E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0176; FRL-12909-01-OCSPP]

Fluopyram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopyram (CASRN 658066-35-4) in or on mango. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), The United States Department of Agriculture - Foreign Agricultural Service (USDA-FAS) 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 rule is effective on **[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-2024-0176, is available 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.*

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-2024-0176 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 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 1, 2024 (89 FR 54,398, 54,401) (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 3E9060) by the USDA Foreign Agricultural Service, 1400 Independence Ave, Washington, DC 20250. The petition requested that 40 CFR 180 be amended by establishing an import tolerance for residues of the fungicide fluopyram, N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on mango at 1 parts per million (ppm). That document referenced a summary of the petition prepared by the petitioner, which is available in the docket, *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*

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

In an effort to streamline its publications in the ***Federal Register*****,** EPA is not reprinting sections that repeat what has been previously published in 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 fluopyram, most recently in the ***Federal Register*** of February 1, 2023 (88 FR 6636) (FRL-10566-01), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluopyram and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the February 1, 2023 rulemaking as described further in this rulemaking, as they remain unchanged.

B. *Toxicological Profile*

For a discussion of the Toxicological Profile of fluopyram, see Unit III.A. of the February 1, 2023 rulemaking.

C. Toxicological Points of Departure/Levels of Concern

A summary of the toxicological endpoints for fluopyram used for the human health risk assessment is discussed in Unit III.B. of the February 1, 2023 rulemaking.

D. *Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fluopyram, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopyram tolerances in 40 CFR 180.661. EPA assessed dietary exposures from fluopyram in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for fluopyram.

In estimating acute dietary exposure, EPA used the 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). As to residue levels in food, the acute dietary exposure assessment used tolerance-level values for mango and for commodities with established tolerances with the exception of cereal grains, canola commodities, and coffee, for which the Highest Average Field Trial (HAFT) values were used. One hundred percent crop treated (PCT) was assumed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA's 2005-2010 NHANES/WWEIA and DEEM-FCID; version 4.02. As to residue levels in food, the chronic dietary exposure assumed tolerance-level residues for mango and used mean field trial data for all other commodities. The chronic dietary assessment used a combination of average PCT for some commodities and 100 PCT for other commodities.

iii. *Cancer*. Based on the toxicological profile in Unit III.A of the February 1, 2023 rulemaking, EPA has concluded that fluopyram does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA's estimated PCTs for existing uses are unchanged from the February 1, 2023 rulemaking and can be found in section Unit III.C.1.iv.

2. *Drinking water, non-occupational, and cumulative exposures*. For more discussion of the estimated drinking water concentrations, non-occupational (residential), and cumulative exposures for fluopyram, see Unit III.C.2., Unit III.C.3. and Unit III.C.4. of the February 1, 2023 rulemaking.

E. *Safety Factor for Infants and Children*

EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1X. See Unit III.D. of the February 1, 2023 rulemaking for a discussion of the Agency's rationale for that determination.

F. *Aggregate Risk and Determination of Safety*

Acute, chronic, short-, and intermediate-term aggregate risk, as well as aggregate cancer risk estimates remain unchanged from the previous rulemaking. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopyram is not expected to pose a cancer risk to humans. For discussion of these exposure estimates, see Unit III.E. of the February 1, 2023 rulemaking.

Consequently, based on these risk assessments and information described in the February 1, 2023 rulemaking, 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 fluopyram residues. More detailed information can be found at *https://www.regulations.gov* in the document titled "Fluopyram. Human Health Risk Assessment for the Proposed Section 3 Tolerance Request without U.S. Registration for Mango." in docket ID number EPA-HQ-OPP-2024-0176.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 1, 2023 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). The Codex Alimentarius 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 established MRLs for fluopyram in or on mango at 1 ppm. These MRLs are the same as the tolerances established for fluopyram in the United States.

V. Conclusion

Therefore, tolerances are established for residues of fluopyram, N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, in or on mango 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 documented in the pesticide-specific registration review documents*, located* in each chemical docket at *https://www.regulations.gov.*

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 3, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 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 § 180.661, table 1 to paragraph (a)(1) is amended by adding in alphabetical order the entry "Mango" to read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Mango[1]	1.0
* * * * * * *	

[1] There are no U.S. registrations.

* * * * *

[FR Doc. 2025-20177 Filed: 11/17/2025 8:45 am; Publication Date: 11/18/2025]