifluconazole, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mefentrifluconazole follows.

B. Aggregate Risk Assessment

In an effort to streamline *Federal Register* publications, EPA is directing readers to certain sections of *Federal Register* notices for previous tolerance rulemakings for the same pesticide that contain information that has not changed in the current risk assessment. To that end, on June 28, 2019, EPA published in the *Federal Register* a final rule establishing a tolerance for residues of mefentrifluconazole in or on many livestock, corn, fruit, grain, nut and vegetable commodities based on the Agency's conclusion that aggregate exposure to mefentrifluconazole is safe for the general population, including infants and children. See 84 FR 30939 (FRL-9994-51). Please refer to the following sections of the aforementioned tolerance rulemaking that contain information that has remained the same under the current risk assessment for this rulemaking: Units III.A (Toxicological Profile); III.B (Toxicological Points of Departure/Levels of Concern); III.C (Exposure Assessment), except as explained in the next paragraph; and III.D (Safety Factor for Infants and Children).

Updates to exposure assessment. The Agency conducted an updated risk assessment to evaluate exposure to residues of mefentrifluconazole on banana and coffee. EPA's acute and chronic dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from use of mefentrifluconazole on banana and coffee. As to residue levels in food, a partially refined chronic dietary exposure and risk assessment was conducted assuming 100 percent crop treated (PCT) and using average field-trial residues for some commodities and tolerance-level residues for other commodities (banana and coffee). There will be no U.S. registrations for use of mefentrifluconazole on banana and coffee, and there is no proposed new residential use. Therefore, EPA's assessments of dietary exposure from drinking water and non-dietary (i.e., residential) exposure, as well as cancer classification and cumulative effects from substances with a common mechanism of toxicity, have not changed and are described in the June 2019 tolerance rulemaking.

Assessment of aggregate risks. Acute aggregate risk estimates are equal to acute dietary

(food and drinking water) risk estimates, which are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): the exposure estimate is 5.6% of the aPAD at the 95th percentile of exposure for females 13 to 49 years old, which is the population subgroup with the highest exposure estimate. Chronic aggregate risk estimates are equal to chronic dietary (food and drinking water) risk estimates, which are below the Agency's level of concern of 100% of the chronic population adjusted does (cPAD): the exposure estimate is 82% of the cPAD for children 1 to 2 years old, which is the population subgroup with the highest exposure estimate. Short-term aggregate risk estimates are equal to the total short-term residential post-application dermal exposure estimates plus average dietary exposure estimates. For adults, the most conservative residential exposure estimate is from post-application dermal exposure from golfing activities after applications to golf courses, with a margin of exposure (MOE) above the Agency's level of concern of 100 (MOE = 2600). For children 6 to less than 11 years old, the most highly exposed child subgroup for residential exposure, the most conservative residential exposure estimate is from post-application dermal exposure from golfing activities after applications to golf courses. The dietary exposure for children 6 to 12 years old was used to calculate aggregate exposure as this subgroup is similar to the subgroup children 6 to less than 11 years old. The MOE is above the Agency's level of concern of 100 (MOE = 1900). Children 1 to <2 years old were the highest exposed child subgroup for dietary exposures, which does not match the most highly exposed child subgroup for residential exposure (children 6 to <11 years old). However, the selected residential exposure scenarios for aggregation, adults and children (6 to <11 years old), represent the worst-case risk estimates and are protective of all other life stages and exposure scenarios. Considering both the total short-term residential post-application dermal exposures and average dietary exposures for both adults and children, EPA has concluded the short-term aggregate MOEs are 790 and 620 for adults and children 6 to less than 11 years old, respectively, which are above the level of concern of 100 and therefore are not of concern. Intermediate-term residential exposures are not expected from the residential use of

mefentrifluconazole; therefore, intermediate-term aggregate risk is not a concern and quantitative estimates were not calculated. Mefentrifluconazole is classified as "not likely to be carcinogenic to humans"; therefore, a quantitative cancer assessment was not conducted.

C. Determination of Safety

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 mefentrifluconazole residues. More detailed information on the subject action to establish a tolerance in or on banana and coffee can be found in the document entitled, "Mefentrifluconazole. Human Health Risk Assessment for Petition for the Establishment of Permanent Tolerances for Use on Banana and Coffee without U.S. Registration." dated 10/20/2021 at *https://www.regulations.gov*, under docket ID number EPA-HQ-OPP-2020-0538.

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical enforcement methodologies found in Unit IV.A. of the final rule published in the *Federal Register* on June 28, 2019, establishing tolerances for residues of mefentrifluconazole in or on multiple commodities are adequate for banana and coffee. See 84 FR 30939 (FRL-9994-51). The methods 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.

There are currently no Codex or Canadian MRLs established for residues of mefentrifluconazole in banana or coffee; therefore, there are no issues with harmonization.

C. Response to Comments

One anonymous comment to the NOF was submitted insisting that no residues of fluoride, which is a different chemical, should be permitted for bananas and coffee. Even so, no additional information was provided that would support a conclusion that the tolerances requested for mefentrifluconazole are not safe. Although some individuals do not want pesticides to be used on food, the FFDCA authorizes EPA to establish tolerances that permit certain levels of pesticide residues in or on food when the Agency can determine that such residues are safe. EPA has made that determination for the tolerances subject to this action, and the commenter provided no information to support a determination that the tolerance is not safe.

D. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance on "coffee, green bean" rather than the requested tolerance on "coffee" to be consistent with the terminology the Agency uses for that commodity.

V. Conclusion

Therefore, tolerances are established for residues of mefentrifluconazole in or on banana at 1.5 ppm and coffee, green bean, at 0.4 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, 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: December 9, 2021.

Marietta Echeverria,

Acting 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 § 180.705, amend table 1 to paragraph (a) by adding in alphabetical order the entries "Banana" and "Coffee, green bean" to read as follows:

§ 180.705 Mefentrifluconazole; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Banana[1]	1.5

	*	*	*	*	*	*	*
Coffee, green bean[1]							0.4
	*	*	*	*	*	*	*

[1] There are no U.S. registrations as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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[FR Doc. 2021-27093 Filed: 12/14/2021 8:45 am; Publication Date: 12/15/2021]