



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0624; FRL-11958-01-OCSP]

Tetraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerance for residues of tetraniliprole in or on tea, dried at 80 ppm. Bayer CropScience LP requested this tolerance 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-2021-0624, 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: 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 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-2021-0624 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).

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.

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-2021-0624, 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 July 5, 2023 (88 FR 42935) (FRL-10579-05-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 3E9059) by Bayer CropScience LP, 800 N Lindbergh Blvd., St. Louis, MO 63167. The petition requested to establish a tolerance in 40 CFR part 180 for residues of the insecticide, tetraniliprole [1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5- (trifluoromethyl)-2*H*-tetrazol-2-yl]methyl]-1*H*-pyrazole-5-carboxamide], in or on Tea, dried at 80 parts per million (ppm). That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. Two comments were received in response to the Notice of Filing. EPA's response to these comments 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 tetraniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tetraniliprole 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 a tolerance rulemaking for tetraniliprole in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to tetraniliprole and established tolerances for residues of that chemical. EPA is incorporating previously published sections from this rulemaking as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the Toxicological Profile of tetraniliprole, see Unit III.A. of the tetraniliprole tolerance rulemaking published in the **Federal Register** of February 24, 2021 (86 FR 11133) (FRL-10005-77).

B. Toxicological Points of Departure/Levels of Concern

Based on a thorough analysis of the toxicology database of tetraniliprole, the Agency has determined that a qualitative risk assessment is more appropriate for tetraniliprole than a

quantitative risk assessment. For more details, please reference Unit III.B. of the February 24, 2021, rulemaking.

C. Exposure Assessment

There is potential for exposure to tetraniliprole via food and feed based on the proposed tolerance for residues on imported tea. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure. Thus, no quantitative dietary exposure assessments are needed for EPA to conclude with reasonable certainty that dietary exposures to tetraniliprole do not pose a significant human health risk.

Drinking water and non-occupational exposures. There are no residues of toxicological concern expected in drinking water from the use of tetraniliprole. Thus, no drinking water exposure assessments are needed for the Agency to conclude with reasonable certainty that drinking water exposures to tetraniliprole do not pose a significant human health risk.

Tetraniliprole is registered for use on golf course turf and sports fields that could result in residential post-application exposures. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure; therefore, a quantitative residential post-application exposure assessment was not conducted. Thus, no residential exposure assessments are needed for the Agency to conclude with reasonable certainty that residential exposures to tetraniliprole do not pose a significant human health risk.

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 tetraniliprole and any other substances.

Tetraniliprole does not also appear to produce a toxic metabolite produced by other substances.

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

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) requires the application of an additional tenfold margin of safety to account for potential risks to infants and children, in the case of threshold effects. For tetraniliprole, EPA has not identified any toxicological endpoints of concern associated with any threshold effects and is conducting a qualitative assessment. That qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. EPA has also evaluated the available data and concluded that there are no residual uncertainties concerning the potential risks to infants and children that would impact its conclusions about threshold effects.

E. 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.

No adverse effects were observed in the submitted toxicological studies at doses relevant to human health pesticide risk assessment for tetraniliprole regardless of the route of exposure. Effects observed in the data base (*e.g.*, decreased body weight) were both marginal and only seen at doses not expected to occur daily or over an extended period.

Based on a lack of toxicity at exposure levels expected from approved application rates and an expectation that aggregate exposures to residues of tetraniliprole will not reach the levels required to cause any adverse effects, 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 tetraniliprole residues. More detailed information on this action can be found in the document titled “Tetraniliprole: Petition for the Establishment of a Tolerance without U.S. Registration for use on Tea. Summary of Analytical Chemistry and Residue Data” in docket ID EPA-HQ-OPP-2021-0624.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 24, 2021, 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).

There are no Codex MRLs for residues of tetraniliprole in or on Tea, dried.

C. Response to Comments

Two comments were received in response to the Notice of Filing from different commenters. One commenter stated in part that “*I totally oppose granting any tolerance changes or added tolerances of any kind to any of the toxic chemicals that are listed in federal register notice*”... “*none of them should ever be approved or used in the world. they are harmful...*” The other commenter opposed granting any tolerances because all active ingredients are harmful. This commenter also mentioned results related to birth defects from pesticides from a study but did not provide a citation of said study. Thus, the information cannot be substantiated or addressed. According to the commenter “*Pesticide exposure during susceptible windows and at certain doses are linked to numerous birth defects.*” Holoprosencephaly (HPE), malformation of

the forebrain in humans was the focus of this study, according to the commenter. Although the Agency recognizes that some individuals believe that pesticides should be banned, the existing legal framework provided by section 408 of the FFDCFA 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 FFDCFA requires EPA to consider, EPA has determined that the tetraniliprole tolerance on tea is safe. The commenters have not provided information indicating that a safety determination cannot be supported.

V. Conclusion

Therefore, tolerances are established for residues of tetraniliprole in or on Tea, dried at 80 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCFA 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).

Because tolerances and exemptions that are established on the basis of a petition under FFDCFA section 408(d), such as the tolerance 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: May 9, 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 § 180.709, amend table 1 to paragraph (a) by adding in alphabetical order an entry “Tea, dried” to read as follows:

§ 180.709 Tetraniliprole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Tea, dried ¹	80
* * * * *	*

¹ There is no U.S. Registration for this commodity as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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