



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0331; FRL-12856-01-OCSP]

Triclopyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triclopyr, including its metabolites and degradates, in or on orange subgroup 10-10A. UPL Chile S.A. 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-2024-0331, is available online at <https://www.regulations.gov> or in-person 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. 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 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>.

D. 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-2024-0331 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-2024-0331, 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>.

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

II. Petitioned-For Tolerance

In the *Federal Register* of January 13, 2025 (90 FR 2661) (FRL-11682-11-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP4E9105) by UPL Chile S.A. (El Rosal 4610, Huechuraba Santiago, Chile, Postal Code: 8590724). The petition requests that EPA amend 40 CFR 180.417 by establishing a tolerance for residues of triclopyr, [(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, including its metabolites and degradates, in or on imported commodities in orange subgroup 10-10A at 0.07 parts per million (ppm). That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of UPL Chile S.A., the petitioner, which is available in docket ID number EPA-HQ-OPP-2024-0331 at <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

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 a tolerance at a different level than petitioned for. The reason for this change is explained in Unit IV.C.

III. Final Tolerance Action

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 triclopyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triclopyr 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 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 triclopyr in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to triclopyr 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.

A. Aggregate Risk 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 risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 88% of the aPAD for females 13-49 years old and 15% of the aPAD for all infants, the most highly exposed population subgroup. No acute residential or recreational exposures are expected, so the acute aggregate risk is equivalent to the acute dietary risk and is not of concern. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 63% of the cPAD for all infants <1 year old, the most highly exposed population subgroup. No long-term residential exposures are expected, so the chronic aggregate risk is equivalent to the chronic dietary risk and is not of concern.

For the short-term aggregate risk assessment, potential residential exposures were

combined with food and drinking water exposures. Specifically, the short-term aggregate assessment for adults combines dietary (food + drinking water) exposures with handler inhalation exposures resulting from the registered turf use and the MOE is 420. For children 1 to <2 years old, the short-term aggregate assessment combines dietary (food + drinking water) exposure with potential post-application incidental oral exposure resulting from the registered turf use and the MOE is 125. For children 3 to <6 years old, the short-term aggregate assessment combines dietary (food + drinking water) exposure with potential post-application inhalation and incidental oral swimmer exposure resulting from the registered aquatic use and the MOE is 380. As the short-term aggregate MOEs are greater than 100, the risks are not of concern.

Although there are intermediate-term residential exposures, intermediate-term aggregate risk was not separately assessed since (1) the short- and intermediate-term points of departure are the same and (2) the short-term aggregate risk assessment provides a worst-case estimate of residential exposure. For these reasons, the short-term aggregate risk assessment is protective of intermediate-term exposures.

As stated in Unit III.A. of the February 25, 2016, final rule, EPA has determined that an aggregate exposure risk assessment for cancer risk is not required based on weight-of-evidence conclusions on the marginal evidence of carcinogenicity in two adequate rodent carcinogenicity studies and the use of the chronic RfD which will adequately account for any potential carcinogenic effects.

B. Toxicological Profile. For a discussion of the Toxicological Profile of triclopyr, see Unit III.A. of the final rule published in the Federal Register of February 25, 2016 (81 FR 9353) (FRL-9941-87).

C. Toxicological Points of Departure/Levels of Concern. Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for

derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints and points of departure for triclopyr used for human risk assessment can be found in the document, “Triclopyr: Section 3 Human Health Risk Assessment for Tolerances without U.S. Registration on Orange Subgroup 10-10A” in docket ID number EPA-HQ-OPP-2024-0331.

D. *Exposure Assessment.* For a summary of the assumptions used in EPA’s exposure assessments for triclopyr, see Unit III.C. of the February 25, 2016, final rule and the updates described below.

EPA’s dietary exposure assessments have been updated to include the additional exposures from the petitioned-for tolerance. Acute and chronic dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the USDA’s National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment was unrefined, using tolerance-level residues for all registered and proposed commodities. The chronic dietary exposure assessment was slightly refined, using tolerance-

level residues for all commodities except milk. An anticipated residue (AR) calculated from a livestock feeding study was used for milk. Default processing factors were used to estimate residues in processed commodities. Drinking water was incorporated directly into the dietary assessment. The acute and chronic dietary exposure assessments assumed 100% crop treated for all registered and proposed commodities.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

EPA revised the triclopyr drinking water assessment since the February 25, 2016, final rule using current models, newly submitted studies, and changes in labels. The estimated drinking water concentrations (EDWCs) were higher for surface water sources than for ground water sources. The acute dietary exposure assessment used the highest 1-in-10-year acute EDWC of 758 parts per billion (ppb) of triclopyr and the chronic dietary exposure assessment incorporated the highest 1-in-10-year chronic EDWC of 396 ppb of triclopyr. As the current action is for a tolerance without a corresponding U.S. registration (i.e., an import tolerance), there will be no effect on the EDWCs, and the previously provided EDWCs are still adequate for use. The drinking water models and their descriptions are available at the EPA internet site: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>.

