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[Rules and Regulations]

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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.

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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](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](mailto: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](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](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

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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,

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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

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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

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1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

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2. In Sec. 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:

Sec. 180.417 Triclopyr; tolerance for residues.

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

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Parts per

Commodity million

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\* \* \* \* \*

Sugarcane, cane............................................ 0.04

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

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