ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0890; FRL–11763–01–OCSPP]

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 sugarcane, cane. The Interregional Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 28, 2024. Objections and requests for hearings must be received on or before April 29, 2024, 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–2022–0890, 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/.*

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/.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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–2022–0890 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 April 29, 2024. 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–2022–0890, 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/.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 5, 2023 (88 FR 42935) (FRL–10579–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP2E9028) by the Interregional Research Project No. 4 (IR–4), North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requests to amend 40 CFR 180.417 by establishing a tolerance for residues of triclopyr, 2-[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, including its metabolites and degradates, in or on sugarcane, cane at 0.04 parts per million (ppm) resulting from the application of the butoxyethyl ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr. The petition also requests to remove the established time-limited tolerance for residues of triclopyr in or on sugarcane, cane at 40 ppm. That document referenced a summary of the petition prepared by IR–4, the petitioner, which is available in the docket (EPA–HQ–OPP–2022–0890), *https://www.regulations.gov.*

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 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.

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).

Toxicological Points of Departure/Levels of Concern. A summary of the toxicological endpoints and points of departure for triclopyr used for human risk assessment can be found in the document, ''Triclopyr. Human Health Risk Assessment for Section 3 Use on Sugarcane'' in docket ID EPA–HQ–OPP–2022–0890. As explained in the Food Quality Protection Act (FQPA) section below, the FQPA safety factor for short- and intermediate-term inhalation exposures has decreased from 10X to 1X since the February 25, 2016, final rule so the level of concern for short- and intermediate-term inhalation exposures is now 100.

Exposure Assessment. 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 calculated from a recently submitted livestock feeding study was used for milk. HED 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.

The Agency classified triclopyr as a ''Group D Chemical—unable to be classified as to human carcinogenicity.'' This is based on marginal evidence of mammary tumors in female rats and mice and benign adrenal pheochromocytomas in male rats. There was no evidence of mutagenicity in a full battery of studies for triclopyr. Therefore, a cancer risk assessment was not conducted. The use of the chronic reference dose (RfD), which is derived from the most protective point of departure (POD) from the tox database, will adequately account for all chronic toxicity, including potential carcinogenicity that could result from exposure to triclopyr. A 100X uncertainty factor (10X for interspecies extrapolation and 10X for intraspecies variation) was incorporated into the chronic RfD. Since the FQPA SF has been reduced to 1X, the chronic population-adjusted dose (cPAD) is equal to the chronic RfD.

Drinking water exposure. EPA revised the triclopyr drinking water assessment since the February 25, 2016, final rule as part of Registration Review 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 ppb of triclopyr and the chronic dietary exposure assessment incorporated the highest 1-in-10-year chronic EDWC of 396 ppb of triclopyr. 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.*

Non-occupational exposure. The proposed use on sugarcane does not involve applications by homeowners or commercial applicators in residential settings. Therefore, no new residential exposure is expected. The residential exposure assessment used the same assumptions as described in the February 25, 2016, final rule.

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 the proposed use on sugarcane 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.

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.

Prenatal and postnatal sensitivity. Offspring and developmental effects occurred in the presence of maternal and parental toxicity. In the two-generation reproduction study with triclopyr acid, rare malformations, including exencephaly (brain protrudes outside of the skull) and ablepharia (absence of eyelids), were seen in rat pups at the mid- and high-doses (25 mg/kg/day and 250 mg/kg/day, respectively). These malformations were considered, using a weight-of-evidence (WOE) approach, to be evidence of increased qualitative susceptibility. In the rat developmental toxicity study with triclopyr acid, cleft palate,

brachycephaly (flat head syndrome), and delayed ossification occurred at the highest dose tested (200 mg/kg/day) while the no-observed-adverse-effect level (NOAEL) for maternal toxicity was not established since clinical signs of severe toxicity due to the bolus administration of a low pH compound were seen at the lowest dose tested (50 mg/kg/day). There were no other concerns for susceptibility identified in the other developmental studies where developmental and maternal effects were seen at 100 mg/kg/day and 300 mg/kg/day in the rabbit and rat, respectively.