The residential exposure assessment used the same assumptions as described in the February 25, 2016, final rule. As this action is for an import tolerance, it does not impact the

domestic use pattern and does not involve applications by homeowners or commercial applicators in residential settings. Therefore, no new residential exposure is expected.

Cumulative exposures. 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 triclopyr and any other substances. 3,5,6-trichloro-2-pyridinol, commonly known as TCP, is a metabolite of triclopyr, chlorpyrifos, and chlorpyrifos-methyl. Risk assessment of TCP was conducted in 2002, which concluded that the acute and chronic dietary aggregate exposure estimates are below EPA's level of concern. As TCP is not a residue of concern in plants and this action is for an import tolerance with no impact on the domestic use pattern, this action will not result in any additional exposure to TCP. The results of the 2002 TCP assessment are still considered valid. For the purposes of this action, EPA has not assumed that triclopyr has a common mechanism of toxicity with other substances.

E. Safety Factor for Infants and Children. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

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. of the final rule published in the Federal Register of February 28, 2024 (89 FR 14591) (FRL-11763-01).

Therefore, based on the risk assessments and information described above, 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 triclopyr residues. More detailed information on this action can be found in the document titled “Triclopyr: Section 3 Human Health Risk Assessment for Tolerances without U.S. Registration on Orange Subgroup 10-10A” in docket ID number EPA-HQ-OPP-2024-0331.

IV. Other Considerations

A. Analytical Enforcement Methodology

For information about the analytical enforcement methodology, see Unit IV.A. of the February 25, 2016, final rule.

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 has not established any MRLs for triclopyr.

C. Revisions to Petitioned-For Tolerance

EPA is establishing the tolerance for residues of triclopyr in or on orange subgroup 10-10A at 0.1 ppm instead of the petitioned-for 0.07 ppm in order to harmonize with the existing European Union (EU) MRLs for triclopyr in oranges and mandarins. The petition requested that EPA establish the tolerance at 0.07 ppm consistent with the European Food Safety Authority (EFSA) Reasoned Opinion “Modification of the existing maximum residue levels for triclopyr in oranges, lemons and mandarins,” dated July 27, 2022. The EFSA Reasoned Opinion concluded that the submitted data were sufficient to derive MRLs of 0.07 mg/kg for oranges and mandarins, but it did not determine whether the existing MRLs of 0.1 mg/kg for these commodities should be maintained or lowered. The EU subsequently maintained the existing MRLs of 0.1 mg/kg in

Commission Regulation (EU) 2023/679, dated March 23, 2023. There are no Codex, Canadian, or Mexican MRLs for triclopyr. Thus, to harmonize with the EU MRLs, EPA is establishing the tolerance at 0.1 ppm, which is sufficient to cover the residues expected on the imported commodities in orange subgroup 10-10A and which EPA has determined is safe. A revised petition was submitted by UPL Chile S.A. to support this change to the petitioned-for tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of triclopyr, [(3,5,6- trichloro-2-pyridinyl)oxy]acetic acid, including its metabolites and degradates, in or on orange subgroup 10-10A at 0.1 ppm.

VI. Statutory and Executive Order Reviews

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 summarized in Unit III.E.

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: July 14, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, 40 CFR chapter I is amended 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 § 180.417, amend the table in paragraph (a)(1) by adding in alphabetical order the entry “Orange subgroup 10-10A¹” and adding footnote 1 to read as follows:

§ 180.417 Triclopyr; tolerance for residues.

(a) * * *

(1) ***

Table 1 to Paragraph (a)(1)

Commodity	Parts per million

Orange subgroup 10-10A ¹	0.1

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

* * * * *

[FR Doc. 2025-13317 Filed: 7/15/2025 8:45 am; Publication Date: 7/16/2025]