



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0386; FRL-9819-01-OCSP]

Pyriofenone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriofenone in or on the tomato subgroup 8-10A and the pepper/eggplant subgroup 8-10B and removes the established tolerance for the vegetable, fruiting, group 8-10 and the expired tolerance for the fruit, small vine climbing subgroup 13-07D. Interregional Research Project Number 4 (IR-4) 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-2021-0386, 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 and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional

information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting 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 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 FFDCFA 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-2021-0386 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-2021-0386, 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/where-send-comments-epa-dockets>.

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 October 21, 2021 (86 FR 58239) (FRL-8792-04-OCSP) 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 1E8905) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The October 21, 2021, document incorrectly identified the petition number as 1E9805. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide pyriofenone in or on the pepper/eggplant subgroup 8-10B at 2 parts per million (ppm) and the tomato subgroup 8-10A at 0.3 ppm. The petition also requested to remove the existing tolerance on vegetable, fruiting, group 8-10 at 0.3 ppm. That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. One comment was submitted by the United States Department of Agriculture (USDA) in response to the notice of filing. The comment was in support of the petition.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing the tolerances at different levels than petitioned for and is modifying the crop group definition to be consistent with Agency terminology. A discussion of these modifications can be found in section 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 pyriofenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriofenone 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 pyriofenone in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyriofenone 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.

Toxicological profile. For a discussion of the Toxicological Profile of pyriofenone, see Unit III.A. of the May 30, 2019, rulemaking (84 FR 24983) (FRL-9993-11).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for pyriofenone used for human

risk assessment, please reference Unit III.B. of the May 30, 2019, rulemaking.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the new greenhouse uses of pyriofenone on the pepper/eggplant subgroup and tomato subgroup. An acute dietary exposure assessment was not performed as there are no appropriate toxicological effects attributable to a single exposure (dose). A conservative chronic dietary exposure assessment was performed for pyriofenone, assuming 100 percent crop treated (PCT), tolerance-level residues, and default processing factors. The chronic dietary exposure assessment was revised to reflect the updated Dietary Exposure Evaluation Model that incorporates the What We Eat in America (WWEIA) consumption data from 2005-2010. The chronic estimated drinking water concentration (EDWC) of 3.9 ppb is unchanged from the May 30, 2019, rulemaking and was directly incorporated into the chronic assessment. A cancer dietary assessment was not conducted because pyriofenone is classified as "not likely to be carcinogenic to humans." Because there are no existing or proposed residential uses associated with pyriofenone, there is not expected to be any residential handler exposure or post-application exposures.

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 pyriofenone and any other substances and pyriofenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pyriofenone has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are

reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the May 30, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

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). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not performed as there were no appropriate toxicological effects attributable to a single exposure (dose) observed in available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 4.9% of the cPAD for children 1 to 2 years old, the group with the highest exposure. There are no proposed or registered residential uses; therefore short- and intermediate-term residential exposure is not expected. Pyriofenone is classified as "Not Likely to Be Carcinogenic to Humans"; therefore, EPA does not expect pyriofenone exposures to pose an aggregate 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 pyriofenone residues. More detailed information on this action can be found in the document titled "Pyriofenone. Human Health Risk Assessment for Section 3 Registration of Pyriofenone in Greenhouses for Crop Groups 8-10 and 9" in docket ID EPA-HQ-OPP-2021-0386.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the May 30, 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 has not established MRLs on crop subgroups 8-10A (tomato subgroup) or 8-10B (pepper/eggplant subgroup).

C. Revisions to Petitioned-For Tolerances

The Organisation for Economic Co-operation and Development (OECD) maximum residue limit (MRL) Calculation Procedures of the tomato residue data result in a tolerance of 0.2 ppm; EPA is thus establishing a tolerance of 0.2 ppm for tomato subgroup 8-10A instead of the petitioned-for level of 0.3 ppm. The correct crop subgroup name for 8-10B is pepper/eggplant subgroup 8-10B, not pepper/eggplant 8-10B. As a housekeeping measure, EPA is removing the tolerance for fruit, small vine climbing subgroup 13-07D, which expired on October 6, 2021.

D. International Trade Considerations

In this rule, EPA is establishing a tolerance for pyriofenone residues in or on the tomato subgroup 8-10A at 0.2 ppm that is lower than the current tolerance of vegetable, fruiting, group 8-10 (0.3 ppm). For the reasons explained in the Pyriofenone Human Health Risk Assessment, the Agency believes these revised, lower tolerances are appropriate based on available residue data.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is retaining the existing tolerances for the commodities in tomato subgroup 8-10A by establishing an expiration date for the tomato subgroup 8-10A at the existing tolerance level of 0.3 ppm to allow this tolerance to remain in effect for a period of six months after the effective date of this final rule. (Although crop group 8-10 also includes a subgroup 8-10C for which EPA is not setting separate tolerances, all of the commodities in subgroup 8-10C are also included in subgroup 8-10B, for which EPA is establishing a higher tolerance at 2 ppm; therefore, there is no need to retain a separate tolerance for subgroup 8-10C.) After the six-month period expires, the allowable residues on members of the tomato subgroup 8-10A must conform to the new lower tolerance level of 0.2 ppm. This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCFA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of pyriofenone in or on the pepper/eggplant subgroup 8-10B at 2 ppm and the tomato subgroup 8-10A at 0.2 ppm. Additionally, the existing tolerance for the vegetable, fruiting, group 8-10 is removed but the tolerance for tomato subgroup 8-10A at the existing level of 0.3 ppm is designated to expire 6 months from the publication of this document. Finally, EPA is removing the tolerance for fruit, small vine climbing subgroup 13-07D that expired on October 6, 2021, which completes the implementation of the pyriofenone tolerance changes in the April

15, 2021 rulemaking (86 FR 17545) (FRL-10019-55). The tolerance for fruit, small vine climbing subgroup 13-07D is no longer needed because, in 2021, EPA established separate tolerances for residues of pyriofenone in/on grape; grape, raisin; and fruit, small vine climbing, except grape, subgroup 13-07E. Subgroup 13-07E includes all the commodities in subgroup 13-07D other than grape.

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 to 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: June 22, 2022.

Marietta Echeverria,

Acting 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 § 180.660, amend the table in paragraph (a) by:

a. Removing the entry for “Fruit, small vine climbing subgroup 13-07D¹”.

b. Adding in alphabetical order entries for “Pepper/eggplant subgroup 8-10B”; “Tomato subgroup 8-10A”; and “Tomato subgroup 8-10A¹”.

c. Removing the entry for “Vegetable, fruiting, group 8-10”; and

d. Revising the footnote.

The additions and revision read as follows:

§ 180.660; Pyriofenone; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	*
Pepper/eggplant subgroup 8-10B	2
Tomato subgroup 8-10A	0.2
Tomato subgroup 8-10A ¹	0.3
* * * * *	*

¹ This tolerance expires on January 5, 2023.

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