Conclusion. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 1X for all exposure scenarios based on the following considerations:

1. The existing toxicological database is adequate for characterizing triclopyr toxicity and quantification of hazard for dietary and occupational exposures. The developmental toxicity studies in rats and rabbits and two-generation reproduction toxicity studies in rats are available to assess potential fetal/offspring sensitivity;

2. There is no evidence of neurotoxicity from triclopyr exposure;

3. While there is evidence of increased qualitative susceptibility to offspring from triclopyr exposure in the two-generation reproduction toxicity study, the concern is low since effects are well-characterized with clearly established NOAEL/lowest-observed-adverse-effect level (LOAEL) values, effects were seen in the presence of parental toxicity, and selected endpoints are protective of the observed effects; and

4. There are no residual uncertainties with respect to exposure data. The dietary food exposure assessment utilizes tolerance-level residues (established or recommended) except milk (an anticipated residue was used for milk in the chronic assessment) and 100% crop treated for all proposed/established commodities. By using these assumptions, the acute and chronic exposures/risks will not be underestimated.

The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters that are designed to provide conservative, health-protective, high-end estimates of water concentrations that will not likely be exceeded. The residential handler and post-application exposure assessments are based upon the residential standard operating procedures (SOPs) in conjunction with Pesticide Handlers Exposure Database unit exposures. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to triclopyr.

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 PAD (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 53% of the aPAD for females 13–49 years old and 8% of the aPAD for all infants, the most highly exposed population subgroup. No acute residential/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 46% of the cPAD for all infants, 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 410. 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 360. 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 120. As the short-term aggregate MOEs are greater than 100, the risks are not of concern. Although there are intermediate-term residential exposures, an intermediate-term aggregate was not separately assessed since: 1. the short- and intermediate-term points of departure are the same and 2. the short-term aggregate provides a worst-case estimate of residential exposure. For these reasons, the short-term aggregate is protective of the longer-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 WOE 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.

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. Human Health Risk Assessment for Section 3 Use on Sugarcane'' in docket ID EPA–HQ–OPP–2022–0890.

IV. Other Considerations

A. Analytical Enforcement Methodology

For details about the analytical enforcement methodology, see Unit IV.A. of the final rule published in the **Federal Register** of February 25, 2016.

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 Tolerances

EPA is not removing the established time-limited tolerance for residues of triclopyr in or on sugarcane, cane at 40 ppm. The use pattern in the emergency exemption for triclopyr on sugarcane is different than the Section 3 use supported by this tolerance rule and there may be sugarcane in the channels of trade with higher residues from use under the emergency exemption.

V. Conclusion

Therefore, a tolerance is established for residues of the herbicide triclopyr, including its metabolites and degradates, in or on sugarcane, cane at

0.04 ppm, resulting from the application of the butoxyethyl ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 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: February 21, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 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 paragraph (a)(1) by adding a heading for the table and adding in alphabetical order an entry for ''Sugarcane, cane'' to read as follows:

§ 180.417 Triclopyr; tolerance for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.04
* * * * *	

[FR Doc. 2024–04017 Filed 2–27–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

Docket No. 220801–0167; RTID 0648–XD737]

International Fisheries; Pacific Tuna Fisheries; Inseason Action for 2024 Commercial Pacific Bluefin Tuna Annual Catch Limit in the Eastern Pacific Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; inseason announcement of 2024 annual catch limit.

SUMMARY: NMFS is announcing that the Pacific bluefin tuna (PBF) 2024 annual catch limit for U.S. commercial fishing vessels in the eastern Pacific Ocean (EPO) is 720 metric tons (mt).

DATES: The rule is effective 12 a.m. local time on March 28, 2024, through 11:59 p.m. local time on December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Tyler Lawson, NMFS West Coast Region, 503–230–5421.

SUPPLEMENTARY INFORMATION: The United States is a member of the Inter-American Tropical Tuna Commission (IATTC), which was established under the Convention for the Establishment of an IATTC signed in 1949 (1949 Convention). The 1949 Convention provides an international agreement to ensure the effective international conservation and management of highly migratory species of fish in the IATTC Convention Area. In 2003, the IATTC updated the 1949 Convention through the adoption of the Convention for the Strengthening of the IATTC Established by the 1949 Convention between the United States of America and the Republic of Costa Rica (Antigua Convention). The IATTC Convention Area, as amended by the Antigua Convention, includes the waters of the EPO bounded by the coast of the Americas, the 50° N and 50° S parallels, and the 150° W meridian.

Fishing for PBF in the EPO is managed, in part, under the Tuna Conventions Act of 1950, as amended (the Act), 16 U.S.C. 951 *et seq.* Under the Act, NMFS must publish regulations to carry out recommendations and decisions of the IATTC in consultation with the Department of State. Regulations implementing conservation and management measures for tuna and tuna-like species in the EPO are codified at 50 CFR part 300, subpart C.